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CryoLife®, Inc.

Biotechnologies for Medicine℠

2003 Annual Report

CryoLife®, Inc.
Biotechnologies for Medicine℠

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KENNESAW, GEORGIA 30144
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CORPORATE PROFILE

CryoLife, Inc. was founded in 1984 to provide cardiovascular surgeons with new alternative treatment options for patients with impaired heart function. Utilizing the Company's cryopreservation technology in concert with a nation-wide network of tissue banks and organ procurement organizations, CryoLife began the processing and preservation of human heart valves for transplant. The cryopreserved human heart valve was recognized as a major advancement in implant technology, providing cardiac surgeons with an alternative to mechanical and animal-based heart valves.

In 1986, CryoLife expanded its cryopreservation processing service to include saphenous veins for use in cardiac and peripheral vascular bypass surgeries.

In 1989, CryoLife began the processing and preservation of orthopaedic tissues, providing orthopaedic surgeons with human tissue for the repair and restoration of knee function following injuries.

The Company's growth and diversification strategy was further enhanced in 1998 with the introduction of BioGlue®, a protein-based surgical adhesive designed to control bleeding in certain vascular and cardiovascular surgical procedures and currently approved in certain international markets for soft tissue repair.

FORM 10-K

Included in this Annual Report to Shareholders is a copy of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, without exhibits, as filed with the Securities and Exchange Commission. Additional copies of this Annual Report and the Form 10-K, without exhibits, are available at no charge. Please send requests to:

Ms. Suzanne K. Gabbert
Corporate Secretary
CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, GA 30144

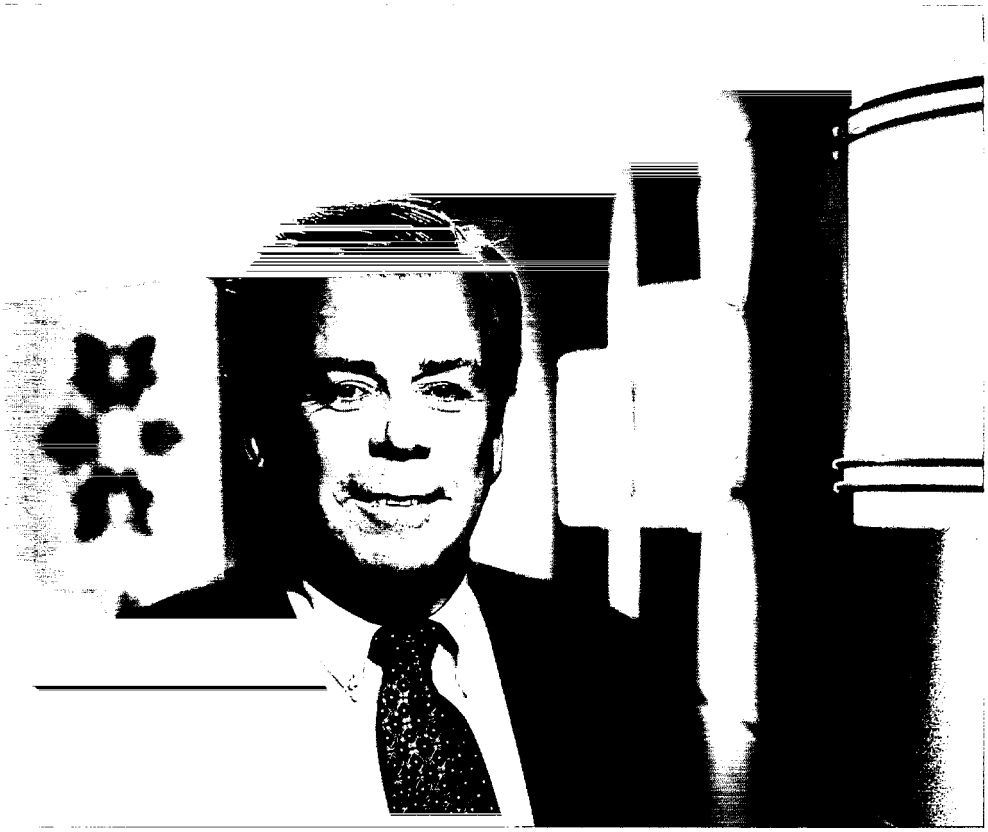
STOCKHOLDER COMMUNICATIONS

Directors may be contacted by mail addressed c/o Ms. Gabbert at the address provided above for requesting copies of Form 10-K.

STOCK LISTING

CryoLife, Inc. Common Stock is traded on the New York Stock Exchange under the Symbol CRY.

CryoLife, Inc. Options are traded on the Chicago Board Options Exchange (CBOE) and the American Stock Exchange®, a subsidiary of the National Association of Securities Dealers, Inc. (NASD®), under the symbol CRY.



Dear CryoLife Shareholder

As 2004 begins, the future for CryoLife looks quite promising. The Company has significantly strengthened its financial position and is expecting continued strong sales growth of its bio-surgical adhesive, BioGlue®, an increase in its tissue processing revenues, and continued strong performance internationally. We also plan to further develop several exciting projects in research and development.

In 2004, we expect an increase in human tissue processing and product revenues of 12% to 19% including an increase in BioGlue revenues of 19% to 26%. With the outstanding success of BioGlue, CryoLife is a more diversified company with a broader customer and revenue base.

BioGlue can be distributed in 50 countries and sales increased 33% to $27.8 million in 2003, compared to the previous year. BioGlue is being accepted by surgeons in the U.S., who are utilizing it as an adjunct to standard methods, such as sutures and staples, to control bleeding in open surgical repair of large vessels. It is being used in the European community in the surgical repair of soft tissues, such as vascular, cardiac, dura mater, pulmonary, and gastrointestinal. International BioGlue sales growth was driven by the U.K. direct sales representatives, strong distribution support throughout Europe, increased usage of BioGlue in the core applications of cardiac and large vascular surgery, and expanded usage in neurologic, pulmonary, and general surgery.

During the past year, there were several presentations and publications, both in the U.S. and abroad, describing the use of BioGlue for various surgical indications. This positive data has been an important factor driving BioGlue sales growth.

We have expanded our BioGlue manufacturing facility in Kennesaw to meet the increasing demand for the product by our customers. Several innovative improvements have been implemented that have increased efficiency, improved manufacturing time, and reduced expenses.

The Company plans to introduce its new BioGlue syringe delivery device in 2004. This prefilled device is fully disposable. It will eliminate the need for resterilization of the dispenser, increasing convenience and reducing costs for our customers. We also expect to file an Investigational Device Exemption (IDE) with the FDA for the use of BioGlue in dura sealing within the next 12 months.

While BioGlue is the first protein hydrogel product marketed by the Company, we are also developing several other promising products using protein hydrogel technology. These development projects include: BioDisc; which is being developed for use as an injectable spinal disc for spinal disc repair; BioFoam for rapid hemostasis for penetrating wounds and severe trauma; and LiquiStent, which has promise as a biological intervascular stent that could prove to be nonthrombogenic and biocompatible, and may avoid a tissue response that would occlude the blood vessel.

Since 1984, when CryoLife was founded, the Company has remained committed to improving health and the quality of life through tissue transplantation. More than 100,000 CryoLife-processed human tissues have been transplanted in patients. Tens of thousands of children with congenital heart defects have received CryoLife aortic valves, pulmonary valves, and other cardiac tissues for reconstructive heart surgery. Approximately 20,000 vascular surgeries have been performed using CryoLife-processed veins, preventing amputations in many patients. Processed human tissues are often the best, and sometimes are the only viable option for many patients.

For the tenth consecutive year, CryoLife published its CryoValve® Clinical Human Heart Valve Experience Report, which documents the positive, long-term results of CryoLife-processed human heart valves implanted in both adult and pediatric patients. CryoLife, the pioneer in tissue transplantation, is the only company

that tracks and publishes long-term clinical performance of human heart valve allografts.

CryoLife is now processing and distributing cardiac, vascular, boned orthopedic, and non-boned orthopedic tissue. The Company recently licensed a patented technology from Clearant, Inc., which is designed to inactivate microorganisms, including pathogens. We plan to develop and validate this technology in our orthopedic tissue processing by the end of the year.

CryoLife is committed to continuing the improvement of its tissue processing and has invested in a comprehensive program to increase the number of tissues available for distribution to patients who require reconstructive cardiac, vascular, and orthopedic surgeries. This program includes recently implemented initiatives with tissue procurement organizations, operating a newly created in-house pathology department and a new rinse recovery processing method. We expect to realize the positive impact of these initiatives beginning in the second quarter of 2004.

CryoLife's SynerGraft® Model #100, vascular graft, made of a bovine ureter, is approved in Europe for arteriovenous (AV) access in dialysis patients. The SynerGraft Model #100 utilizes the Company's antigen reduction technology (ART). This patented process removes antigens from the tissues, which appears to allow the patient to receive the implant without using immunosuppressant therapy. We now have over 125 patients in the Europe with SynerGraft Model #100 implants.

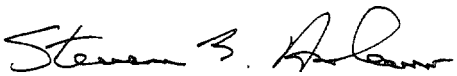
The Company filed its application for accreditation with the American Association of Tissue Banks (AATB) on October 13, 2003. The AATB is a scientific, not-for-profit peer group organization that facilitates the provision of high quality transplantable human tissues in quantities sufficient to meet national needs.

In December, I was pleased to announce that Thomas Ackerman, CFO of Charles River Laboratories, and Dan Bevevino, CFO of Respironics, joined CryoLife's Board of Directors. Their extensive business and financial experience will greatly benefit CryoLife.

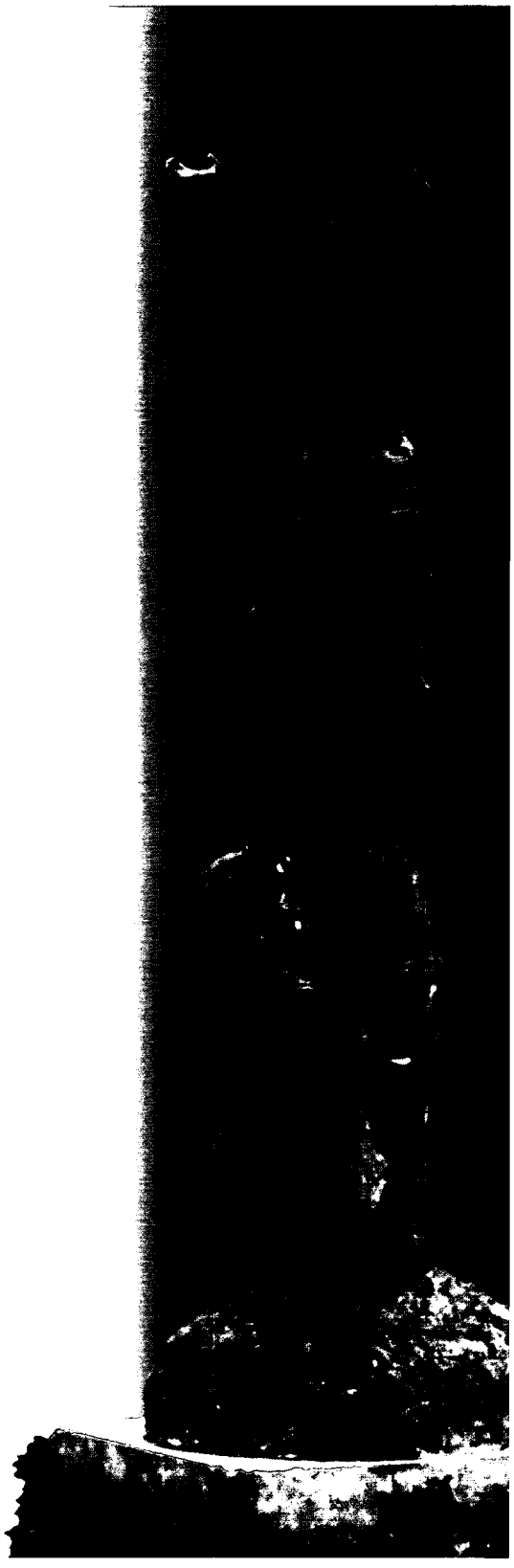
We met the many challenges we faced in 2003, and now the Company is poised to achieve future success. The recent private equity investment of approximately $20 million in CryoLife by several highly regarded institutions is further evidence of the Company's promising future. Based on these favorable developments, our potential growth in revenues, our innovative pipeline of products, and our strong financial position, we are looking ahead with great optimism.

Finally, I would especially like to express my appreciation to the Company's employees for their numerous contributions and to our shareholders for their continued support. Your efforts and commitment have made a meaningful difference in improving the lives of thousands of patients.

Very truly yours,



Steven G. Anderson,
President and Chief Executive Officer
May 1, 2004



This signature sculpture at the entrance of CryoLife's corporate headquarters commemorates the donor families and recognizes the volunteer contributions of surgeons and medical centers that help make the CryoKids program a reality.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2003
OR

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

For the transition period from to

Commission file number 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida	59-2417093
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

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

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

None

Indicate by check mark 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. [X] 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). [X] Yes ☐ No

As of June 30, 2003, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $167,414,148 computed using the closing price of $10.35 per share of Common Stock on June 30, 2003, 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 24, 2004 the number of outstanding shares of Common Stock of the registrant was 23,227,066.

Documents Incorporated By Reference

Part III: Portions of Registrant's Proxy Statement relating to the Annual Meeting of Shareholders to be filed not later than April 29, 2004.

PART I

Item 1. Business.

Overview

CryoLife, Inc. ("CryoLife" or the "Company"), incorporated January 19, 1984 in Florida, is a leader in the preservation of human tissues for cardiovascular and vascular transplant applications. The Company also develops and commercializes implantable medical devices, including BioGlue® Surgical Adhesive, a glutaraldehyde-fixed stentless porcine heart valve, and SynerGraft® processed bovine vascular grafts. The Company uses its expertise in biochemistry, cell biology, immunology, and protein chemistry and its understanding of the needs of the cardiovascular, vascular, and orthopaedic surgery medical specialties, to continue development of its core preservation and surgical adhesive businesses and to develop or acquire complementary implantable products and technologies for these surgical specialties. For detailed financial information on CryoLife's operating segments and international revenues, see Note 20 to the consolidated financial statements.

CryoLife processes and distributes for transplantation preserved human cardiovascular and vascular tissue. Management believes that cryopreserved human heart valves and conduits offer specific advantages over mechanical, synthetic, and animal-derived alternatives. Depending on the alternative, these advantages include a more natural hemodynamic functionality, the elimination of a long-term need for anti-coagulation drug therapy, a reduced incidence of reoperation, and a reduced risk of catastrophic failure, thromboembolism (stroke), or calcification. The Company estimates that the potential annual U.S. market for implantable products targeting indications addressed by the preserved tissues processed by the Company, including orthopaedic tissue, was in excess of $1 billion in 2003. However, supply constraints of human tissue limit market share potential. Although the Company estimates that it provided in excess of 70% of the preserved human heart valve tissue implanted in the U.S. in 2001, as a result of the adverse effects from the U.S. Food and Drug Administration ("FDA") Order issued on August 13, 2002, reported tissue infections, subsequent FDA activity, and the resulting adverse publicity, as discussed below, the Company's market share declined subsequent to August 2002. The Company estimates that 10-15% of its preserved human tissue market share has been absorbed by competitors. The Company seeks to expand the availability of human tissue through its established relationships with approximately 80 tissue banks and organ procurement agencies nationwide.

Historically, CryoLife had been a leader in the preservation of human tissues for orthopaedic transplant applications. The Company has provided preservation services for surgical replacements for the meniscus and the anterior and posterior cruciate ligaments, which are critical to the proper function of the human knee, as well as osteochondral grafts used for the repair of cartilage defects in the knee. The Company processed orthopaedic tissue until August 2002 when the Company received a recall order from the FDA (see further discussions below at "FDA Order on Human Tissue Preservation"). The Company resumed limited processing of orthopaedic tissue in late February 2003.

The Company estimates that the annual worldwide market for surgical sutures and staples in 2003 was in excess of $2.5 billion. The Company began shipping BioGlue Surgical Adhesive for distribution in the European Economic Area ("EEA") in the second quarter of 1998 for use in vascular applications and in the first quarter of 1999 for use in pulmonary applications. In December 1999 the Company began shipping BioGlue Surgical Adhesive in the U.S. pursuant to a Humanitarian Device Exemption ("HDE") for use as an adjunct in repair of acute thoracic aortic dissections. The Company received approval to distribute BioGlue Surgical Adhesive for vascular and pulmonary repair in Canada and Australia in January 2000 and February 2001, respectively. In December 2001 the Company received FDA approval to distribute BioGlue for use as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. In January 2002 BioGlue's Conformité Européene ("CE") Mark (product certification) was expanded to include its use in soft tissue repair procedures. In February 2003 the Company received an expanded approval in Canada for use of BioGlue in soft tissue repair procedures. This approval expands the application of BioGlue in Canada from vascular and pulmonary repair to include soft tissue repair. Additional approvals have been granted in 2002 and 2003 in other countries worldwide.

CryoLife has developed and markets outside of the U.S. bioprosthetic cardiovascular and vascular devices for implantation, consisting of a SynerGraft processed bovine vascular graft and a glutaraldehyde-fixed stentless porcine heart valve, the CryoLife O'Brien® aortic heart valve. In July of 2001 the Company received CE Mark approval for its SynerGraft Model 100 vascular graft, which is presently being marketed for dialysis access. SynerGraft involves the depopulation of cells leaving a collagen matrix that has the potential to be repopulated with the recipient's cells. This process is designed to increase graft longevity, and to improve the biocompatibility and functionality of such tissue. The SynerGraft Model 100 vascular graft is produced from a bovine ureter in lengths of 25, 35, and 50 cm and can be stored at room temperature. The SynerGraft Model 100 vascular graft is marketed in Europe and the Middle East. The Company's CryoLife O'Brien heart valve is a glutaraldehyde-fixed porcine heart valve, which is often preferred by surgeons for procedures involving elderly patients because it eliminates the risk of patient non-compliance with long-term anti-coagulation drug therapy associated with mechanical valves, is less expensive than human heart valves, and its shorter longevity is more appropriately matched with these patients' life expectancies. Glutaraldehyde-fixed porcine and bovine heart valves address a worldwide annual target heart valve market estimated to have been approximately $800 million in 2003. Unlike most other available porcine heart valves, the Company's stentless porcine heart valve contains minimal amounts of synthetic materials, which decreases the risk of endocarditis, a debilitating and potentially fatal infection. The Company's CryoLife O'Brien heart valve, currently marketed in the EEA and certain other territories outside the U.S., is a stentless porcine heart valve which contains a matched composite leaflet design that approximates human heart valve blood flow characteristics and requires only a single suture line for implantation. For information regarding international revenues, see Note 20 to the consolidated financial statements.

In February 2001 the Company formed AuraZyme Pharmaceuticals, Inc. ("AuraZyme") to foster the commercial development of its Activation Control Technology ("ACT"). The ACT is a reversible linker technology that has potential uses in the areas of cancer therapy, 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. This strategy is designed to allow the Company to continue development of this technology without incurring additional research and development expenditures, other than through AuraZyme, and allow the Company to focus its resources on the commercial development of its BioGlue Surgical Adhesive, SynerGraft technology, and other products under development.

In the U.S. the Company markets its preservation services for human cardiovascular and vascular tissue and its BioGlue Surgical Adhesive through its direct technical service representatives. The Company relies on independent sales representatives to market its orthopaedic preservation services. Internationally, BioGlue Surgical Adhesive, preserved human tissues, and bioprosthetic cardiovascular and SynerGraft vascular devices, are distributed through independent representatives located throughout Europe, the Middle East, Canada, South America, Australia, Africa, and Asia. The Company also uses direct technical service representatives in the U.K. to market its BioGlue Surgical Adhesive, preservation services, and bioprosthetic devices.

Recent Events

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 3.4 million shares of stock at a price of $6.25 per share. The sale generated net proceeds of approximately $19.9 million, after commissions, registration fees, and other related charges, which will be used for general corporate purposes. On February 10, 2004 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. The Company has agreed to pay 1% of the aggregate price paid per month, subject to certain limitations, if the registration statement is not declared effective within 75 days of the closing date of January 27, 2004.

FDA Order on Human Tissue Preservation

FDA Order

On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001 (the "FDA Order"). The FDA Order followed an April 2002 FDA Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter dated June 17, 2002, ("Warning Letter"). Revenue from human tissue preservation services accounted for 78% of the Company's revenues for the six months ended June 30, 2002, (the last period ended prior to the issuance of the FDA Order) and of those revenues 67%, or $26.9 million, were derived from preservation of tissues subject to the FDA Order. The FDA Order contained the following principal provisions:

- The FDA alleged that, based on its inspection of the Company's facility on March 25 through April 12, 2002, certain human tissue processed and distributed by the Company may be in violation of 21 Code of Federal Regulations ("CFR") Part 1270. (Part 1270 requires persons or entities engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue to perform certain medical screening and testing on human tissue intended for transplantation. Part 1270 also imposes requirements regarding procedures for the prevention of contamination or cross-contamination of tissues during processing and the maintenance of certain records related to these activities.)
- The FDA alleged that the Company had not validated procedures for the prevention of infectious disease contamination or cross-contamination of tissue during processing at least since October 3, 2001.
- Non-valved cardiac, vascular, and orthopaedic tissue processed by the Company from October 3, 2001 to September 5, 2002 was required to be retained until recalled, destroyed, the safety was confirmed, or an agreement was reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.
- The FDA strongly recommended that the Company perform a retrospective review of all tissue in inventory (i.e. currently in storage at the Company) that was not referenced in the FDA Order to assure that it was recovered, processed, stored, and distributed in conformance with 21 CFR 1270.
- The Center for Devices and Radiological Health ("CDRH"), a division of the FDA, would evaluate whether there are similar risks that may be posed by the Company's allograft heart valves, and would take further regulatory action if appropriate.

Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order on quality assurance quarantine and recalled the non-valved cardiac, vascular, and orthopaedic tissues subject to the FDA Order (i.e. processed since October 3, 2001) 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 "Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to 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. Specifically, the Company was required to obtain physician prescriptions, and tissue packaging was required to contain specified warning labels. The Agreement called for the Company to undertake to identify third-party records of donor tissue testing and to destroy tissue from donors in which certain microorganisms or an infection were found. The Agreement had a 45-business day term and was renewed on November 8, 2002, January 8, 2003, March 17, 2003, and June 13, 2003. This most recent renewal expired on September 5, 2003 and was not renewed. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). In addition, pursuant to the 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.

On December 31, 2002 the FDA clarified the Agreement, noting that non-valved cardiac and vascular tissues processed after September 5, 2002 were not subject to the FDA Order. Specifically, for non-valved cardiac and vascular tissue processed since September 5, 2002, the Company is not required to obtain physician prescriptions,

label the tissue as subject to a recall, or require special steps regarding procurement agency records of donor screening and testing beyond those required for all processors of human tissue. These restrictions also do not apply to orthopaedic tissue processed by the Company after September 5, 2002. A renewal of the Agreement that expired on September 5, 2003 was, therefore, not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

After receiving the FDA Order, the Company met with representatives of the FDA's CDRH division regarding CDRH's review of the Company's processed allograft heart valves, which were not subject to the FDA Order. On August 21, 2002 the FDA publicly stated that allograft heart valves had not been included in the FDA Order as these devices were essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. The FDA also published a public health web notification at that time stating that it had serious concerns regarding the Company's processing and handling of allograft heart valves. On June 27, 2003 the FDA modified the notification by labeling it as an "archived document – no longer current information – not for official use." There have been no further conversations with the FDA's CDRH division on this matter.

An FDA 483 Notice of Observations ("February 2003 483") was issued in connection with the FDA inspection in February 2003. Corrective action was implemented on most of its observations during the inspection. The Company believes the observations, most of which focus on the Company's systems for handling complaints, will not materially affect the Company's operations. The Company responded to the February 2003 483 in March 2003. The Company has met with the FDA to review its response to the February 2003 483. No additional comments regarding the adequacy of its response were issued at that time. The Company continues to work with the FDA to review process improvements.

The FDA inspected the Company in October of 2003 in response to a reported orthopaedic infection and issued a 483 Notice of Observations ("October 2003 483"). The observation in the October 2003 483, which was a reissuance of a previous observation, required the Company to complete the validation of its processing operations and procedures for decontaminating tissues, its written procedures for the prevention of infectious disease contamination during processing, and its anti-microbial solution. The Company submitted responses to the October 2003 483 on October 28, 2003 and on November 21, 2003.

The FDA inspected the Company's tissue processing operations in February 2004 focusing primarily on the validation work the Company has performed over the past one and half years. The FDA issued a 483 Notice of Observations ("February 2004 483"), which the Company is addressing.

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

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 CryoValve® SG and that premarket approval marketing authorization should be obtained for the Company's 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.

The Company voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular and vascular tissue and has suspended the distribution of tissues on hand that have been preserved with the SynerGraft technology until the regulatory status of the CryoValve SG and CryoVein SG is resolved. Additionally, the Company discontinued labeling its vascular grafts for use as A-V access grafts. The FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SynerGraft treated tissues are resolved, the Company will employ its traditional processing methods on these tissues. Distribution of allograft heart valves and vascular tissue processed using the Company's traditional processing protocols will continue. The Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue on hand.

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 that additional information be provided to support the 510(k) premarket notification for the CryoValve SG. The requested information may require that additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume processing and distribution of SynerGraft processed cardiovascular tissue. The Company is still in discussions with the FDA regarding the type of submissions necessary for the CryoVein 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. The outcome of the discussions and filing with the FDA regarding the use of the SynerGraft process on human tissue could result in an inability to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted.

See Part I, Item 3 "Legal Proceedings" for a discussion of certain material legal proceedings.

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 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:

- *Continue Preservation of Cardiovascular Tissue.* The Company intends to increase the market penetration of its CryoLife preserved human heart valves and conduits by (i) expanding awareness of clinical advantages of cryopreserved human tissues through continuing educational efforts directed to physicians, prospective heart valve and conduit recipients, and tissue procurement agencies, (ii) expanding its relationships with the approximately 80 tissue banks and organ procurement agencies across the U.S. which have recovered and sent tissue to the Company for preservation, (iii) expanding its physician training activities, and (iv) resuming the application of its SynerGraft technology to human heart valves and conduits, if required FDA approvals are obtained.

- *Expand Distribution of Preserved Human Vascular Tissue and Distribution of Orthopaedic Tissue.* Using the same strategy it has successfully employed to expand its preservation services for cardiovascular tissue, the Company intends to increase its preservation revenues from human vascular tissue and orthopaedic tissue distribution by (i) continuing educational efforts directed to surgeons about the clinical advantages of preserved tissue, (ii) expanding its relationships with tissue banks and organ procurement agencies, (iii) expanding its programs for training physicians in the use of tissue preserved by the Company, and (iv) expanding its product offerings by applying its SynerGraft technology to human 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 preservation.

- *Expand Distribution of Biomaterials for Surgical Adhesive and Sealant Applications.* The Company began commercial marketing of its proprietary BioGlue Surgical Adhesive in the EEA through its independent representatives for vascular and pulmonary applications upon receipt of a CE Mark in 1997 and 1999, respectively, and in the U.S. as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels upon receipt of FDA approval in December 2001 which follows the December 1999 FDA approval to distribute BioGlue Surgical Adhesive under an HDE for use as an adjunct in the repair of acute thoracic aortic dissections. The Company has since been successful in broadening the scope for approved uses outside the U.S. and the number of countries that accept it. The Company continues to seek additional marketing approvals in other countries. In addition to these adhesive and sealant applications of BioGlue, the Company intends to pursue, either directly or through

strategic alliances, additional indications for BioGlue technology, including replacement for spinal disc nuclei. The Company also intends to pursue additional approvals for hernia repair and dura mater sealing in the U.S.

- *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. for dialysis access.

- *Develop and Commercialize Other Technologies.* The Company intends to leverage its current distribution channel and its expertise in the cardiovascular and orthopaedic medical specialties by selectively pursuing the potential distribution or licensing of additional technologies that compliment existing services and products.

Services and Products

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 (not to exceed 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 efficiency and 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 58,200 cryopreserved human heart valves and conduits from 1984 through 2003. Revenues from human heart valve and conduit preservation services accounted for 33%, 30%, and 29% of total revenues, respectively, in 2001, 2002, and 2003. Based on CryoLife's records of documented implants, management believes that the Company's success in the allograft heart valve market 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 these areas as compared to other allograft processors and that the Company's

cryopreserved 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 non-valved conduit and patch tissue to surgeons who wish to perform certain specialized cardiac repair procedures. Each of these 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. depopulated cryopreserved human heart valves and conduits utilizing its SynerGraft antigen reduction technology. As discussed in "Other FDA Correspondence and Notices," the Company has 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 2003 was approximately $400 million. Management believes that approximately 83,000 heart valve surgeries were conducted in the U.S. in 2003. Of this total number of heart valve and conduit surgeries, approximately 26,000, or 31%, involved mechanical heart valves, and approximately 57,000, or 69%, involved tissue heart valves, including porcine, bovine, and cryopreserved human tissues. Approximately 2,800 human heart valves and conduits cryopreserved by the Company were shipped for implantation in 2003.

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 most patients:

	Preserved Human	Porcine		Mechanical (3)	Bovine Pericardium
		Stented	Stentless(1)		
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
(Required Pressure): (2)	(0-5)	(10-20)	(5-15)	(10-25)	(10-30)
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

(1) Limited long-term clinical data is available since stentless porcine heart valves only recently became commercially available.
(2) Pressure measured in mmHg.
(3) Mechanical valves also require chronic anti-coagulation drug therapy.

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 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 36,000 human vascular tissues from 1986 through 2003, which includes 3,200 shipments in 2003. Revenues from human vascular preservation services accounted for 28%, 23%, and 21% of total revenues, respectively, in 2001, 2002, and 2003.

A surgeon's first choice for replacing diseased or damaged vascular tissue is generally the patient's own tissue. However, in cases of advanced vascular disease, the patient's tissue is often unusable, and the surgeon may consider using synthetic grafts or transplanted human vascular tissue. Small diameter synthetic vascular grafts are generally not suitable for below-the-knee surgeries because they have a tendency to occlude since the synthetic materials in these products attract cellular material from the blood stream, which in turn closes off the vessel to normal blood flow. Cryopreserved 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 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 coronary artery bypass surgeries, peripheral vascular reconstruction, and venous valve transplantation.

In 1986 the Company began a program to cryopreserve saphenous veins for use in coronary artery bypass surgeries. The Company estimates there were approximately 450,000 to 500,000 coronary artery bypass procedures performed in the U.S. in 2003. A subset of these coronary artery bypass procedures are re-operations and are candidates for preserved vascular tissue when patients do not have suitable autologous tissue available.

In 1989 the Company began a program to cryopreserve long segment saphenous veins for use in peripheral vascular reconstruction. 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. Analysis of the Company's data on file of approximately 425 implants has shown that approximately 72% of patients receiving CryoLife's preserved vascular tissues in this type of surgical procedure still have the use of the affected leg four years after surgery. The only alternative for many of these patients was amputation. The Company estimates that in 2003 approximately 82,000 peripheral vascular reconstruction surgeries were performed in the U.S. in which its cryopreserved human vascular tissues could have been used.

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 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. CryoLife shipped approximately 27,900 human connective tissues for the knee through the end of 2003, which includes approximately 400 shipments in 2003. Revenues from human orthopaedic preservation services accounted for 26%, 18%, and 2% of total revenues, respectively, in 2001, 2002, and 2003.

Human menisci provide orthopaedic surgeons with an alternative treatment in cases where a patient's meniscus has been completely removed. 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 2003 approximately 750,000 U.S. patients underwent partial or total meniscectomies. The Company believes up to 25% 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 cryopreserved 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 2003 approximately 325,000 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, which are preserved and maintained in a living state. The Company is not currently processing these grafts but is evaluating resuming processing in mid to late 2004. The success of transplanted osteoarticular grafts is attributed to the presence of viable chondrocytes (cells of the cartilage). The Company estimates that in 2003 the cartilage repair market was approximately $26 million of which the osteoarticular allograft market represented approximately $7.6 million with approximately 1,100 procedures.

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 has developed and commercialized its BioGlue Surgical Adhesive. BioGlue Surgical Adhesive is a polymeric surgical bioadhesive based on a derivative of an animal blood protein and a cross-linking agent. BioGlue Surgical Adhesive has a tensile strength that is four to five times that of fibrin sealants. Worldwide clinical applications for BioGlue Surgical Adhesive include cardiovascular, vascular, pulmonary, and soft tissue repair. Other potential applications for BioGlue Surgical Adhesive in the U.S. include hernia repair and dura mater sealing. BioGlue also has the potential to be used as a replacement for spinal disc nuclei. A derivative of the BioGlue technology is BioLastic™, an implantable biomaterial under development, which is capable of exchanging oxygen and carbon dioxide. BioLastic is being investigated for use in reinforcing or patching vascular tissue, reducing adhesions, repairing air leaks in lungs, and sealing holes in or replacing dura mater.

The Company estimates that the annual worldwide market for surgical sutures and staples in 2003 was in excess of $2.5 billion. The Company received a CE Mark in 1997 for use of its BioGlue Surgical Adhesive in vascular applications and began marketing this product in April 1998 in the EEA. In March 1999 the Company was awarded a second CE Mark allowing the use of BioGlue in pulmonary indications, including sealing of air leaks in lungs. In December 1999 the Company received FDA approval to distribute BioGlue Surgical Adhesive under a HDE for use as an adjunct in the repair of acute thoracic aortic dissections and immediately began marketing this product in the U.S. pursuant to the HDE. The Company received approval to distribute BioGlue Surgical Adhesive for vascular and pulmonary repairs in Canada and Australia in January 2000 and February 2001, respectively. 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. In January 2002 BioGlue's CE Mark was expanded to include its use in soft tissue repair procedures. Additional marketing approvals were granted in the Czech Republic, Colombia, Mexico, Peru, Romania, South Korea, Singapore and Uruguay in 2002 for one or more of the various indications discussed above. In February 2003 the Company received an expanded approval in Canada for use of BioGlue in soft tissue repair procedures. This approval expands the application of BioGlue, from vascular and pulmonary repair to include soft tissue repair. Additional marketing approvals for its use in soft tissue repair were granted in 2003 for Malaysia, Slovakia, and Thailand. Revenues from BioGlue Surgical Adhesive represented 12%, 27%, and 47% of total revenues, respectively, in 2001, 2002, and 2003.

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 2001, 2002, and 2003.

Glutaraldehyde-fixed porcine and bovine heart valves are often preferred by surgeons for procedures involving elderly patients because they eliminate the risk of patient non-compliance with anti-coagulation drug therapy associated with mechanical valves, they are less expensive than allograft valves, and their shorter longevity is more appropriately matched with these patients' life expectancies. Glutaraldehyde-fixed porcine and bovine heart valves address an annual worldwide target heart valve market estimated to have been $800 million in 2003.

The CryoLife O'Brien aortic valve is a stentless porcine valve with design features which management believes provide significant advantages over 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, currently marketed in the EEA and certain other territories outside the U.S., contains a matched composite leaflet design that approximates human heart valve blood flow characteristics and requires only a single suture line for surgical implantation.

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 treated with the SynerGraft process, also referred to as ART, 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.

Procurement, Sales, Distribution, and Marketing

Preservation Services

CryoLife markets its preservation services to tissue procurement agencies, implanting physicians, and prospective tissue recipients. The Company works with tissue banks and organ procurement agencies to ensure consistent and continued availability of donated human tissue for transplant and educates physicians and prospective tissue recipients with respect to the benefits of cryopreserved human tissues.

Procurement of Tissue. Donated human tissue is procured from deceased human donors by organ procurement agencies and tissue banks. After procurement, the tissue is packed and shipped, together with certain information about the tissue and its donor, to the Company in accordance with the Company's protocols. The tissue is transported to the Company's laboratory facilities via commercial airlines pursuant to arrangements with qualified courier services. Timely receipt of procured tissue is important, as tissue that is not received promptly cannot be cryopreserved successfully. The procurement agency is reimbursed by the Company for the costs associated with these procurement services. The procurement fee and related shipping costs, together with the charges for the preservation services of the Company, are ultimately paid to the Company by the hospital with which the implanting physician is associated. The Company has developed relationships with approximately 80 tissue banks and organ procurement agencies throughout the U.S. Management believes these relationships are critical 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, seven 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 comprehensive quality assurance program. This program, which includes an extensive 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.

Cardiovascular, vascular, and orthopaedic tissue, except osteochondral grafts, are cryopreserved in a proprietary freezing process conducted according to strict 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. Prior to the issuance of the FDA Order, osteochondral grafts were refrigerated in proprietary solutions from 2°C to 8°C for up to 45 days. The entire preservation process is rigidly controlled by guidelines established by the Company.

Distribution of Tissue to Implanting Physicians. Once 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 without charge. The Company has currently installed approximately 350 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 record 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 30 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. The Company also coordinates laboratory sessions that utilize animal tissue to demonstrate the 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.

Backlog. The limited supply of tissue that is donated and available for processing 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 BioGlue or SynerGraft bovine vascular grafts.

European Operations

In September 1999 the Company established its European subsidiary, CryoLife Europa, Ltd. ("Europa"), to provide customer service, logistics, marketing and clinical support to the surgical community and sales and distribution network in Europe, the Middle East, and Africa. Europa headquarters are located in Fareham, England. Europa distributes the Company's products through a network of 35 distributors or agents in Europe, the Middle East, and Africa. Europa currently has ten employees including a team of direct sales representatives in England and Wales. Marketing efforts are directed toward cardiovascular, vascular, thoracic, and general surgeons.

BioGlue Surgical Adhesive

The Company markets and distributes its BioGlue Surgical Adhesive in the U.S. through its existing direct technical representatives. The Company markets and distributes its BioGlue Surgical Adhesive in international markets through Europa and other existing independent representatives. Through its technical representatives, the Company conducts on-site training for doctors with respect to the application and administration of BioGlue Surgical Adhesive.

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.

Bioprosthetic Cardiovascular Devices

The Company markets the CryoLife O'Brien stentless porcine heart valve in Europe through its European subsidiary. Marketing efforts for the CryoLife O'Brien Valve are directed toward cardiac surgeons in Europe. The Company markets the SynerGraft Model 100 vascular graft for AV access through its European subsidiary in Europe and the Middle East. Marketing efforts for the SynerGraft Model 100 are primarily directed toward vascular surgeons.

Research and Development

The Company uses its expertise in immunology, biochemistry, and cell biology, and its understanding of the needs of the cardiovascular, vascular, and orthopaedic surgery medical specialties, to expand its core preservation and surgical adhesive 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 15 people in its research and development department, including six PhDs with specialties in the fields of immunology, 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 additional applications of its SynerGraft technology, its Protein Hydrogel Technology ("PHT") (of which BioGlue is the first PHT product to be introduced) and its ACT. 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 similar to human tissue. Materials and implantable replacement devices created with PHT have the potential to provide structure, form, and function of human body tissue. Because of its versatility and ease of application, PHT is being developed for application in hernia repair and dura mater sealing in the U.S., in the repair of denucleated intervertebral discs, and for the delivery of bone material for orthopaedic bone repair. The Company is also currently investigating certain drug delivery applications for its ACT, such as administering antibiotics and attaching chemotherapy drugs to tumors. To the extent the Company identifies additional applications for these 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. In addition the Company continues to explore technologies that may further enhance the safety of its tissue processing. The Company may

attempt to license these technologies from third parties; such as it did with Clearant, Inc. in December 2003. The Company and Clearant are working together to develop and validate a process to incorporate the use of the Clearant technology in the processing of certain orthopaedic tissue. 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 2001, 2002, and 2003 the Company spent approximately $4.7 million, $4.6 million, and $3.6 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 5%, 6%, and 6% of the Company's revenues for those respective years. 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 all 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 2003 the laboratory packaged approximately 12,000 human allografts. The current processing level is estimated to be at about 20% of total capacity. Increasing this processing level could be accomplished by increasing employees and expanding the Company's third shift.

BioGlue Surgical Adhesives

BioGlue Surgical Adhesive is presently manufactured at the Company's headquarters facility, which has an annual capacity of approximately 2 million units. The current processing level is about one-twentieth of total capacity. This laboratory contains approximately 13,500 square feet, including a suite of six clean rooms. Currently, there are 17 technicians employed in this area.

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 five 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 CryoLife Europa, that contains approximately 5,600 square feet of office, warehousing and training laboratory space.

Quality Assurance

The Company's operations encompass the provision of human tissue preservation services and the manufacturing of bioprosthetics and bioadhesives. 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 regulations. The Company also operates according to ISO 9001 Quality System Requirements, an internationally recognized voluntary system of quality management for companies that design, develop, manufacture, distribute and service products. The Company maintains a Certification of Approval to the ISO 9001 and ISO 13485, as well as EN46001 and ANSI/ISO/ASQC/Q9001, the European and U.S. versions of the international standard, respectively. 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 semi-annual 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.

Preservation Services

The Company employs a comprehensive quality assurance program in all of its tissue processing activities. The Company is subject to Quality System Regulations, additional FDA regulations, ISO 9001, 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. Blood samples from each tissue donor are subjected to a variety of serologic tests to screen for infectious diseases. Samples of some tissues are also sent to independent laboratories 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 strict 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, and California as facilities that process, store, and distribute human tissue for implantation. The regulatory bodies of these states perform inspections 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 to 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 "Other FDA Notices and Correspondence" for a discussion of recent inspections.

Bioprosthetic and Bioadhesive 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 9001 and ISO 13485 requirements.

All materials and components utilized in the production of the Company's products are received and thoroughly 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 assure that they are capable of consistently producing product meeting the Company's specifications. The Company maintains a rigorous quality assurance program of measuring devices used for manufacturing and inspection to ensure 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 assure the Company's compliance with its systems and regulatory requirements.

Patents, Licenses and Other Proprietary Rights

The Company relies on a combination of patents, trade secrets, trademarks, and confidentiality agreements to protect its proprietary products, processing technology, 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 36 U.S. patents and 96 foreign patents, including patents relating to its technology for human cardiovascular, vascular, and orthopaedic tissue preservation; tissue revitalization prior to freezing; tissue transport; BioGlue Surgical Adhesive; ACT; organ storage solution; and packaging. The Company has approximately 20 pending U.S. patent applications and 75 pending foreign applications that relate to areas including heart valve and tissue processing technology and delivery of bioadhesives for anastomosis and other uses. There can be no assurance that any patents pending will result in issued patents. The Company also has exclusive licensing rights for technology relating to light-sensitive enzyme inhibitors. The remaining duration of the Company's issued patents ranges from 6 months to 17 years. The Company has licensed from third parties certain technologies used in the development of its ACT and other technologies in licenses that call for the payment of both development milestones and royalties based on product sales, when and if such products are approved for marketing. The loss of these licenses could adversely affect the Company's ability to successfully develop its ACT or other 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 are not 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

selling certain of its products or could be required to obtain licenses from the owners of such patents or be required to redesign its products 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 processes to avoid infringement. The Company's failure to obtain these licenses or to redesign its products 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.

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

Cryopreserved Human Tissues and Bioprosthetic Cardiovascular Devices

The Company faces competition from at least one for-profit company and at least three 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 favorably with other entities that cryopreserve human tissue on the basis of technology, customer service, and quality assurance. As a result of the decrease in the Company's procurement and processing of human tissue, the 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. This interruption in the Company's services may make it difficult for the Company to regain the level of revenues reported prior to the FDA Order.

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. Although human tissue cryopreserved by the Company is initially higher priced than mechanical alternatives, these alternatives typically require that the patient take anti-coagulation drug therapy for the lifetime of the implant. As a result of the costs associated with anti-coagulants, mechanical valves are generally, over the life of the implant, more expensive than tissue cryopreserved by the Company. Notwithstanding the foregoing, management believes that, to date, price has not been a significant competitive factor.

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 four 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 nine other companies that offer porcine and bovine pericardium heart valves.

Human Vascular Tissue. Synthetic alternatives to veins cryopreserved by the Company are available primarily in medium and large diameters. Currently, management believes that there are at least four other providers 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 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. Prior to the issuance of the FDA Order, tendons cryopreserved by the Company constituted one of the principal treatment options for injuries that required anterior cruciate ligament reconstruction.

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 will compete primarily with Baxter Healthcare's Tiseel, FloSeal and CoSeal products. Competitive products may also be under development by other large medical device, pharmaceutical and biopharmaceutical companies, including 3M and Johnson & Johnson. 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—Rapid Technological Change."

Government Regulation

U.S. Federal Regulation of Medical Devices

Because BioGlue Surgical Adhesive 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 and that it is as safe and effective as a legally marketed 510(k) device and 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, known as a 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). 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, which 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 "Other FDA Correspondence and Notices", the Company has filed a 510(k) premarket notification with the FDA for the CryoValve SG and has received a letter from the FDA requesting that additional information be provided to support the 510(k) submission.

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 Surgical Adhesive. BioGlue Surgical Adhesive 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 a HDE in December 1999 for BioGlue Surgical Adhesive 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 or FDA regulation as medical devices. See "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 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. Pending regulations expand the requirements for donor suitability and good manufacturing practices. In March 2002 the FDA issued a guidance document, "Validation of Procedures for Processing of Human Tissues Intended for Transplantation." This guidance

represented the FDA's current status on the topic of validation of procedures to prevent contamination during processing of human tissues for transplantation. It is likely that the FDA's regulation of processed human tissue will continue to evolve in the future. Moreover, the FDA may determine that the vascular and orthopaedic tissues that are processed by the Company are medical devices, or the FDA may decide to regulate human heart valves as "human tissue" rather than 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 is expected to 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.

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, 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 (18 countries; 15 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. For example, France and an increasing number of EEA members require additional information for products containing material of animal origin. 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 Surgical Adhesive, 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, and Switzerland. The Company's SynerGraft Model 100 vascular graft may also be exported to Switzerland 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 15, 2004 the Company had approximately 326 employees. These employees included ten persons with PhD degrees. None of the Company's employees is 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 Securities and Exchange Commission ("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

Since 2002 CryoLife Has Faced Several Extraordinary Challenges, Including The 2002 FDA Recall Order, Decreased Revenues, And Increased Expenses, And May Not Be Successful In Addressing Them

CryoLife has faced extraordinary challenges since 2002. It received, on August 13, 2002, an FDA order calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife since October 3, 2001 (the "FDA Order"). 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 cost 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 suits, both of which remain pending. Products 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. Since 2002, a U.S. Senate committee has inquired into safety in the tissue processing industry, making inquiries of CryoLife. The SEC has initiated and continues to pursue a formal investigation of CryoLife. 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 tissues subject to the FDA recall and resolved many of the products liability suits pending against it, the foregoing factors will continue to challenge CryoLife in its efforts to return to the sales and profitability it enjoyed prior to 2002. No assurances can be made that CryoLife will succeed in those efforts in the near future.

The August 2002 FDA Order On Human Tissue and Subsequent FDA Activity Continue to Adversely Impact CryoLife's Business, Including Demand For Its Services And 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 the fourth quarter of 2003, these revenues were approximately $4.9 million or 39% of fourth quarter 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 profits 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 the types of tissues subject to the FDA Order 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. Although CryoLife expects them to decrease somewhat beginning in the second quarter of 2004, these high costs could have a material adverse effect on CryoLife's business, results of operations, and financial position.

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 could restrict CryoLife's growth. 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. If CryoLife's relationships with procurement agencies continue to be adversely affected or 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.

The FDA Order And Subsequent Activity Have Had and Continue To Have An Adverse Impact On Liquidity And Capital Resources

Based upon the lower levels of revenues and profits since the FDA Order, FDA activity, and associated adverse publicity, CryoLife expects that its cash and cash equivalents will continue to decrease over the near term and working capital could decrease from levels now on hand. Although CryoLife has reduced its level of operations and the number of personnel, there is a possibility that CryoLife may not have sufficient funds to fund its primary capital requirements or to meet its operating and development needs in the long-term.

Revenue from Orthopaedic Tissue Preservation Services Is Minimal And May Not Return

The Company has received only nominal revenue from the preservation of orthopaedic tissue since August 14, 2002. For the year ended December 31, 2001, human tissue preservation services 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 $11.9 million (prior to the reduction for estimated tissue recall returns), which represented 23% of CryoLife's revenues. For the year ended December 31, 2003, revenues for preservation services for orthopaedic tissue were $1.1 million, which represented 2% of CryoLife's revenues. The demand for orthopaedic tissue from CryoLife may remain minimal and may never return to the levels in existence before the FDA Order, even though CryoLife has resumed processing. As a result, this portion of CryoLife's business may have to be permanently discontinued or may only continue at substantially reduced levels. Any of these occurrences would result in a continued significant decrease in CryoLife's preservation services revenues and profitability in the future as compared to prior to the FDA Order.

Physicians May Be Reluctant To Implant CryoLife's Preserved Tissues

There is a risk that physicians or implanting institutions will be 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, hospital risk managers may forbid implanting surgeons to utilize CryoLife's tissues where alternatives are available. If a significant number of implanting hospitals or physicians refused to use tissues preserved by the Company, CryoLife's preservation services revenues and profits would be materially adversely affected.

Products And Services Not Included In The FDA Recall May Come Under Increased Scrutiny

Although CryoLife's heart valve processing services, BioGlue Surgical Adhesive and bioprosthetic devices were not included in the FDA recall, the processing and manufacturing facilities for these products may come under increased scrutiny from the FDA. A negative review from the FDA of these processing and manufacturing facilities could have a material adverse effect on CryoLife's business, results of operations, and financial position.

Demand For Heart Valves Processed By CryoLife Has Decreased And May Continue To Decrease

Some physicians and implanting institutions have remained reluctant to choose CryoLife's allograft heart valves for use in implantation, perhaps due to a perception that they may not be safe or to a belief that the implanting institutions or hospitals may be subject to a heightened liability risk if CryoLife's preserved tissues are used, especially if alternatives are available. Demand for CryoLife's allograft heart valves could decrease. In such an event, CryoLife's preservation services revenues and profits would be materially adversely affected.

Adverse Publicity May Reduce Demand For Products and Services Not Affected By The FDA Recall

Even though CryoLife's BioGlue, porcine heart valves and bovine vascular grafts (of which the porcine and bovine products are not sold in the U.S.) 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 Notice of Observations in February 2003, October 2003, and February 2004. If CryoLife's responses to the FDA's observations contained in these 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 cashflows.

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

On February 20, 2003 CryoLife received a letter from the FDA stating that a 510(k) premarket notification for the CryoValve SG was required before the product can be marketed. The letter also contended that a premarket approval application was required in order to market the CryoVein SG when used for A-V (arteriovenous) access. The agency's position is that femoral veins used for A-V access are medical devices that require premarket approval. CryoLife submitted a 510(k) premarket notification for the CryoValve SG, and received a response requesting additional information. There can be no assurance as to when clearance will be obtained, if at all.

Regulatory Action Outside Of The U.S. May Also Affect CryoLife's Business

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.

CryoLife Is The Subject Of An Ongoing SEC Investigation

CryoLife is the subject of an ongoing SEC investigation. An adverse finding by the SEC could have a material adverse effect on CryoLife's business, financial position, results of operations, and cash flows. At the present time, CryoLife is unable to predict the outcome of this matter.

CryoLife's Insurance Coverage May Be Insufficient

Product Liability Claims

In the normal course of business as a medical device and services company, CryoLife has product liability complaints filed against it. Following the FDA Order, products liability lawsuits increased to unprecedented numbers for CryoLife. 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.

For the 2000/2001 and 2001/2002 insurance policy years, CryoLife maintained claims-made insurance policies, which CryoLife believes to be adequate to defend against the suits filed during this period. For the 2002/2003 insurance policy year, CryoLife maintained claims-made insurance policies with three carriers. CryoLife used all of its insurance coverage, aggregating $25.0 million, for the 2002/2003 insurance policy year, as well as funds of its own, to resolve claims outstanding in the relevant policy period. CryoLife continues to attempt to reach settlements of the remaining litigation. CryoLife recorded a liability on its December 31, 2003, Consolidated Balance Sheet and a corresponding expense for the estimated cost of resolving these claims and reflecting the uninsured portion of the estimated liability. 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 product liability insurance policies do not include coverage for any punitive damages. 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 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 product liability claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of CryoLife.

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, which principally alleges that the Company made misrepresentations and omissions relating to product safety and the Company'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. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the United States 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, the case remains in the discovery phase. The Company carries directors' and officers' liability insurance policies, which the Company presently believes to be adequate to defend against this action. However, 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.

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 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. As previously disclosed, CryoLife's Board of Directors 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. An adverse decision in the case could have a material adverse effect on CryoLife. Although the derivative suit is brought nominally on behalf of the Company, the Company expects to continue to incur defense costs and indemnification 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

Because of 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.

Intense Competition May Affect CryoLife's Ability To Recover From The FDA Order And Develop Its Surgical Adhesive Business

CryoLife faces competition from other companies that cryopreserve human tissue, as well as companies that market mechanical valves and synthetic and animal tissue for implantation and companies that market wound closure products. Management believes that at least four 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 is aware that a few companies have surgical adhesive products under development. 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.

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.

Rapid Technological Change Could Cause CryoLife's Services And Products To Become Obsolete

The technologies underlying CryoLife's products and services are subject to rapid and profound technological change. CryoLife expects competition to intensify 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 offers or is seeking to develop. Any such occurrence could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows.

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, including new applications of its BioGlue 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.

Although CryoLife has conducted pre-clinical studies on many of 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 or application, or a determination by CryoLife, for financial, technical or other reasons, not to complete development of any product or application, 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. CryoLife's 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 human tissue services or products 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. In such cases, CryoLife may be unable to recover its initial investment in the license, distribution right, or purchase of initial inventory, 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 cancer therapy, 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. This strategy is designed 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, especially in light of the recent FDA Order. If such funding is not obtained, CryoLife may be unable to effectively test and develop the ACT, and may, therefore, be unable to determine its effectiveness. Even if such financing is obtained, there is no guarantee that the ACT will in fact prove to be effective in the above applications.

Uncertainties Regarding The SynerGraft Technology

CryoLife processes bovine tissues with the SynerGraft antigen reduction technology and processed human tissues with that technology until February 22, 2003, following the receipt of the informal February FDA letter. In animal studies, explanted SynerGraft treated allograft heart valves have been shown to repopulate with the hosts' cells. However, should such treated tissues implanted in humans not consistently and adequately repopulate with the human host cells, they may not have the improved longevity over the CryoLife standard processing technology that CryoLife currently expects. This could have a material adverse effect on future expansion plans and could limit future growth.

Extensive Government Regulation May Adversely Affect CryoLife's 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 products. The allograft heart valves to which CryoLife applies its preservation services 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 proposed and is refining 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 practices regulations when promulgated will enhance regulatory oversight of CryoLife and other processors of human tissue. See "Risk Factor - The FDA Has Notified CryoLife of Its Belief that Marketing of CryoValve SG and CryoVein SG Require Additional Regulatory Submissions and/or Approvals."

BioGlue Surgical Adhesive 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 its CE Mark ISO 9001 and ISO 13485 certifications, of which there can be no assurance.

Most of CryoLife's products and services in development, 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, 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 to CryoLife and adversely affect CryoLife'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 CryoLife has the exclusive right to commercialize patented products.

Also, delays or rejections may 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 CryoLife's or its collaborative partners' development focus, and disclosure of trial results by competitors.

Even if regulatory approval is obtained for any of CryoLife's products or services, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. Products or services marketed by CryoLife 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, 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 CryoLife's methods of charging for its preservation services. CryoLife's laboratory operations 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 CryoLife's 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 CryoLife's 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 CryoLife's 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.

CryoLife Is Dependent On Its Key Personnel

CryoLife's business and future operating results significantly depend 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 significantly depend 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. 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.

The Consolidated Financial Statements As Of And For The Year Ended December 31, 2001 Included In CryoLife's 10-K Were Audited By Arthur Andersen LLP, Which Has Been Found Guilty Of Obstruction Of Justice And The Subject Of Additional Litigation

Arthur Andersen LLP has been found guilty of obstruction of justice with respect to its activities in connection with Enron Corp. and may be the subject of additional litigation. Arthur Andersen LLP has also ceased practicing before the SEC. Arthur Andersen LLP or any successor in interest may have insufficient assets to satisfy any claims that may be made by investors with respect to the financial statements as of and for the year ending December 31, 2001 included in CryoLife's Form 10-K for the year ending December 31, 2003.

In addition, Arthur Andersen LLP has not consented to the inclusion of their report dated March 27, 2002 in CryoLife's Form 10-K for the year ending December 31, 2003, and as a result, only a copy of such report has been included. Because Arthur Andersen LLP has not consented to the inclusion of their report in our Form 10-K for the year ending December 31, 2003 which is incorporated into CryoLife's Form 10-K for the year ending December 31, 2003, claimants may not be able to recover against Arthur Andersen LLP for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen LLP or any omissions to state a material fact required to be stated therein.

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 recently and may continue to be subject to such volatility 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 stock price in the period January 1, 2002 to February 17, 2004 has ranged from a high of $31.31 to a low of $1.89.

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

CryoLife's Articles of Incorporation and Bylaws contain provisions that may discourage or make more difficult any attempt by a person or group to obtain control of CryoLife, including provisions authorizing the issuance of preferred stock without shareholder approval, restricting the persons who may call a special meeting of the shareholders, and prohibiting shareholders from taking action by written consent. In addition CryoLife is subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of CryoLife's common stock. Further, pursuant to the terms of a shareholder rights plan adopted in 1995, 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.

Dividends Are Not Likely To Be Paid In The Foreseeable Future

CryoLife has not paid, and does not presently intend to pay, cash dividends. Future credit agreements may contain financial covenants, including covenants to maintain certain levels of net worth and certain leverage ratios, which could have the effect of restricting the amount of dividends that CryoLife may pay. It is not likely that any cash dividends will be paid in the foreseeable future.

Forward-Looking Statements

This Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995.

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, including statements regarding the impact of recent accounting pronouncements, the impact of the FDA Order and subsequent FDA activity on future revenues, profits, and business operations, the effect of the FDA Order and subsequent FDA activity on sales of BioGlue, future tissue procurement levels resulting from the FDA Order and subsequent FDA activity, expected future impact of BioGlue on revenues, the estimates underlying the charges recorded in the second and third quarter of 2002 due to the FDA Order, the impact of the FDA 483s, the estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies, the estimates of the amounts accrued for known product loss claims and for product loss claims incurred but not reported at December 31, 2003, adequacy of product liability insurance to defend against lawsuits, the adequacy of insurance coverage, future revenues, future costs of human tissue preservation services, changes in liquidity and capital resources as a result of the FDA Order and subsequent FDA activity, the outcome of the FDA letter regarding the SynerGraft processed cardiovascular and vascular tissues, the outcome of any evaluation of allograft heart valves by the FDA, the possible adverse outcome of the SEC investigation, future product development plans as a result of the FDA Order and subsequent FDA activity, the amount and timing of tax refunds the Company expects to receive, the Company's competitive position, funding available to continue development of the ACT, estimated dates relating to the Company's proposed regulatory submissions, the Company's expectations regarding the adequacy of current financing, product demand and market growth, the potential of the ACT for use in cancer therapies, fibrinolysis (blood clot dissolving), and other drug delivery applications, the outcome of litigation, 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, and similar expressions concerning matters that are not historical facts are forward-looking statements.

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 the Company. 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 the case have been filed. As of February 24, 2004 the Company was aware of approximately nine pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, six allege product liability claims arising out of the Company's orthopaedic tissue services, two allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, when it was a subsidiary of the Company.

During the fourth quarter of 2003, 15 lawsuits and claims against the Company were settled including the complaints filed against the Company by Jeffrey Andronaco and Christina Andronaco and Jolene and Robert Moulton. The total settlements involved in these lawsuits and claims including amounts paid by the Company or its insurer were $14.6 million. Through February 25, 2004, four lawsuits and claims against the Company were settled or dismissed. The total settlements involved in these lawsuits and claims including amounts paid by the Company or its insurer were $1.5 million.

Of the nine open lawsuits, two lawsuits were filed in the 2000/2001 insurance policy year, two were filed in the 2001/2002 insurance policy year, two were filed in the 2002/2003 insurance policy year and three were filed in the 2003/2004 insurance policy year. For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. As of December 31, 2003 the Company has an accrual of $100,000 for retention levels related to the 2000/2001 and 2001/2002 policy years.

For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. The Company used all of its insurance coverage, aggregating $25 million, for the 2002/2003 insurance policy year, as well as funds of its own, to resolve claims outstanding in the relevant policy period. The Company will be required to fund any amounts needed to defend against the remaining suits filed during the 2002/2003 insurance policy year. For the 2003/2004 insurance policy year, the Company maintains a first year claims-made insurance policy, i.e. only claims incurred and reported during the policy period April 1, 2003 through March 31, 2004 are covered by this policy. Of the three lawsuits filed in the 2003/2004 insurance policy year, one is covered by insurance and two are not. The Company believes its 2003/2004 insurance policy to be adequate to defend against the one suit filed during this time period. 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, 2003 of the pending uninsured product liability claims based on settlement negotiations to date and advice from counsel. As of December 31, 2003 the Company had accrued a total of $5.5 million for uninsured product liability claims. The $5.5 million balance is included as a component of accrued expenses and other current liabilities on the December 31, 2003 Consolidated Balance Sheet.

The amounts recorded are reflective of potential legal fees and settlement costs related to these claims, and do 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.

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. During 2003 the Company retained an independent actuarial firm to perform a revised estimate of the unreported claims.

As a result of the actuarial valuation, the Company accrued an additional $4.3 million during 2003 for estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. The $4.3 million expense was recorded in general, administrative, and marketing expenses. As of December 31, 2003 the Company had accrued a total of $7.9 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. 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 $7.9 million balance is included as a component of accrued expenses and other current liabilities of $3.9 million and other long-term liabilities of $4.0 million on the December 31, 2003 Consolidated Balance Sheet.

Class Action Lawsuit

Several putative class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that the Company made misrepresentations and omissions relating to product safety and the Company'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. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the United States 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, the case remains in the discovery phase. 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.

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. 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 into certain matters relating to the Company's August 14, 2002 announcement of the recall order issued by the FDA. Since that time, the Company has been cooperating with the SEC in its inquiry, which as the SEC notified the Company in July 2003, became a formal investigation in June 2003. The Company plans to continue to cooperate with the SEC in its investigation.

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 alleges that Mr. Payne received a tissue implant processed by a third party unaffiliated with the Company, and that he was subsequently diagnosed with an infection attributed to the implant. The claim against the Company asserts 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 asserts that the Company had a duty to notify two of 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 allege the recipient received an implant processed by the same unaffiliated third party processor, from the same donor as Mr. Payne, and contracted an infection. The Company intends to vigorously defend against these claims, although the Company is presently unable to predict the outcome.

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

Inapplicable.

Item 4A. Executive Officers of the Registrant.

Each of the executive officers of the Registrant 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. The following table lists the executive officers of the Registrant and their ages, positions with the Registrant, and the dates from which they have continually served in their present positions with the Registrant.

Name	Age	Position	Date First Elected to Present Office
Steven G. Anderson	65	President, Chief Executive Officer, and Chairman	February, 1984
Sidney B. Ashmore	45	Vice President, Marketing	March, 2001
Kirby S. Black, PhD	49	Senior Vice President, Research and Development	July, 1995
David M. Fronk	40	Vice President, Clinical Research	December, 1998
Albert E. Heacox, PhD	53	Senior Vice President, Laboratory Operations	June, 1989
D. Ashley Lee, CPA	39	Vice President, Finance, Chief Financial Officer, and Treasurer	December, 2002
Thomas J. Lynch, JD, PhD	53	Vice President, Regulatory Affairs and Quality Assurance	August, 2003
Joseph Schepers	46	Vice President, Corporate Communications	April 2003
James C. Vander Wyk, PhD	59	Vice President, Product Integrity	December, 2002

Steven G. Anderson, a founder of the Company, has served as the Company's President, Chief Executive Officer, and Chairman since its inception. Mr. Anderson has more than 30 years of experience in the implantable medical device industry. Prior to joining the Company, Mr. Anderson was Senior Executive Vice President and Vice President, Marketing, from 1976 until 1983 of Intermedics, Inc. (now Guidant, Inc.), a manufacturer and distributor of pacemakers and other medical devices. Mr. Anderson received his BA from 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 BA from Vanderbilt University in 1981, his MS from the University of Hawaii in 1985, and his MBA from Northwestern University in 1991.

Kirby S. Black, PhD, has served as Vice President of Research and Development since July 1995. Dr. Black was promoted to Senior Vice President in December of 2000. Dr. Black is responsible for the continued development of the Company's current products as well as the evaluation of new technologies. Dr. Black is listed on six patents and has authored over 130 publications. Prior to joining the Company, Dr. Black was Director, Medical Information and Project Leader from July 1993 until July 1994 at Advanced Tissue Sciences, LaJolla, California. Dr. Black has also held a number of positions at the University of California at Irvine, including Director, Transplantation and Immunology Laboratories, Department of Surgery. Dr. Black received his BSME degree from the University of California, Los Angeles, and his PhD degree in immunology from the University of California at Irvine.

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 BS in Mechanical Engineering from Ohio State University in 1985 and his MS in Biomedical Engineering from Ohio State University in 1986.

Albert E. Heacox, PhD, has served as Vice President of Laboratory Operations since June 1989 and has been with the Company since June 1985. 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. 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 BA and an MS in Biology from Adelphi University, received his PhD 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 Vice President of Finance and Chief Financial Officer of the Company since April 2000 and as Vice President of Finance, Chief Financial Officer, and Treasurer since December 2002. Mr. Lee previously served 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 information technology, human resources, and purchasing. 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 BS in Accounting from the University of Mississippi.

Thomas J. Lynch, JD, PhD 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 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 BA and MBA from Seton Hall University.

James C. Vander Wyk, PhD, has served as Vice President, Product Integrity since December 2002 and had previously served as Vice President, Regulatory Affairs and Quality Assurance of the Company since February 1996. Prior to joining the Company, Dr. Vander Wyk held senior management positions at Schneider (USA), Inc. from 1993 until 1996, Pharmacia Deltec, Inc. from 1985 until 1993, Delmed, Inc. from 1980 until 1985 and Pharmaco, Inc. from 1975 to 1979, gaining 20 years of experience in Regulatory Affairs and Quality Assurance. Dr. Vander Wyk received his BS in Pharmacy from the Massachusetts College of Pharmacy and his PhD in Microbiology from the University of Massachusetts. Dr. Vander Wyk performed his NIH Postdoctoral Fellowship at the University of Illinois.

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.

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

2002	High	Low
First quarter	30.74	20.05
Second quarter	32.00	14.90
Third quarter	16.06	1.40
Fourth quarter	7.92	2.12

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 will 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 January 31, 2004 the Company had 431 shareholders of record.

The Company did not repurchase any shares in the fourth quarter of 2003.

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. The selected data presented below for and as of the end of the years ended December 31, 2003 and 2002 are derived from the Company's consolidated financial statements that have been audited by Deloitte and Touche LLP, independent auditors, and which are included elsewhere in this Report and are qualified by reference to such Consolidated Financial Statements and Notes thereto. The selected data presented below for and as of the years ended December 31, 2001, 2000 and 1999 are derived from the Company's consolidated financial statements that have been audited by Arthur Andersen LLP, independent auditors. The historical results are not necessarily indicative of future results of operations.

Selected Financial Data
(in thousands, except percentages and per share data)

	December 31,				
Operations	**2003**	**2002**	**2001**	**2000**	**1999**
Revenues	$ 59,532	$ 77,795	$ 87,671	$ 77,096	$ 66,722
Net (loss) income	(32,294)	(27,761)	9,166	7,817	4,451
Research and development as a percentage of revenues	6.1%	5.9%	5.4%	6.8%	6.6%
(Loss)/Earnings Per Share[1]					
Basic	$ (1.64)	$ (1.43)	$ 0.49	$ 0.42	$ 0.24
Diluted	$ (1.64)	$ (1.43)	$ 0.47	$ 0.41	$ 0.24
Year-End Financial Position					
Total assets	$ 75,027	$ 106,414	$ 129,310	$ 112,009	$ 94,025
Working capital	14,790	39,385	66,668	69,063	59,597
Long term liabilities	5,716	4,552	10,071	12,192	6,177
Shareholder's equity	48,338	79,800	101,439	89,395	80,226
Current ratio[2]	2:1	3:1	5:1	8:1	9:1
Shareholders' equity per diluted common share[1]	$ 2.46	$ 4.11	$ 5.16	$ 4.65	$ 4.27

[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

CryoLife, Inc., incorporated January 19, 1984 in Florida, preserves and distributes human tissues for cardiovascular, vascular, and orthopedic transplant applications and develops and commercializes implantable medical devices, including its BioGlue® Surgical Adhesive ("BioGlue"), the CryoLife-O'Brien® aortic heart valve, a glutaraldehyde-fixed stentless porcine heart valve, and SynerGraft® processed bovine vascular grafts for use as arteriovenous access devices. The Company distributes preserved human cardiovascular, vascular, and orthopedic tissue throughout the U.S., Canada, and Europe. The Company can distribute BioGlue throughout the U.S. and more than 40 other countries for designated applications. 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 in the U.S. In Europe CryoLife distributes BioGlue under Conformité Européene ("CE") Mark product certification for vascular applications, pulmonary indications, such as the repair of air leaks in lungs, and soft tissue repair procedures. CryoLife has also received approval and distributes BioGlue for vascular, pulmonary, and soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in Australia, and in several countries in South America and Asia. CryoLife markets the SynerGraft processed bovine vascular graft in Europe and the Middle East. CryoLife currently markets its CryoLife-O'Brien aortic heart valve in Europe and certain other territories outside the U.S.

See Item 1. Business. "FDA Order on Human Tissue Preservation" and "Other FDA Notices and Correspondence" for a discussion of events surrounding FDA compliance activities in 2002 and 2003.

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.

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, net of reserve, on a first-in, first-out basis.

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. 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 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 value 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, on the Company's statement of operations.

During 2002 the Company recorded a write-down of deferred preservation costs of $8.7 million for valved cardiac tissues, $2.9 million for non-valved cardiac tissues, $11.9 million for vascular tissues, and $9.2 million for orthopaedic tissue, totaling $32.7 million. These write-downs were recorded as a result of the FDA Order as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation". 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 these tissues become available for distribution. The cost of human tissue preservation services has been favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services may continue to be favorably affected depending on the future level of tissue shipments related to previously written-down deferred preservation costs, but such impact is not expected to be material. Management continues to evaluate the recoverability of the deferred preservation costs and will record additional write-downs if it becomes clear that additional impairments have occurred.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. During 2003 the Company recorded $6.9 million 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, 2003 deferred preservation costs were $3.6 million for allograft heart valve tissues, $499,000 for non-valved cardiac tissues, $3.5 million for vascular tissues, and $1.2 million for orthopaedic tissues.

Deferred Income Taxes: Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company

generated deferred tax assets in 2003 and 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 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 and 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 is more likely than not that the Company's deferred tax assets will not be realized. Therefore, during 2003 the Company recorded valuation allowances totaling $13.7 million due to the effect of temporary differences between book and tax income, the net deferred tax assets generated in 2003, and the net deferred tax asset balance at December 31, 2002. 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.

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

- Significant underperformance relative to expected historical or projected future operating results;
- Significant negative industry or economic trends;
- Significant decline in the Company's stock price for a sustained period; and
- Significant decline in the Company's market capitalization relative to net book value.

Statement of Financial Accounting Standards 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 a fourteen-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, 2003 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 tissue preservation business or medical device business. However, depending on the Company's ability to rebuild demand for its tissue preservation services and the future effects of events surrounding the FDA Order, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

Beginning with the Company's adoption of Statement of Financial Accounting Standards ("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 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, 2003 the Company does not believe an additional impairment exists related to its other non-amortizing intangible assets. Management does not believe an impairment exists related to the other intangible assets that were assessed in accordance with SFAS No. 144.

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 the case 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. During 2003 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed as of December 31, 2003. 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.

As a result of the actuarial valuation, the Company accrued an additional $4.3 million during 2003 for estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. The $4.3 million expense was recorded in general, administrative, and marketing expenses. As of December 31, 2003 the Company had accrued a total of $7.9 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. 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 $7.9 million balance is included as a component of accrued expenses and other current liabilities of $3.9 million and other long-term liabilities of $4.0 million on the December 31, 2003 Consolidated Balance Sheet.

For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. As of December 31, 2003 the Company has an accrual of $100,000 for retention levels related to the 2000/2001 and 2001/2002 policy years. For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. The Company used all of its insurance coverage, aggregating $25 million, for the 2002/2003 insurance policy year, as well as funds of its own, to resolve claims outstanding in the relevant policy period. The Company will be required to fund any amounts needed to defend against the remaining suits filed during the 2002/2003 insurance policy year. For the 2003/2004 insurance policy year, the Company maintains a first year claims-made insurance policy, i.e. only claims incurred and reported during the policy period April 1, 2003 through March 31, 2004 are covered by this policy. Of the three lawsuits filed in the 2003/2004 insurance policy year, one is covered by insurance and two are uncovered. The Company believes its 2003/2004 insurance policy to be adequate to defend against the one suit filed to date during this insurance policy year. 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, 2003 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of December 31, 2003 the Company had remaining in an accrual a total of $5.5 million for the uninsured product liability claims. The $5.5 million balance is included as a component of accrued expenses and other current liabilities on the December 31, 2003 Consolidated Balance Sheet.

The amounts recorded are reflective of potential legal fees and settlement costs related to these claims, and do 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.

New Accounting Pronouncements

The Company was required to adopt SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143") on January 1, 2003. SFAS 143 addresses accounting and reporting for retirement costs of long-lived assets resulting from legal obligations associated with acquisition, construction, or development transactions. The adoption of SFAS 143 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

The Company was required to adopt SFAS No. 145, "Rescission of FASB Statements 4, 44 and 64, Amendment to FASB Statement 13, and Technical Corrections" ("SFAS 145"), on January 1, 2003. SFAS 145 rescinds SFAS Nos. 4, 44 and 64, which required gains and losses from extinguishments of debt to be classified as extraordinary items. SFAS 145 also amends SFAS No. 13, eliminating inconsistencies in certain sale-leaseback transactions. The provisions of SFAS 145 are effective for fiscal years beginning after May 15, 2002. The adoption of SFAS 145 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

The Company was required to adopt SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") on January 1, 2003. SFAS 146 requires that costs associated with exit or disposal activities be recorded at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The adoption of SFAS 146 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

The Company was required to adopt SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure: An amendment of FASB Statement No. 123" ("SFAS 148") on December 31, 2002. SFAS 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation", to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirement of SFAS No.123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The adoption of the additional disclosure requirements of SFAS 148 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

In May 2003, the FASB issued SFAS No. 150 "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS 150"). SFAS 150 requires that certain instruments be classified as liabilities in statements of financial position. Most of the guidance in SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. Because the Company does not have any of the effected financial instruments, the Company believes that the adoption of SFAS 150 will not have a material effect on its financial condition, results of operations, or cash flows.

Results of Operations
(In thousands)

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

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 Surgical Adhesive, 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 is 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 Surgical Adhesive.

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.

[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.

BioGlue Surgical Adhesive

	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 Surgical Adhesive 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 continues 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.

The Company anticipates that revenues from BioGlue Surgical Adhesive will continue to grow in 2004. On December 1, 2003 the Company initiated price changes for BioGlue, which increased the list price of BioGlue Surgical Adhesive, delivery devices, and applicator tips. The Company anticipates that this price increase will generate additional revenues in 2004, in addition to continued growth in BioGlue sales volume.

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", 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", 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 recent procurement levels remain approximately 19% below procurement levels prior to the FDA Order in the second quarter of 2002.

The Company anticipates that cardiovascular service revenues will decrease in 2004 as compared to 2003, if the Company continues to process and ship tissues using only its traditional cryopreservation process. Increases in cardiovascular revenues in the long term are contingent on the Company's ability to increase the amount of tissues available for implantation by decreasing tissue processing times and increasing yields of implantable tissue per donor and to resume processing and shipping tissues processed using SynerGraft technology.

As discussed in Item 1. Business. the Company has voluntarily 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 preserved with the SynerGraft technology until the regulatory status of the CryoValve SG is resolved. 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 be provided to support the 510(k) premarket notification for the CryoValve SG. The requested information may require additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume processing and distribution of SynerGraft processed cardiovascular tissue. The outcome of the 510(k) premarket notification application with the FDA regarding the use of the SynerGraft process on human tissue could result in the elimination of SynerGraft processed cardiovascular tissue.

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", 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", 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 has 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 recent procurement levels remain approximately 48% below procurement levels prior to the FDA Order in the second quarter of 2002.

The Company anticipates that vascular service revenues will increase in 2004 as compared to 2003 based on expected procurement levels, consumer demand, and an improvement in yields of implantable tissues. Increases in vascular revenues in the long term are contingent on the Company's ability to increase the amount of tissues

available for implantation by decreasing tissue processing times and increasing yields of implantable tissue per donor and to increase the level of procurement as necessary based on customer demand and processing capacity.

As discussed in Item 1. Business. "Other FDA Correspondence" the Company has voluntarily suspended the use of the SynerGraft technology in the processing of vascular tissue and in late September 2003 suspended the distribution of tissues on hand that have been preserved with the SynerGraft technology until the regulatory status of the CryoVein SG is resolved. Additionally, the Company has discontinued labeling its vascular grafts for use as A-V access grafts. On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that vascular tissues processed with the SynerGraft technology should be regulated as medical devices. The outcome of the discussions and filing with the FDA regarding the use of the SynerGraft process on human tissue could result in an inability to process and distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted.

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". 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", 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", 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 has 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 are still approximately 75% below procurement levels prior to the FDA Order in the second quarter of 2002.

The Company anticipates that orthopaedic service revenues will show a significant increase in 2004 as compared to 2003 based on expected procurement levels, consumer demand, and an improvement in yields of implantable tissues. Revenues from orthopaedic tissue services are still expected to be well below 2002 levels prior to the FDA Order. Increases in orthopaedic revenues in the long term are contingent on the Company's ability to increase the amount of tissues available for implantation by decreasing tissue processing times and increasing yields of implantable tissue per donor and to increase the level of procurement as necessary based on processing capacity and customer demand.

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. The Company does not currently anticipate receiving distribution revenues from any third party processors in 2004.

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 treated with the higher margin SynerGraft process as compared to traditional processing.

The Company anticipates cost of human tissue preservation services will increase in 2004 when compared to 2003, due to projected increases in cryopreservation service revenues during 2004. The cost of human tissue preservation services as a percentage of revenue will 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. Decreases in cost of human tissue preservation services as a percentage of preservation service revenues in the long term are contingent on the Company's ability to reestablish sufficient margins on its tissue preservation services by increasing the amount of tissues processed, decreasing tissue processing times, and increasing yields of implantable tissue per donor.

The cost of human tissue preservation services may be favorably affected in 2004 by shipments of tissue with a cost basis that has previously been written-down to zero, but such impact is not expected to be material. 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.

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 treated 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 Surgical Adhesive, which carries higher gross margins than bioprosthetic devices.

The Company anticipates aggregate cost of products will increase slightly in 2004 when compared to 2003, primarily due to projected increases in BioGlue revenues during 2004.

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.

The Company anticipates general, administrative, and marketing expenses will decrease in 2004 when compared to 2003, as the large accruals recorded in 2003 related to product liability claims are not expected to recur in 2004. The Company anticipates that insurance costs, legal costs, and professional fees will continue to be higher in 2004 than those experienced prior to the FDA Order. 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 2004, 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 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.

The Company anticipates research and development expenses will increase slightly in 2004 when compared to 2003, but those expenses should continue to represent approximately 6% of total revenues.

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 recorded in the third quarter of 2002 as discussed in Critical Accounting Policies above.

Interest expense decreased 40% to $415,000 in 2003, compared to $692,000 in 2002. The decrease was due to the Company's reduced 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 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 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. See additional discussion of the Company's cash position in the Liquidity and Capital Resources section below.

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.

Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Revenues

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2002	2001	2002	2001
Revenues as reported	$ 12,171	$ 21,975	$ 77,795	$ 87,671
Estimated tissue recall returns	--	--	3,466	--
Adjusted revenues[a]	$ 12,171	$ 21,975	$ 81,261	$ 87,671

Adjusted revenues decreased 45% and 7%, respectively, for the three and twelve months ended December 31, 2002. This decrease in revenues for the three and twelve months ended December 31, 2002, respectively, was primarily due to a 66% and 22% decrease in human tissue preservation service revenues as a result of the FDA Order's restriction on shipments of certain tissues, the Company's cessation of orthopaedic processing, and decreased demand as a result of the adverse publicity surrounding the FDA Order, partially offset by an 81% and 97% increase in BioGlue Surgical Adhesive revenues for the three and twelve months ended December 31, 2002, respectively. The BioGlue increases were primarily attributable to the receipt of FDA approval in December 2001 for the use of BioGlue in the U.S. as an adjunct to sutures and staples in open surgical repair of large vessels for adult patients.

Revenues as reported decreased 11% for the twelve months ended December 31, 2002. Revenues were adversely impacted 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 during the twelve months ended December 31, 2002. As discussed below, the estimated amount of recall returns includes credits for tissues actually returned to the Company to date and the expected credits for future tissues to be returned to the Company as a result of the FDA Order. No adjustments were made to the original estimate of recall returns as actual returns to date have approximated the original estimate of recall returns.

BioGlue Surgical Adhesive

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2002	2001	2002	2001
Revenues as reported	$ 5,590	$ 3,090	$ 20,898	$ 10,595
BioGlue revenues as reported as a percentage of total revenue as reported	46%	14%	27%	12%
BioGlue revenues as reported as a percentage of total adjusted revenues[a]	46%	14%	26%	12%

Revenues as reported from the sale of BioGlue Surgical Adhesive increased 81% and 97%, respectively, for the three and twelve months ended December 31, 2002. The increase in revenues for the three and twelve month periods ended December 31, 2002 was due to an increase in the milliliters of BioGlue shipped of 56% and 75%, respectively, and a 15% and 12%, respectively, increase in the average selling price of the BioGlue shipped. The increase in shipments was primarily due to the receipt of FDA approval in December 2001 for the use of BioGlue in the U.S. as an adjunct to sutures and staples in open surgical repair of large vessels for adult patients. Domestic revenues accounted for 81% and 65% of total BioGlue revenues for the three months ended December 31, 2002 and 2001, respectively. Domestic revenues accounted for 79% and 66% of total BioGlue revenues for the twelve months ended December 31, 2002 and 2001, respectively.

Cardiovascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2002	2001	2002	2001
Revenues as reported	$ 3,283	$ 6,304	$ 23,413	$ 28,606
Cardiovascular revenues as reported as a percentage of total revenue as reported	27%	29%	30%	33%
Adjusted revenues[a]	$ 3,283	$ 6,304	$ 23,924	$ 28,606
Cardiovascular adjusted revenues as a percentage of total adjusted revenues[a]	27%	29%	29%	33%

Adjusted revenues from cardiovascular preservation services decreased 48% and 16%, respectively, for the three and twelve months ended December 31, 2002. This decrease in revenues for the three and twelve month periods ended December 31, 2002 was primarily due to a decline in customer demand due to the adverse publicity surrounding the FDA Order, the FDA Letter posted on its website, certain reported tissue infections and the related adverse publicity, and the restrictions on shipments of certain tissues subject to the FDA Order.

Revenues as reported from cardiovascular preservation services decreased 18% for the twelve months ended December 31, 2002. In addition to the factors discussed above, the revenues as reported from cardiovascular preservation services were adversely impacted by the estimated effect of the non-valved cardiac tissues returned

subject to recall by the FDA Order, which resulted in an estimated decrease of $511,000 in service revenues during the twelve months ended December 31, 2002.

Vascular Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2002	2001	2002	2001
Revenues as reported	$ 2,908	$ 5,865	$ 17,826	$ 24,488
Vascular revenues as reported as a percentage of total revenue as reported	24%	27%	23%	28%
Adjusted revenues[a]	$ 2,908	$ 5,865	$ 20,373	$ 24,488
Vascular adjusted revenues as a percentage of total adjusted revenues[a]	24%	27%	25%	28%

Adjusted revenues from human vascular tissue preservation services decreased 50% and 17%, respectively, for the three and twelve months ended December 31, 2002. This decrease in revenues for the three and twelve month periods ended December 31, 2002 was primarily due to a decline in customer demand due to the adverse publicity surrounding the FDA Order, certain reported tissue infections, and the restrictions on shipments of certain tissues subject to the FDA Order.

Revenues as reported from human vascular tissue preservation services decreased 27% for the twelve months ended December 31, 2002. In addition to the factors discussed above, the revenues as reported from vascular tissue preservation services were adversely impacted by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of $2.5 million in vascular preservation service revenues during the twelve months ended December 31, 2002.

Orthopaedic Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2002	2001	2002	2001
Revenues as reported	$ 108	$ 6,314	$ 14,134	$ 22,458
Orthopaedic revenues as reported as a percentage of total revenue as reported	1%	29%	18%	26%
Adjusted revenues[a]	$ 108	$ 6,314	$ 14,542	$ 22,458
Orthopaedic adjusted revenues as a percentage of total adjusted revenues[a]	1%	29%	18%	26%

Adjusted revenues from human orthopaedic tissue preservation services decreased 98% and 35% for the three and twelve months ended December 31, 2002. This decrease in revenues for the three and twelve month periods ended December 31, 2002 was primarily due to a decline in customer demand due to the adverse publicity surrounding the FDA Order, certain reported tissue infections, cessation of processing of orthopaedic tissue, and the restrictions on shipments of tissues subject to the FDA Order. Revenues since August 14, 2002 have been from shipments of orthopaedic tissues that were processed prior to October 3, 2001.

Revenues as reported from human orthopaedic tissue preservation services decreased 37% for the twelve months ended December 31, 2002. In addition to the factors discussed above, the revenues as reported from orthopaedic tissue preservation services were adversely impacted by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of $408,000 in orthopaedic preservation service revenues during the twelve months ended December 31, 2002.

Bioprosthetic Devices

Revenues from bioprosthetic cardiovascular devices increased 31% to $699,000 in 2002 from $535,000 in 2001, representing 1% of total revenues during such periods. This increase in revenues was primarily due to an increase in the demand for the Company's SynerGraft bovine vascular grafts which received CE Mark approval in August 2001.

Distribution and Grant Revenues

Grant revenues decreased to $348,000 in 2002 from $985,000 in 2001. Grant revenues in both years were primarily attributable to the SynerGraft research and development programs. Distribution revenues increased to $477,000 in 2002 from $4,000 in 2001. Distribution revenues are for commissions received for the distribution of orthopaedic tissues for another processor.

Cost of Human Tissue Preservation Services

Cost of human tissue preservation services aggregated $55.4 million in 2002 compared to $31.2 million in 2001, representing 100% and 41%, respectively, of total human tissue preservation service revenues during each period. Cost of human tissue preservation services aggregated $2.1 million in fourth quarter of 2002 compared to $7.6 million in 2001, representing 34% and 41%, respectively, of total human tissue preservation service revenues during each period. The increase in the full year 2002 cost of preservation was due to the $32.7 million write-down of deferred preservation costs recorded in the second and third quarters of 2002 related to the FDA Order (See Item 1. Business. "FDA Order on Human Tissue Preservation"). The decrease in the fourth quarter cost of preservation was due to decreased demand and shipments of tissue for which approximately $1.4 million of deferred preservation costs that were written-off in the second and third quarter of 2002.

Cost of Products

Cost of products aggregated $10.3 million in 2002 compared to $5.5 million in 2001, representing 48% and 49%, respectively, of total product revenues during such periods. Cost of products aggregated $1.5 million in the fourth quarter of 2002 compared to $1.4 million in the fourth quarter of 2001, representing 25% and 46%, respectively, of total product revenues during such periods. The 2002 cost of products includes a $3.1 million write-down of bioprosthetic valves, including SynerGraft and non-SynerGraft treated 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 vascular graft product lines. The decrease in the fourth quarter 2002 cost of products as a percentage of total product revenues is due to a favorable product mix that was impacted by the increase in revenues from BioGlue Surgical Adhesive, which carries higher gross margins than bioprosthetic devices.

General, Administrative, and Marketing Expenses

General, administrative, and marketing expenses increased 40% to $47.5 million in 2002, compared to $33.8 million in 2001, representing 61% and 39%, respectively, of total revenues during such periods. The increase in expenditures for the twelve months ended December 31, 2002 was primarily due to increased overhead costs in connection with the expansion of the corporate headquarters and manufacturing facility, which was substantially completed in the first quarter of 2002, a $3.6 million accrual for estimated product loss claims that have been incurred but not reported as of December 31, 2002, an increase of $1.1 million in insurance premiums, an increase of $1.7 million in legal and accounting costs due to the response to the FDA Order and increased litigation, a $1.2 million accrual for retention levels under the Company's liability and directors' and officers' insurance policies, additional professional fees of $1.5 million required to address the observations detailed in the Warning Letter and severance and related costs of approximately $690,000 due to the reduction in employee force of approximately 105 employees.

Research and Development Expenses

Research and development expenses decreased 3% to $4.6 million in 2002, compared to $4.7 million in 2001, representing 6% and 5%, respectively, of total revenues during such periods. Research and development spending in 2002 was primarily focused on the Company's SynerGraft and Protein Hydrogel Technologies.

Other Costs and Expenses

The Company recorded a $1.4 million write-down of its goodwill, which is shown as a separate line on the Consolidated Statements of Operations for the twelve months ended December 31, 2002.

Interest income, net of interest expense, was $203,000 for the twelve months ended December 31, 2002 as compared to $1.9 million for the twelve months ended December 31, 2001. The 2002 decrease in net interest income was due to reduced interest rates in 2002 as compared to 2001, a reduction in the principal debt amount outstanding due to scheduled payments, and the lack of interest expense capitalized in 2002 in connection with the expansion of the corporate headquarters and manufacturing facility, which was substantially completed in the first quarter of 2002.

The effective income tax rate was 33% and 32% for the years ended December 31, 2002 and 2001, respectively.

Seasonality

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 BioGlue Surgical Adhesive 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 high 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 human vascular and orthopaedic tissue preservation services and bioprosthetic cardiovascular and vascular devices does not appear to experience seasonal trends.

Liquidity and Capital Resources

Net Working Capital

At December 31, 2003 net working capital (current assets of $35.8 million less current liabilities of $21.0 million) was $14.8 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of $39.3 million, with a current ratio of 3 to 1 at December 31, 2002. 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 2003 the Company's primary capital requirements arose out of working capital needs created by increasing costs of operations combined with decreasing revenues due to the effects of the FDA Order, subsequent FDA activity, and related events as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation". Specifically, the Company had costs related to its employees and recently expanded corporate headquarters and manufacturing facilities during a period of reduced tissue processing and reduced tissue service revenues. Operating results were also negatively impacted by increases in general, administrative, and marketing costs as a result of increased legal and professional fees and settlement costs as discussed in the results of operations section above. Liquidity was further impacted by cash used in financing activities as discussed below. The Company funded these requirements primarily through sales and

maturities of marketable securities totaling $9.1 million and the receipt of significant tax refunds totaling $12.2 million during the year.

Overall Liquidity and Capital Resources

The Company expects that its operations will continue to generate negative cash flows over the next twelve months due to

- The anticipated lower preservation revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activity, and related events,
- The increase in cost of human tissue preservation services as a percent of revenue as a result of lower tissue processing volumes and changes in processing methods,
- An expected use of cash related to the defense and resolution of lawsuits (discussed in Note 9 to the consolidated financial statements), and
- The legal and professional costs related to its ongoing FDA compliance.

The Company has obtained additional equity financing subsequent to December 31, 2003, discussed below, and management believes that this funding coupled with anticipated revenue generation, expense management, tax refunds expected to be approximately $2.4 million, and the Company's existing cash and marketable securities will enable the Company to meet its liquidity needs through at least December 31, 2004.

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 3.4 million shares of stock at a price of $6.25 per share. The sale generated net proceeds of approximately $19.9 million, after commissions, registration fees, and other related charges, which will be used for general corporate purposes. On February 10, 2004 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. The Company has agreed to pay 1% of the aggregate purchase price per month, subject to certain limitations, if the registration statement is not declared effective within 75 days of the closing date of January 27, 2004.

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

- The Company's ability to return to the level of demand for its tissue services that existed prior to the FDA Order,
- The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs,
- The Company's spending levels on its research and development activities, including research studies, to develop and support its product pipeline,
- The outcome of litigation against the Company (discussed in Note 9 to the consolidated financial statements), and
- The amount and the timing of the resolution of the remaining outstanding product liability claims (discussed in Note 9 to the consolidated financial statements).

The Company 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, 2004. 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 9 to the consolidated financial statements, at December 31, 2003 the Company had $5.5 million remaining in an accrual for the estimated expense of resolving the remaining outstanding product liability claims in excess of insurance coverage. The $5.5 million accrual is an estimate of the costs required to resolve outstanding claims, and does not reflect actual settlement arrangements or judgments, including punitive damages, which may be assessed by the courts. The $5.5 million accrual is not a cash reserve. The timing of actual future payments related to the accrual is dependent on when and if judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, 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 9 to the consolidated financial statements.

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 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 9 to the consolidated financial statements, at December 31, 2003 the Company had $7.9 million remaining in an accrual for the estimated costs of unreported product liability claims related to services performed and products sold prior to December 31, 2003. The $7.9 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 $5.9 million in 2003, as compared to $2.1 million in 2002. The $5.9 million of cash used in 2003 was primarily due to a decrease in revenues and an increase in cash expenditures, both of which are related to the FDA Order, subsequent FDA activity, and related events, as discussed in Item 1. Business. "FDA Order on Human Tissue Preservation". Spending, including the cost of employees and facilities, was not sufficiently supported by cash received from revenues. Increased spending on general and administrative expenses from increased professional fees and legal and settlement costs also contributed to the cash shortfall in operations.

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) income, which is then adjusted to remove all non-cash items. The Company's net loss from operations included significant recurring non-cash items in the normal course of business that generated favorable and unfavorable adjustments to net income. These adjustments included a favorable $5.2 million in depreciation and $316,000 in amortization, a favorable $954,000 due to the timing differences between the recording of accounts receivable and the actual receipt of cash from customers, an unfavorable $11.3 million due to the buildup of deferred preservation costs for which vendors and employees have already been paid, a favorable $2.3 million primarily due to prepaid insurance, and an unfavorable $1.7 million due to the timing differences between the recording of accounts payable and the actual payment of cash to vendors and employees. The Company's net loss from operations also included significant non-cash items, which are unusual or not expected to recur, that generated favorable and unfavorable adjustments to net income. These adjustments included a favorable $6.9 million in write-downs for impairment of deferred preservation costs, a favorable $5.7 million due to valuation reserves placed on the Company's deferred tax assets, a favorable $9.5 million in income tax receivables largely due to the receipt of $12.2 million in tax refunds which were recorded during the previous year, and a favorable $8.0 million in accrued expenses and other current liabilities primarily due to accruals for expected future product liability expenditures as discussed above.

The Company anticipates that cash from operations will continue to be negative in 2004. This cash used will primarily be a result of the Company's projected net loss for 2004. The Company does not currently expect that it will be required to record significant additional non-cash write-downs of inventory or additional significant accruals related to product liabilities during 2004, but such items would not have a direct effect on net cash from operations. Significant additional cash payments related to settlements, as discussed above, could have a negative impact on future cash flows. The Company anticipates that it will continue to record a valuation allowance against its deferred tax assets generated from operating losses and to record write-downs of deferred preservation costs which exceed market value, but such items would not have a direct effect on net cash from operations. The Company expects to receive tax refunds totaling $2.4 million in 2004, which is substantially less than the $12.2 million received in 2003.

Net Cash from Investing Activities

Net cash provided by investing activities was $9.4 million in 2003, as compared to $6.3 million in 2002. The $9.4 million in current year cash provided was primarily due to $9.1 million in cash generated from sales and maturities of marketable securities. This cash was used to fund the Company's operations, which used $5.0 million in cash during 2003 as discussed above and to pay down the Company's Term Loan as discussed below. The Company generated an additional $1.1 million in cash from investing activities through the sale of a parcel of land adjacent to the Company's existing corporate headquarters and manufacturing facilities. The Company also used cash of $955,000 for capital spending in 2003, primarily to purchase equipment to support process changes in the Company's tissue processing laboratory and microbiology department and for equipment and leasehold improvements related to the creation of an in-house pathology department during 2003.

Net Cash from Financing Activities

Net cash used in financing activities was $8.0 million in 2003, as compared to $1.4 million in 2002. The $8.0 million in cash used in 2003 was primarily due to $5.6 million in principal payments on the Term Loan, including a lump sum payment of $4.5 million in the third quarter of 2003 to pay off the remaining balance of the Term Loan as discussed in Note 6 to the consolidated financial statements. In addition the Company used cash of $2.4 million to make principal payments on a note payable, which financed the Company's insurance policy renewals for the 2003/2004 policy year, and $651,000 in principal payments on the Company's capital leases. The Company generated $660,000 in cash from financing activities as a result of the purchase of stock by the Company's employees through the employee stock purchase program and through the exercise of Company stock options.

Scheduled Contractual Obligations and Future Payments

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

	Total	2004	2005	2006	2007	2008	Thereafter
Capital Lease Obligations	$ 2,794	$ 843	$ 843	$ 843	$ 265	$ --	$ --
Operating Leases	26,058	2,276	2,197	2,030	2,068	2,108	15,379
Purchase Commitments	889	889	--	--	--	--	--
Total Contractual Obligations	$ 29,741	$ 4,008	$ 3,040	$ 2,873	$ 2,333	$ 2,108	$ 15,379

The Company's capital lease obligations result from the financing of certain of the Company's equipment and leasehold improvements 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 as described in Note 6 to the consolidated financial statements. Therefore, the $1.5 million due under these capital leases is reflected as a current liability on the Consolidated Balance Sheets as of December 31, 2003 and 2002. 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 an exclusive agreement with curasan AG for U.S. distribution of Cerasorb® Ortho bone graft substitute. CryoLife is in the process of negotiating a settlement with curasan for the dissolution of the distribution agreement and resolution of the guaranteed purchase requirements for 2004. Additional purchase commitments result from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production.

Interest Rate Swap Agreement

The Company's Term Loan, which was paid in full on August 15, 2003, accrued interest computed at Adjusted LIBOR plus 1.5%, and 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 August 2002 the Company determined that changes in the derivative's fair value could no longer be recorded in other comprehensive income, as a result of the uncertainty of future cash payments on the Term Loan caused by the lender's ability to declare an event of default as discussed in Note 6 to the consolidated financial statements. Beginning in August 2002 the Company began recording all changes in the fair value of the derivative into other expense/income on the Consolidated Statements of Operations, and amortized the amounts previously recorded in other comprehensive income into other expense/income over the remaining life of the swap agreement.

During the quarter ended June 30, 2003 the Company became aware of the lender's intention to accelerate the payment of the Term Loan, as discussed in Note 6 to the consolidated financial statements. Therefore, the Company recorded an expense of $222,000, to reclassify the unamortized portion of the other comprehensive loss to other expense/income on the Consolidated Statements of Operations. 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.

Stock Repurchase

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. The Company did not repurchase any common stock in 2003. 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, 2003, the Company had made no purchases under this authorization.

On October 12, 1998 the Company's Board of Directors authorized the Company to purchase up to 1.5 million shares of its common stock. As of December 31, 2001, the Company had purchased an aggregate of 1.2 million shares of its common stock for an aggregate purchase price of $8.3 million and an average price of $7.13 per share.

On February 24, 2004 the Company's Board of Directors rescinded its purchase authorizations dated March 27, 2002 and October 12, 1998, therefore no further purchases will be made under these authorizations.

Capital Expenditures

The Company expects that its capital expenditures in 2004 will show a modest increase over its expenditures in 2003, which were approximately $1.0 million. Capital expenditures in 2003 were restricted due to the Company's cash position. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to rebuild its tissue processing business and maintain adequate cash flows. The Company does not currently anticipate any major purchase of equipment as a result of the FDA inspections of its facilities.

Forward Looking Statements

The Company's statements addressing events or developments which will or may occur in the future, including those regarding the Company's competitive position, funding to continue development of the ACT, expectations regarding the impact of estimates required by U.S. generally accepted accounting policies, expectations regarding the outcome of the Form 483s and other FDA activity, product demand and market size and growth, anticipated levels of expense, the impact of products 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 $5.7 million and short-term investments in municipal obligations of $5.3 million as of December 31, 2003. A 10% adverse change in interest rates affecting the Company's cash equivalents and short-term investments would not have a material impact on the Company's financial position, results of operations, and cash flows for 2003.

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 Vice President of Finance, Treasurer, 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, 2003, 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, 2003, 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.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The response to Item 10 is incorporated herein by reference to the information set forth in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 29, 2004, with the exception of information concerning executive officers, which is included in Part I, Item 4A of this Form 10-K.

Item 11. Executive Compensation.

The response to Item 11 is incorporated herein by reference to the information set forth in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 29, 2004.

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

The response to Item 12 is incorporated herein by reference to the information set forth in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 29, 2004.

Item 13. Certain Relationships and Related Transactions.

The response to Item 13 is incorporated herein by reference to the information set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission not later than April 29, 2004.

Item 14. Principal Accounting Fees and Services.

The response to Item 14 is incorporated herein by reference to the information set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission not later than April 29, 2004.

PART IV

Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

The following are filed as part of this report:

(a) 1. Financial Statements

Independent Auditors' Report-Deloitte & Touche LLP, Report of Independent Public Accountants-Arthur Andersen LLP, Copy of Report of Independent Public Accountants, Consolidated Balance Sheets as of December 31, 2003 and 2002, Consolidated Statements of Operations for the years ended December 31, 2003, 2002 and 2001, Consolidated Statements of Cash Flows for the years ended December 31, 2003, 2002 and 2001, Consolidated Statements of Shareholders' Equity for the years ended December 31, 2003, 2002, and 2001 and Notes to consolidated financial statements.

2. Financial Statement Schedule

Independent Auditors' Report on Schedule II

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.

3. A. 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, as amended.
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) 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(b) 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(c) 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(d) 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 Reserved.

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) 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 fiscal year ended December 31, 1995.)

10.9(e) Employment Agreement, by and between the Company and Kirby S. Black, Ph.D. (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.)

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) 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.)

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 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.

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 Research and License Agreement by and between Medical University of South Carolina and CryoLife dated November 15, 1985, as amended by Amendment to the Research and License Agreement dated February 25, 1986 by and between the parties and an Addendum to Research and License Agreement by and between the parties, dated March 4, 1986. (Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)

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 Reserved.

10.20 Reserved.

10.21 Reserved.

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 Reserved.

10.24 Reserved

10.25 Reserved.

10.26 Reserved.

10.27 Reserved.

10.28 Subordinated Convertible Debenture dated March 5, 1997 between the Company and J. Crayton Pruitt, Sr., M.D. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1997.)

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 Letter Agreement between the Company and FDA, dated September 5, 2002. (Incorporated by reference to Exhibit 10.38 to the registrant's report on Form 8-K filed on September 6, 2002).

10.44 Letter Agreement between the Company and FDA, dated November 8, 2002. (Incorporated by reference to Exhibit 10.44 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.)

10.45 Letter Agreement between the Company and FDA, dated January 8, 2003. (Incorporated by reference to Exhibit 10.45 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.)

10.46 Letter Agreement between the Company and FDA, dated March 17, 2003. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly report in Form 10-Q for the quarter ended March 31, 2003.)

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 Letter Agreement between the Company and FDA, dated June 13, 2003. (Incorporated by reference to Exhibit 12.1 to the Registrant's Quarterly report in Form 10-Q for the quarter ended June 30, 2003.)

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.

23.2* Notice regarding consent of Arthur Andersen 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.

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. Reserved.

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. (Filed as Exhibit 10.9(o) to this Form 10-K.

(b) Reports on Form 8-K

The Registrant filed a Current Report on Form 8-K with the Commission on November 4, 2003 with respect to the Press Release dated November 4, 2003 announcing the registrant's results of operations for the third quarter 2003.

The Registrant filed a Current Report on Form 8-K with the Commission on January 7, 2004 with respect to the Press Release dated January 7, 2004 announcing the registrant's revenues for the year ending December 31, 2003.

The Registrant filed a Current Report on Form 8-K with the Commission on January 26, 2004 with respect to the Press Release dated January 26, 2004 announcing a $20 million private placement of the registrant's common stock.

The Registrant filed a Current Report on Form 8-K with the Commission on February 9, 2004 with respect to the Press Release dated February 6, 2004 announcing an update on its 510K premarket notification for CryoValve SG decellularized human heart valves.

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 1, 2004

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 1, 2004
/s/ D. ASHLEY LEE **D. Ashley Lee**	Vice President, Treasurer, and Chief Financial Officer (Principal Financial and Accounting Officer)	March 1, 2004
/s/ THOMAS F. ACKERMAN **Thomas F. Ackerman**	Director	March 1, 2004
/s/ DAN BEVEVINO **Dan Bevevino**	Director	March 1, 2004
/s/ JOHN M. COOK **John M. Cook**	Director	March 1, 2004
/s/ RONALD CHARLES ELKINS, M.D. **Ronald Charles Elkins, M.D.**	Director	March 1, 2004
/s/ VIRGINIA C. LACY **Virginia C. Lacy**	Director	March 1, 2004
/s/ RONALD D. MCCALL **Ronald D. McCall**	Director	March 1, 2004
/s/ BRUCE J. VAN DYNE, M.D. **Bruce J. Van Dyne, M.D.**	Director	March 1, 2004

INDEPENDENT AUDITORS' REPORT

To the Board of Directors
CryoLife, Inc.

We have audited the accompanying consolidated balance sheets of CRYOLIFE, INC. (a Florida corporation) AND SUBSIDIARIES ("the Company") as of December 31, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity, and cash flows for the years then ended. Our audits also included the 2003 and 2002 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 these financial statements and financial statement schedules based on our audits. The financial statements and financial statement schedules of the Company as of December 31, 2001 and for the year then ended were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements and stated that such 2001 financial statement schedules, when considered in relation to the 2001 consolidated financial statements taken as a whole, presented fairly, in all material respects, the information set forth therein, in their reports dated March 27, 2002.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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, the financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2003 and 2002, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the 2003 and 2002 financial statement schedules, when considered in relation to the 2003 and 2002 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.

Deloitte & Touche LLP
Atlanta, Georgia
March 1, 2004

The following report of Arthur Andersen LLP ("Andersen") is a copy of the report previously issued by Andersen on March 27, 2002. The report of Andersen is included in this annual report on Form 10-K pursuant to rule 2-02(e) of regulation S-X. The Company has not been able to obtain a reissued report from Andersen. Andersen has not consented to the inclusion of its report in this annual report on Form 10-K. Because Andersen has not consented to the inclusion of its report in this annual report, it may be difficult to seek remedies against Andersen, and the ability to seek relief against Andersen may be impaired.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To CryoLife, Inc.

We have audited the accompanying consolidated balance sheets of CYROLIFE, INC. (a Florida corporation) AND SUBSIDIARIES as of December 31, 2001 and 2000 and the related consolidated statements of income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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, the financial statements referred to above present fairly, in all material respects, the financial position of CryoLife, Inc. and subsidiaries as of December 31, 2001 and 2000 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

Arthur Andersen LLP
Atlanta, Georgia
March 27, 2002

CryoLife, Inc.
Consolidated Balance Sheets
(in thousands, except per share data)

ASSETS

December 31,	2003	2002
Current assets:		
Cash and cash equivalents	$ 5,672	$ 10,277
Cash held in escrow	972	--
Marketable securities, at market	5,272	14,583
Receivables:		
Trade accounts, less allowance for doubtful accounts of $65 in 2003 and $75 in 2002	6,377	6,930
Income taxes	1,783	11,312
Other	82	512
Total receivables	8,242	18,754
Deferred preservation costs, net	8,811	4,332
Inventories	4,450	4,585
Prepaid expenses	2,344	2,182
Deferred income taxes	--	6,734
Total current assets	**35,763**	**61,447**
Property and equipment:		
Land	--	1,009
Equipment	22,909	22,403
Furniture and fixtures	5,422	5,275
Leasehold improvements	32,800	32,971
Construction in progress	37	189
Total property and equipment	61,168	61,847
Less accumulated depreciation and amortization	28,282	23,717
Net property and equipment	**32,886**	**38,130**
Other assets:		
Patents, less accumulated amortization of $1,281 in 2003 and $1,014 in 2002	5,244	5,324
Trademarks and other intangibles, less accumulated amortization of $374 in 2003 and $397 in 2002	343	460
Other	791	1,053
Total assets	**$ 75,027**	**$ 106,414**

See accompanying notes to consolidated financial statements.

CryoLife, Inc.
Consolidated Balance Sheets
(in thousands, except per share data)

LIABILITIES AND SHAREHOLDERS' EQUITY

December 31,	**2003**	**2002**
Current liabilities:		
Accounts payable	$ 2,171	$ 3,874
Accrued expenses and other current liabilities	11,570	5,023
Accrued compensation	1,136	1,627
Accrued procurement fees	4,358	3,769
Current maturities of capital lease obligations	1,738	2,169
Current maturities of long-term debt	--	5,600
Total current liabilities	**20,973**	**22,062**
Capital lease obligations, less current maturities	751	971
Deferred income taxes	--	986
Other long-term liabilities	4,965	2,595
Total liabilities	**26,689**	**26,614**
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 $.01 par value per share; authorized 75,000 shares; issued 21,130 shares in 2003 and 20,935 shares in 2002	211	209
Additional paid-in capital	74,460	73,630
Retained (deficit) earnings	(19,508)	12,786
Deferred compensation	(9)	(21)
Accumulated other comprehensive income, net of tax	365	282
Treasury stock; 1,371 shares in 2003 and 1,361 shares in 2002, at cost	(7,181)	(7,086)
Total shareholders' equity	**48,338**	**79,800**
Total liabilities and shareholders' equity	**$ 75,027**	**$ 106,414**

See accompanying notes to consolidated financial statements.

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

Year Ended December 31,	2003	2002	2001
Revenues:			
Human tissue preservation services	$ 30,777	$ 55,373	$ 75,552
Products	28,263	21,597	11,130
Research grants and distribution	492	825	989
Total revenues	**59,532**	**77,795**	**87,671**
Costs and expenses:			
Human tissue preservation services (including write-down of $6,861 in 2003 and $32,715 in 2002)	23,976	55,363	31,165
Products	7,506	10,270	5,464
General, administrative, and marketing	53,630	47,530	33,844
Research and development	3,644	4,597	4,737
Goodwill impairment	--	1,399	--
Interest expense	415	692	96
Interest income	(425)	(895)	(1,967)
Other expense, net	12	273	852
Total costs and expenses	**88,758**	**119,229**	**74,191**
(Loss) income before income taxes	**(29,226)**	**(41,434)**	**13,480**
Income tax expense (benefit)	3,068	(13,673)	4,314
Net (loss) income	**$ (32,294)**	**$ (27,761)**	**$ 9,166**
(Loss) earnings per share:			
Basic	$ (1.64)	$ (1.43)	$ 0.49
Diluted	$ (1.64)	$ (1.43)	$ 0.47
Weighted average shares outstanding:			
Basic	19,684	19,432	18,808
Diluted	19,684	19,432	19,660

See accompanying notes to consolidated financial statements.

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

Year Ended December 31,	2003	2002	2001
Net cash flows from operating activities:			
Net (loss) income	$ (32,294)	$ (27,761)	$ 9,166
Adjustments to reconcile net (loss) income to net cash from operating activities:			
(Gain) loss on sale of marketable equity securities	(19)	240	(9)
Gain on sale of assets	(65)	--	--
Depreciation of property and equipment	5,191	5,222	4,203
Amortization	316	201	404
Provision for doubtful accounts	29	50	304
Write-down of deferred preservation costs and inventories	6,861	35,816	--
Other non-cash adjustments to income	347	1,419	348
Deferred income taxes	5,726	(5,568)	624
Tax effect of non-qualified option exercises	77	481	421
Changes in operating assets and liabilities:			
Trade and other receivables	954	7,076	(2,707)
Income taxes	9,543	(9,755)	(983)
Deferred preservation costs	(11,340)	(12,848)	(3,888)
Inventories	135	(1,427)	(2,265)
Prepaid expenses and other assets	2,281	(59)	(1,121)
Accounts payable	(1,717)	3,313	(1,814)
Accrued expenses and other liabilities	8,043	1,489	3,796
Net cash flows (used in) provided by operating activities	**(5,932)**	**(2,111)**	**6,479**
Net cash flows from investing activities:			
Capital expenditures	(955)	(4,100)	(14,329)
Net proceeds from sale of assets	1,093	--	--
Other assets	155	(2,598)	(689)
Purchases of marketable securities	--	(9,970)	(29,336)
Sales and maturities of marketable securities	9,059	21,780	24,235
Proceeds from notes receivable	--	1,169	2,020
Net cash flows provided by (used in) investing activities	**9,352**	**6,281**	**(18,099)**
Net cash flows from financing activities:			
Principal payments of debt	(5,600)	(1,600)	(1,050)
Proceeds from debt issuance	--	--	1,165
Principal payments on obligations under capital leases	(651)	(609)	(291)
Principal payments on short-term note payable	(2,443)	--	--
Proceeds from exercise of options and issuance of stock	660	1,472	1,502
Purchase of treasury stock	--	(663)	--
Net cash flows (used in) provided by financing activities	**(8,034)**	**(1,400)**	**1,326**
(Decrease) increase in cash	**(4,614)**	**2,770**	**(10,294)**
Effect of exchange rate changes on cash	9	303	18
Cash and cash equivalents, beginning of year	10,277	7,204	17,480
Cash and cash equivalents, end of year	**$ 5,672**	**$ 10,277**	**$ 7,204**

See accompanying notes to consolidated financial statements.

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

	Common Shares Outstanding		Additional Paid-In	Retained Earnings		Accumulated Other Comprehensive	Treasury Stock		Total Shareholders'
	Shares	Amount	Capital	(Deficit)	Deferred Compensation	(Loss) Income	Shares	Amount	Equity
Balance at December 31, 2000	**20,077**	**$ 201**	**$ 64,936**	**$ 31,381**	**$ (45)**	**$ (1,088)**	**(1,356)**	**$ (5,990)**	**$ 89,395**
Net income	--	--	--	9,166	--	--	--	--	9,166
Other comprehensive income, net of taxes	--	--	--	--	--	943	--	--	943
Comprehensive income									10,109
Exercise of options	87	1	1,268	--	--	--	46	(78)	1,191
Employee stock purchase plan	8	--	624	--	--	--	24	108	732
Amortization of deferred compensation	--	--	--	--	12	--	--	--	12
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**

See accompanying notes to consolidated financial statements.

1. Summary of Significant Accounting Policies

Nature of Business

CryoLife, Inc., incorporated January 19, 1984 in Florida, preserves and distributes human tissues for cardiovascular, vascular, and orthopedic transplant applications and develops and commercializes implantable medical devices, including its BioGlue® Surgical Adhesive ("BioGlue"), the CryoLife-O'Brien® aortic heart valve, a glutaraldehyde-fixed stentless porcine heart valve, and SynerGraft® processed bovine vascular grafts for use as arteriovenous access devices. The Company distributes preserved human cardiovascular, vascular, and orthopedic tissue throughout the U.S., Canada, and Europe. The Company can distribute BioGlue throughout the U.S. and more than 40 other countries for designated applications. 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 in the U.S. In Europe CryoLife distributes BioGlue under Conformité Européene ("CE") Mark product certification for vascular applications, pulmonary indications, such as the repair of air leaks in lungs, and soft tissue repair procedures. CryoLife has also received approval and distributes BioGlue for vascular, pulmonary, and soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in Australia, and in several countries in South America and Asia. CryoLife markets the SynerGraft processed bovine vascular graft in Europe and the Middle East. CryoLife currently markets its CryoLife-O'Brien aortic heart valve in Europe and certain other territories outside the U.S.

The Company expects that its operations will continue to generate negative cash flows over the next twelve months due to:

- The anticipated lower preservation revenues as compared to preservation revenues prior to the FDA Order (as discussed in Note 2), subsequent FDA activity, and related events,
- The increase in cost of human tissue preservation services as a percent of revenue as a result of lower tissue processing volumes and changes in processing methods,
- An expected use of cash related to the defense and resolution of lawsuits (discussed in Note 9), and
- The legal and professional costs related to its ongoing FDA compliance.

The Company has obtained additional equity financing subsequent to December 31, 2003, as discussed in Note 21, and management believes that this funding coupled with anticipated revenue generation, expense management, tax refunds expected to be approximately $2.4 million, and the Company's existing cash and marketable securities will enable the Company to meet its liquidity needs through at least December 31, 2004.

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

- The Company's ability to return to the level of demand for its tissue services that existed prior to the FDA Order,
- The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs,
- The Company's spending levels on its research and development activities, including research studies, to develop and support its product pipeline,
- The amount and the timing of the resolution of the remaining outstanding product liability claims (discussed in Note 9), and
- The outcome of other litigation against the Company (discussed in Note 9).

The Company 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, 2004. 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.

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 and claims incurred but not reported, 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, 2003 approximately $972,000 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):

	2003	2002	2001
Cash paid during the year for:			
Interest	$ 358	$ 636	$ 896
Income taxes	169	2,874	4,996
Non-cash investing and financing activities:			
Finance insurance policies through issuance of short-term note payable	$ 2,443	$ --	$ --
Conversion of convertible debenture	--	4,393	--
Establishment of capital lease obligation	--	--	2,506
Purchase of property and equipment in accounts payable and accrued expenses	--	6	844

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 as of each balance sheet date. 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. At December 31, 2003 and 2002 all marketable equity securities and debt securities were designated as available-for-sale.

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.

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, net of reserve, on a first-in, first-out basis.

During 2002 the Company recorded a write-down of deferred preservation costs of $8.7 million for valved cardiac tissues, $2.9 million for non-valved cardiac tissues, $11.9 million for vascular tissues, and $9.2 million for orthopaedic tissue, totaling $32.7 million. These write-downs were recorded as a result of the FDA Order as 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 did differ from these estimates. The write-down created a new cost basis, which cannot be written back up if these tissues become available for distribution. The cost of human tissue preservation services has been favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services may continue to be favorably affected depending on the future level of tissue shipments related to previously written-down deferred preservation costs, but such impact is not expected to be material. Management continues to evaluate the recoverability of the deferred preservation costs and will record additional write-downs if it becomes clear that additional impairments have occurred. In the year ended December 31, 2003 cost of human tissue preservation services was impacted by the favorable effect 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 Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. During 2003 the Company recorded $6.9 million 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, 2003 deferred preservation costs were $3.6 million for allograft heart valve tissues, $499,000 for non-valved cardiac tissues, $3.5 million for vascular tissues, and $1.2 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. Interest has been capitalized in connection with the expansion of the corporate headquarters and manufacturing facility in 2001 and 2000.

Long-lived Assets

Statement of Financial Accounting Standards 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 a fourteen-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, 2003 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 tissue preservation business or medical device business. However, depending on the Company's ability to rebuild demand for its tissue preservation services and the future effects of events surrounding the FDA Order, these assets may become impaired. Management will continue to evaluate the recoverability of these assets under the provisions of SFAS 144.

Intangible Assets

Beginning with the Company's adoption of Statement of Financial Accounting Standards ("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 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, 2003 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):

2004	$ 275
2005	275
2006	275
2007	274
2008	274
	$ 1,373

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 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 the

case 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. During 2003 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed as of December 31, 2003. 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.

As a result of the actuarial valuation, the Company accrued an additional $4.3 million during 2003 for estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. The $4.3 million expense was recorded in general, administrative, and marketing expenses. As of December 31, 2003 the Company had accrued a total of $7.9 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. 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 $7.9 million balance is included as a component of accrued expenses and other current liabilities of $3.9 million and other long-term liabilities of $4.0 million on the December 31, 2003 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 pending product liability claims based on settlement negotiations to date, advice from counsel, and historical claim settlements. As of December 31, 2003 the Company had accrued a total of $5.5 million for uninsured product liability claims. The $5.5 million balance is included as a component of accrued expenses and other current liabilities on the December 31, 2003 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 effect of outstanding stock options, computed using the treasury stock method.

Stock-Based Compensation
On December 31, 2002 the Company was required to adopt SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure" ("SFAS 148"). SFAS 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition for companies that voluntarily elect to adopt the fair value recognition and measurement methodology prescribed by SFAS 123. In addition, regardless of the method a company elects to account for stock-based compensation arrangements, SFAS 148 requires additional disclosures in the Summary of Significant Accounting Policies footnote of both interim and annual financial statements regarding the method the company uses to account for stock-based compensation and the effect of such method on the Company's reported results. The Company has determined that the adoption of the additional disclosure provisions of SFAS 148 did not have a material effect on the financial position, results of operations, or cash flows of the Company.

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 123 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.

Pro forma information regarding net income and earnings 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 with the following weighted-average assumptions:

	2003	2002	2001
Expected dividend yield	0%	0%	0%
Expected stock price volatility	.616	.630	.600
Risk-free interest rate	2.35%	3.67%	4.73%
Expected life of options	3.6 Years	5.3 Years	4.2 Years

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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):

	2003	2002	2001
Net (loss) income--as reported	$ (32,294)	$ (27,761)	$ 9,166
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of tax	1,715	2,703	2,232
Net (loss) income--pro forma	$ (34,009)	$ (30,464)	$ 6,934
(Loss) earnings per share--as reported:			
Basic	$ (1.64)	$ (1.43)	$ 0.49
Diluted	$ (1.64)	$ (1.43)	$ 0.47
(Loss) earnings per share--pro forma:			
Basic	$ (1.73)	$ (1.57)	$ 0.37
Diluted	$ (1.73)	$ (1.57)	$ 0.35

Comprehensive Income

SFAS No. 130, "Reporting Comprehensive Income" ("SFAS 130"), established standards for the reporting and display of comprehensive income and its components in a full set of comparative general-purpose financial statements. The statement became effective for the Company in 1998. 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 at a weighted-average of 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 SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143") on January 1, 2003. SFAS 143 addresses accounting and reporting for retirement costs of long-lived assets resulting

from legal obligations associated with acquisition, construction, or development transactions. The adoption of SFAS 143 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

The Company was required to adopt SFAS No. 145, "Rescission of FASB Statements 4, 44 and 64, Amendment to FASB Statement 13, and Technical Corrections" ("SFAS 145"), on January 1, 2003. SFAS 145 rescinds SFAS Nos. 4, 44 and 64, which required gains and losses from extinguishments of debt to be classified as extraordinary items. SFAS 145 also amends SFAS No. 13, eliminating inconsistencies in certain sale-leaseback transactions. The provisions of SFAS 145 are effective for fiscal years beginning after May 15, 2002. The adoption of SFAS 145 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

The Company was required to adopt SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") on January 1, 2003. SFAS 146 requires that costs associated with exit or disposal activities be recorded at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The adoption of SFAS 146 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

The Company was required to adopt SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure: An amendment of FASB Statement No. 123" ("SFAS 148") on December 31, 2002. SFAS 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation", to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirement of SFAS No.123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The adoption of the additional disclosure requirements of SFAS 148 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

In May 2003, the FASB issued SFAS No. 150 "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity" ("SFAS 150"). SFAS 150 requires that certain instruments be classified as liabilities in statements of financial position. Most of the guidance in SFAS No. 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. Because the Company does not have any of the effected financial instruments, the Company believes that the adoption of SFAS 150 will not have a material effect on its financial condition, results of operations, or cash flows.

2. FDA Order on Human Tissue Preservation

FDA Order

On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues processed by the Company since October 3, 2001 (the "FDA Order"). The FDA Order followed an April 2002 FDA Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter dated June 17, 2002, ("Warning Letter"). Revenue from human tissue preservation services accounted for 78% of the Company's revenues for the six months ended June 30, 2002, (the last period ended prior to the issuance of the FDA Order) and of those revenues 67%, or $26.9 million, were derived from preservation of tissues subject to the FDA Order. The FDA Order contained the following principal provisions:

- The FDA alleged that, based on its inspection of the Company's facility on March 25 through April 12, 2002, certain human tissue processed and distributed by the Company may be in violation of 21 Code of Federal Regulations ("CFR") Part 1270. (Part 1270 requires persons or entities engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue to perform certain medical screening and testing on human tissue intended for transplantation. Part 1270 also imposes requirements regarding procedures for the prevention of contamination or cross-contamination of tissues during processing and the maintenance of certain records related to these activities.)

- The FDA alleged that the Company had not validated procedures for the prevention of infectious disease contamination or cross-contamination of tissue during processing at least since October 3, 2001.
- Non-valved cardiac, vascular, and orthopaedic tissue processed by the Company from October 3, 2001 to September 5, 2002 was required to be retained until recalled, destroyed, the safety was confirmed, or an agreement was reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.
- The FDA strongly recommended that the Company perform a retrospective review of all tissue in inventory (i.e. currently in storage at the Company) that was not referenced in the FDA Order to assure that it was recovered, processed, stored, and distributed in conformance with 21 CFR 1270.
- The Center for Devices and Radiological Health ("CDRH"), a division of the FDA, would evaluate whether there are similar risks that may be posed by the Company's allograft heart valves, and would take further regulatory action if appropriate.

Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order on quality assurance quarantine and recalled the non-valved cardiac, vascular, and orthopaedic tissues subject to the FDA Order (i.e. processed since October 3, 2001) 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 "Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to 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. Specifically, the Company was required to obtain physician prescriptions, and tissue packaging was required to contain specified warning labels. The Agreement called for the Company to undertake to identify third-party records of donor tissue testing and to destroy tissue from donors in which certain microorganisms or an infection were found. The Agreement had a 45-business day term and was renewed on November 8, 2002, January 8, 2003, March 17, 2003, and June 13, 2003. This most recent renewal expired on September 5, 2003 and was not renewed. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). In addition, pursuant to the 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.

On December 31, 2002 the FDA clarified the Agreement, noting that non-valved cardiac and vascular tissues processed after September 5, 2002 were not subject to the FDA Order. Specifically, for non-valved cardiac and vascular tissue processed since September 5, 2002, the Company is not required to obtain physician prescriptions, label the tissue as subject to a recall, or require special steps regarding procurement agency records of donor screening and testing beyond those required for all processors of human tissue. These restrictions also do not apply to orthopaedic tissue processed by the Company after September 5, 2002. A renewal of the Agreement that expired on September 5, 2003 was, therefore, not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

After receiving the FDA Order, the Company met with representatives of the FDA's CDRH division regarding CDRH's review of the Company's processed allograft heart valves, which were not subject to the FDA Order. On August 21, 2002 the FDA publicly stated that allograft heart valves had not been included in the FDA Order as these devices were essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA also published a public health web notification at that time stating that it had serious concerns regarding the Company's processing and handling of allograft heart valves. On June 27, 2003 the FDA modified the notification by labeling it as an "archived document – no longer current information – not for official use." There have been no further conversations with the FDA's CDRH division on this matter.

An FDA 483 Notice of Observations ("February 2003 483") was issued in connection with the FDA inspection in February 2003. Corrective action was implemented on most of its observations during the inspection. The Company believes the observations, most of which focus on the Company's systems for handling complaints, will

not materially affect the Company's operations. The Company responded to the February 2003 483 in March 2003. The Company has met with the FDA to review its response to the February 2003 483. No additional comments regarding the adequacy of its response were issued at that time. The Company continues to work with the FDA to review process improvements.

The FDA inspected the Company in October of 2003 in response to a reported orthopaedic infection and issued a 483 Notice of Observations ("October 2003 483"). The observation in the October 2003 483, which was a reissuance of a previous observation, required the Company to complete the validation of its processing operations and procedures for decontaminating tissues, its written procedures for the prevention of infectious disease contamination during processing, and its anti-microbial solution. The Company submitted responses to the October 2003 483 on October 28, 2003 and on November 21, 2003.

The FDA inspected the Company's tissue processing operations in February 2004 focusing primarily on the validation work the Company has performed over the past one and half years. The FDA issued a 483 Notice of Observations ("February 2004 483"), which the Company is addressing.

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 in 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.

3. Cash Equivalents and Marketable Securities

The following is a summary of cash equivalents and marketable securities, all of which are classified as available-for-sale (in thousands):

December 31, 2003	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 1,079	$ --	$ 1,079
Municipal obligations	775	--	775
	$ 1,854	$ --	$ 1,854
Marketable securities:			
Municipal obligations	$ 5,148	$ 124	$ 5,272

December 31, 2002	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 52	$ --	$ 52
Municipal obligations	7,175	--	7,175
	$ 7,227	--	$ 7,227
Marketable securities:			
Municipal obligations	$ 14,276	$ 307	$ 14,583

Gross realized gains on sales of available-for-sale securities totaled $19,000 in 2003 and gross realized losses on sales of available-for-sale securities totaled $240,000 in 2002. Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of $42,000 and $104,000, at December 31, 2003 and 2002, respectively, are included as a separate component of other comprehensive income in shareholders' equity.

At December 31, 2003 and 2002 approximately $2.0 million and $1.2 million, respectively, of marketable securities had a maturity date of less than 90 days, approximately zero and $8.0 million, respectively, had a maturity date between 90 days and 1 year, and approximately $3.3 million and $5.4 million, respectively, had a maturity date between 1 and 5 years.

4. Ideas for Medicine, Inc.

On March 5, 1997 the Company acquired the stock of Ideas for Medicine, Inc. ("IFM"), a medical device company specializing in the manufacture and distribution of single-use medical devices, for consideration of approximately $4.5 million in cash and approximately $5.0 million in convertible debentures plus related expenses. The acquisition was recorded under the purchase method of accounting.

On September 30, 1998 the Company completed the sale of substantially all of the IFM product line and certain related assets, consisting of inventory, equipment, and intellectual property, to Horizon Medical Products, Inc. ("HMP") for $15 million in cash pursuant to an asset purchase agreement. On October 9, 2000 the Company sold substantially all of the remaining assets of IFM to HMP. The assets consisted primarily of inventory, equipment, and leasehold improvements, which had a net book value of $2.4 million at the date of sale. The terms of the transaction required HMP to pay the Company the sum of approximately $5.9 million, payable in equal monthly installments of principal and interest of $140,000. The note consisted of a portion, approximately $3.8 million, which accrued interest at 9% per year, and a non-interest-bearing portion of approximately $2.1 million. The note also required an additional $1 million principal payment at any time prior to April 3, 2001. If the $1 million payment was made when due, and no other defaults existed under the note, then $1 million of the non-interest-bearing portion of the note would be forgiven. In addition, at such time as the principal balance has been paid down

to $1.1 million and there have been no defaults under the promissory note, the remainder of the note would be forgiven and the note would be canceled. The Company had recorded as notes receivable only the balances owed on the interest-bearing portion of the note. Due to uncertainties regarding HMP's ability to pay the full amount of the note, the Company also recorded reserves against these notes such that the gain from the sale was deferred until the full amount of the note was deemed collectible. In addition, the Company entered into a sublease agreement with HMP under which HMP assumed responsibility for the IFM manufacturing facility. Also, substantially all of the employees of IFM became employees of HMP.

On March 30, 2001, HMP sold the IFM assets to a wholly owned subsidiary of LeMaitre Vascular, Inc. ("LeMaitre"), and the remaining portion of the Company's note receivable from HMP and the sublease agreement was assumed by the LeMaitre subsidiary and the payment schedule was restructured. On April 2, 2001 the Company received a scheduled $1 million principal payment from LeMaitre and, as a result, $1 million of the non-interest-bearing portion of the note was forgiven in accordance with the terms of the assumed note. At December 31, 2001 the Company reassessed the collectibility of the note receivable based on the payment record and general creditworthiness of LeMaitre. As a result, the Company reduced the reserve on the note receivable to $250,000 from $963,000, and recorded a non-recurring pretax gain of $713,000 in the fourth quarter of 2001 that is included within Other Income in the Consolidated Statements of Operations. During 2002, LeMaitre remitted payment for the remaining balance of the note receivable, and, therefore, the Company reduced the reserve on the note receivable to zero, by recording a $250,000 non-recurring pretax gain that is included within Other Income in the Consolidated Statements of Operations.

5. Inventories

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

	2003	2002
Raw materials	$ 2,906	$ 2,341
Work in process	229	306
Finished goods	1,315	1,938
	$ 4,450	$ 4,585

6. Debt

Long-term debt at December 31 consists of the following (in thousands):

	2003	2002
5-year term loan, bearing interest equal to the Adjusted LIBOR plus 1.5%, to be adjusted monthly	$ --	$ 5,600
Less current maturities	--	5,600
Total long-term debt	$ --	$ --

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%. The Term Loan was secured by substantially all of the Company's assets. The Term Loan contained certain restrictive covenants including, but not limited to, maintenance of certain financial ratios, a minimum tangible net worth requirement, and the requirement that no materially adverse event had occurred.

In the third quarter of 2002, the lender notified the Company that the FDA Order, as described in Note 2, and the inquiries of the SEC, as described in Note 9, had had a material adverse effect on the Company that constituted an event of default. Additionally, since June 30, 2002, the Company had been in violation of the debt coverage ratio and net worth financial covenants of the Term Loan. In the quarter ended June 30, 2003, the lender indicated its

intention to enter into a forbearance agreement with the Company and to accelerate the principal payments on the Term Loan. As a result, on August 15, 2003 the Company made a voluntary payment of $4.5 million to pay off the outstanding balance of the Term Loan. The Company also paid approximately $11,000 to the lender in fees associated with the Term Loan payoff. As of December 31, 2003 the balance of the Term Loan was zero.

On July 30, 2002 the Company entered into a line of credit agreement with the same lender as for the Term Loan, permitting the Company to borrow up to $10 million. Borrowings under the line of credit agreement accrue interest equal to Adjusted LIBOR plus 1.25% adjusted monthly. This loan is secured by substantially all of the Company's assets. On August 21, 2002 the lender notified the Company that, as a result of the FDA Order, as discussed in Note 2, it was not entitled to any further advances under the line of credit. On November 27, 2002 the lender notified the Company that it had cancelled the unfunded commitment of the line of credit, as the Company was in default of certain provisions and financial covenants of the line of credit agreement. The Company had no outstanding borrowings on the line of credit at the time of cancellation.

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.

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.

Total interest costs were $415,000, $692,000, and $915,000 in 2003, 2002, and 2001, respectively. Interest costs in 2001 included $819,000 of interest capitalized in connection with the expansion of the corporate headquarters and manufacturing facilities.

7. Derivatives

The Company's Term Loan, which was paid in full on August 15, 2003, accrued interest computed at Adjusted LIBOR plus 1.5%, and 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 August 2002 the Company determined that changes in the derivative's fair value could no longer be recorded in other comprehensive income, as a result of the uncertainty of future cash payments on the Term Loan caused by the lender's ability to declare an event of default as discussed in Note 6. Beginning in August 2002 the Company began recording all changes in the fair value of the derivative into other expense/income on the Consolidated Statements of Operations, and amortized the amounts previously recorded in other comprehensive income into other expense/income over the remaining life of the swap agreement.

During the quarter ended June 30, 2003 the Company became aware of the lender's intention to accelerate the payment of the Term Loan, as discussed in Note 6 above. Therefore, the Company recorded an expense of $222,000, to reclassify the unamortized portion of the other comprehensive loss to other expense/income on the Consolidated Statements of Operations. 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.

8. 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, 2003 and 2002.

9. Commitments and Contingencies

Leases

The Company leases equipment, furniture, office, and manufacturing space under various leases with terms of up to 15 years. Commencing January 5, 1998 the Company leased office and manufacturing facilities under a capital lease for $24,125 per month with an interest rate at 8% per annum through January 2008 from the former majority shareholder of IFM. This lease is subject to a sublease agreement as discussed in Note 4. 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, 2003 are as follows (in thousands):

	Capitalized Leases	Operating Leases
2004	$ 843	$ 2,276
2005	843	2,197
2006	843	2,030
2007	265	2,068
2008	--	2,108
Thereafter	--	15,379
Total minimum lease payments	2,794	$ 26,058
Less amount representing interest	305	
Present value of net minimum lease payments	2,489	
Less current maturities	1,738	
Capital lease obligations, less current maturities	$ 751	

Property acquired under capital leases through December 31, 2003 consists of the following (in thousands):

Equipment	$ 403
Furniture and fixtures	890
Leasehold improvements	3,199
Accumulated depreciation	(907)
	$ 3,585

Total rental expense for operating leases amounted to $2.6 million, $2.5 million, and $2.2 million, for 2003, 2002, and 2001, respectively. Total rental income under the sublease was $310,000 in 2003, 2002, and 2001.

Due to cross default provisions included in the Company's debt agreements, as of December 31, 2003 the Company was in default of certain capital lease agreements maintained with the lender of the Term Loan. Therefore, all amounts due under these capital leases are reflected as a current liability on the Consolidated Balance Sheets as of December 31, 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 the case have been filed. As of February 24, 2004 the Company was aware of approximately nine pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, six allege product liability claims arising out of the Company's orthopaedic tissue services, two allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, when it was a subsidiary of the Company.

During the fourth quarter of 2003, 15 lawsuits and claims against the Company were settled including the complaints filed against the Company by Jeffrey Andronaco and Christina Andronaco and Jolene and Robert Moulton. The total settlements involved in these lawsuits and claims including amounts paid by the Company or its insurer were $14.6 million. Through February 25, 2004, four lawsuits and claims against the Company were settled or dismissed. The total settlements involved in these lawsuits and claims including amounts paid by the Company or its insurer were $1.5 million.

Of the nine open lawsuits, two lawsuits were filed in the 2000/2001 insurance policy year, two were filed in the 2001/2002 insurance policy year, two were filed in the 2002/2003 insurance policy year and three were filed in the 2003/2004 insurance policy year. For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. As of December 31, 2003 the Company has an accrual of $100,000 for retention levels related to the 2000/2001 and 2001/2002 policy years.

For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. The Company used all of its insurance coverage, aggregating $25 million, for the 2002/2003 insurance policy year, as well as funds of its own, to resolve claims outstanding in the relevant policy period. The Company will be required to fund any amounts needed to defend against the remaining suits filed during the 2002/2003 insurance policy year. For the 2003/2004 insurance policy year, the Company maintains a first year claims-made insurance policy, i.e. only claims incurred and reported during the policy period April 1, 2003 through March 31, 2004 are covered by this policy. Of the three lawsuits filed in the 2003/2004 insurance policy year, one is covered by insurance and two are uncovered. The Company believes its 2003/2004 insurance policy to be adequate to defend against the one suit filed during this time period. 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, 2003 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of December 31, 2003 the Company had accrued a total of $5.5 million for uninsured product liability claims. The $5.5 million balance is included as a component of accrued expenses and other current liabilities on the December 31, 2003 Consolidated Balance Sheet.

The amounts recorded are reflective of potential legal fees and settlement costs related to these claims, and do 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.

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. During 2003 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed as of December 31, 2003.

As a result of the actuarial valuation, the Company accrued an additional $4.3 million during 2003 for estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. The $4.3 million expense was recorded in general, administrative, and marketing expenses. As of December 31, 2003 the Company had accrued a total of $7.9 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2003. 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 $7.9 million balance is included as a component of accrued expenses and other current liabilities of $3.9 million and other long-term liabilities of $4.0 million on the December 31, 2003 Consolidated Balance Sheet.

Class Action Lawsuit

Several putative class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that the Company made misrepresentations and omissions relating to product safety and the Company'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. 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, the case remains in the discovery phase. 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.

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. 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 into certain matters relating to the Company's August 14, 2002 announcement of the recall order issued by the FDA. Since that time, the Company has been cooperating with the SEC in its inquiry, which as the SEC notified the Company in July 2003, became a formal investigation in June 2003. The Company plans to continue to cooperate with the SEC in its investigation.

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 alleges that Mr. Payne received a tissue implant processed by a third party unaffiliated with the Company, and that he was subsequently diagnosed with an infection attributed to the implant. The claim against the Company asserts 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 asserts that the Company had a duty to notify two of 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 allege the recipient received an implant processed by the same unaffiliated third party processor, from the same donor as Mr. Payne, and contracted an infection. The Company intends to vigorously defend against these claims, although the Company is presently unable to predict the outcome.

10. Stock Option Plans

The Company has stock option plans which provide for 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 typically become exercisable over a five-year vesting period and expire within ten years of the grant dates. Under the 1993 Employee Incentive Stock Option Plan, the 1998 Long-Term Incentive Plan, the 2002 Stock Incentive Plan, and the amended and restated Nonemployee Director's Plan, the Company has authorized the grant of options of up to 1,050,000, 900,000, 974,000, and 594,000 shares of common stock, respectively. As of December 31, 2003 and 2002, there were 88,000 and 427,000, respectively, shares of common stock reserved for future issuance under the Company's stock option plans. A summary of stock option transactions under the plans follows:

	Exercise Shares	Price	Weighted Average Exercise Price
Outstanding at December 31, 2000	1,550,000	$ 5.67-29.15	$ 10.67
Granted	370,000	23.68-34.10	30.02
Exercised	(145,000)	5.67-11.63	7.68
Canceled	(13,000)	8.50-29.15	16.38
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

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	590,000	4.05	$ 2.20	224,000	$ 2.20
4.78-6.70	474,000	4.62	5.86	33,000	6.70
6.72-11.42	529,000	1.41	9.02	451,000	9.22
11.50-23.68	451,000	2.38	12.72	292,000	12.27
27.90-30.86	352,000	3.54	29.34	179,000	28.81
31.99-31.99	127,000	2.46	31.99	114,000	31.99
$ 2.20-31.99	2,523,000	3.15	$ 11.48	1,293,000	$ 13.34

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").

Other information concerning stock options follows:

	2003	2002	2001
Weighted average fair value of options granted during the year	$ 2.88	$ 4.23	$ 15.20
Number of shares as to which options are exercisable at end of year	1,293,000	1,175,000	915,000

11. 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.

12. Stock Repurchase

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. The Company did not repurchase any common stock in 2003. 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, 2003, the Company had made no purchases under this authorization.

On October 12, 1998 the Company's Board of Directors authorized the Company to purchase up to 1.5 million shares of its common stock. As of December 31, 2001, the Company had purchased an aggregate of 1.2 million shares of its common stock for an aggregate purchase price of $8.3 million and an average price of $7.13 per share.

On February 24, 2004 the Company's Board of Directors rescinded its purchase authorizations dated March 27, 2002 and October 12, 1998, therefore no further purchases will be made under these authorizations.

13. Accumulated Other Comprehensive (Loss) Income

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

	2003	2002	2001
Net (loss) income	$ (32,294)	$ (27,761)	$ 9,166
Unrealized (loss) gain on investments	(119)	95	1,124
Change in fair value of interest rate swap (including cumulative effect of adopting SFAS 133 in 2001)	172	30	(200)
Translation adjustment	30	303	18
Comprehensive (loss) income	$ (32,211)	$ (27,333)	$ 10,108

The tax effect on the change in unrealized (loss) gain on investments is $65,000, $55,000, and $575,000 for the years ended December 31, 2003, 2002, and 2001 respectively. The tax effect on the change in fair value of the interest rate swap is $88,000, $4,000, and $93,000 for the years ended December 31, 2003, 2002, and 2001 respectively. The tax effect of the translation adjustment is $167,000, zero, and zero for the years ended December 31, 2003, 2002, and 2001 respectively.

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

	2003	2002
Unrealized loss on investments	$ (85)	$ (31)
Translation adjustment	(280)	(251)
Total accumulated other comprehensive loss	$ (365)	$ (282)

14. Employee Benefit Plans

The Company has a 401(k) savings plan (the "Plan") providing retirement benefits to all employees who have completed at least three months of service. In 2003, 2002, and 2001 the Company made matching contributions of 50% of each participant's contribution up to 5% of each participant's salary. Total company contributions approximated $350,000, $404,000, and $384,000, for 2003, 2002, and 2001, 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 2003, 2002, or 2001.

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, 2003 and 2002 there were 407,000 and 543,000, respectively, shares of common stock reserved under the ESPP and there were 493,000 and 357,000, respectively, shares issued under the plan.

15. (Loss) Earnings Per Share

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

	2003	2002	2001
Numerator for basic and diluted (loss) earnings per share:			
(loss) income available to common shareholders	$ (32,294)	$ (27,761)	$ 9,166
Denominator for basic (loss) earnings per share:			
weighted-average shares	19,684	19,432	18,808
Effect of dilutive stock options	--	--	852
Denominator for diluted earnings per share:			
adjusted weighted-average shares	19,684	19,432	19,660
(Loss) earnings per share:			
Basic	$ (1.64)	$ (1.43)	$ 0.49
Diluted	$ (1.64)	$ (1.43)	$ 0.47

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

16. Income Taxes

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

	2003	2002	2001
Current:			
Federal	$ (2,502)	$ (8,000)	$ 4,680
State	(23)	(164)	115
	(2,525)	(8,164)	4,795
Deferred	5,593	(5,509)	(481)
	$ 3,068	$ (13,673)	$ 4,314

Such amounts differ from the amounts computed by applying the U.S. federal and state income tax rate of 34% in 2003, 34% in 2002, and 35% in 2001 to pretax income as a result of the following (in thousands):

	2003	2002	2001
Tax (benefit) expense at statutory rate	$ (9,937)	$ (14,088)	$ 4,718
Increase (reduction) in income taxes Resulting from:			
Deferred tax valuation	13,701	658	--
Entertainment expenses	70	83	50
State income taxes, net of federal benefit	(218)	(167)	108
Nontaxable interest income	(110)	(202)	(242)
Research and development credits	--	--	(200)
Foreign sales corporation	(20)	(27)	(60)
Other	(418)	70	(60)
	$ 3,068	$ (13,673)	$ 4,314

For the year ended December 31, 2003, the Company generated federal income tax losses that can be carried back to prior years to offset income taxes paid and should result in approximately $2.4 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):

	2003	2002
Long-term deferred tax (liabilities) assets:		
Property	$ (1,408)	$ (865)
Intangible assets	52	(210)
Loss Carryforwards	10,605	658
Other	65	89
Less valuation allowance	(9,314)	(658)
	--	(986)
Current deferred tax assets (liabilities):		
Unrealized loss on marketable securities	(25)	(104)
Allowance for bad debts	22	26
Accrued expenses	4,763	1,875
Prepaid items	(609)	(56)
Deferred preservation costs and inventory reserves	610	4,845
Other	284	148
Less valuation allowance	(5,045)	--
	--	6,734
Net deferred tax assets	$ --	$ 5,748

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, FDA Warning Letter, subsequent FDA activity, and reported tissue infections and 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 is more likely than not that the Company's deferred tax assets will not be realized. Therefore, during 2003 the Company recorded valuation allowances totaling $13.7 million due to the effect of temporary differences between book and tax income, the net deferred tax assets generated in 2003, and the net deferred tax asset balance at December 31, 2002. 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.

17. 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 2003. The Company's aggregate premium contributions under this program were $74,000, and $75,000 for 2002 and 2001, respectively.

18. Equipment on Loan to Implanting Hospitals

The Company consigns liquid nitrogen freezers with certain implanting hospitals for tissue storage. The freezers are the property of the Company. At December 31, 2003 freezers with a total cost of approximately $2.3 million and related accumulated depreciation of approximately $1.7 million were located at the implanting hospitals' premises. Depreciation is provided over the estimated useful lives of the freezers on a straight-line basis.

19. Transactions with Related Parties

The Company expensed $101,000, $90,000, and $87,000, during 2003, 2002, and 2001, 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 $5,000, $100,000, and $100,000 in 2003, 2002 and 2001, 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 $19,000, $240,000, and $473,000 in 2003, 2002, and 2001, respectively, relating to research performed by the university where the same Director and shareholder holds a significant position. The Company expensed zero, $8,000, and zero in 2003, 2002 and 2001, 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, $35,000, and $210,000 in 2003, 2002, and 2001, respectively, relating to consulting services performed by a shareholder of the Company.

20. Segment and Geographic Information

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

The Human Tissue Preservation Services segment includes external revenue from cryopreservation services of cardiovascular, vascular, and orthopaedic human tissue. The Implantable Medical Devices segment includes external revenue from product sales of BioGlue Surgical Adhesive and bioprosthetic devices, including stentless porcine heart valves, SynerGraft treated porcine heart valves, and SynerGraft treated bovine vascular grafts, and Cerasorb Ortho bone graft substitute. 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
2003:			
Human Tissue Preservation Services	$ 30,777	$ 23,976	$ 6,801
Implantable Medical Devices	28,263	7,506	20,757
All Other [a]	492	--	492
	$ 59,532	$ 31,482	$ 28,050
2002:			
Human Tissue Preservation Services	$ 55,373	$ 55,363	$ 10
Implantable Medical Devices	21,597	10,270	11,327
All Other [a]	825	--	825
	$ 77,795	$ 65,633	$ 12,162
2001:			
Human Tissue Preservation Services	$ 75,552	$ 31,165	$ 44,387
Implantable Medical Devices	11,130	5,464	5,666
All Other [a]	989	--	989
	$ 87,671	$ 36,629	$ 51,042

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

Net revenues by product for the years ended December 31, 2003, 2002, and 2001 were as follows (in thousands):

	2003	2002	2001
Human tissue preservation services:			
Cardiovascular tissue	$ 17,059	$ 23,413	$ 28,606
Vascular tissue	12,655	17,826	24,488
Orthopaedic tissue	1,063	14,134	22,458
Total preservation services	30,777	55,373	75,552
BioGlue Surgical Adhesive	27,784	20,898	10,595
Bioprosthetic devices	479	699	535
Grant and distribution revenue	492	825	989
	$ 59,532	$ 77,795	$ 87,671

Net revenues [b] by geographic location for the years ended December 31, 2003, 2002, and 2001 were as follows (in thousands):

	2003	2002	2001
U.S.	$ 51,949	$ 71,188	$ 81,657
International	7,583	6,607	6,014
	$ 59,532	$ 77,795	$ 87,671

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

At December 31, 2003, 2002, and 2001, 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.

21. Subsequent Events

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 3.4 million shares of stock at a price of $6.25 per share. The sale generated net proceeds of approximately $19.9 million, after commissions, registration fees, and other related charges, which will be used for general corporate purposes. On February 10, 2004 the Company filed a Registration Statement on Form S-3 with the SEC covering the resale of the shares sold in the PIPE by the investors. The Company has agreed to pay 1% of the aggregate price paid per month, subject to certain limitations, if the registration statement is not declared effective within 75 days of the closing date of January 27, 2004.

SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

(in thousands, except per share data)

	Year	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE					
	2003	$ 15,920	$ 15,713	$ 15,097	$ 12,802
	2002	25,471	23,264	16,889	12,171
	2001	21,432	21,697	22,567	21,975
GROSS MARGIN					
	2003	$ 11,836	$ 8,547	$ 5,834	$ 1,867
	2002	15,173	4,218	(15,828)	8,432
	2001	12,327	12,577	13,183	12,564
NET (LOSS) INCOME					
	2003	$ (434)	$ (19,921)	$ (4,695)	$ (7,244)
	2002	3,104	(5,522)	(19,646)	(5,697)
	2001	1,970	2,540	2,692	1,964
(LOSS) EARNINGS PER SHARE – DILUTED					
	2003	$ (0.02)	$ (1.01)	$ (0.24)	$ (0.37)
	2002	0.16	(0.28)	(1.01)	(0.29)
	2001	0.10	0.13	0.14	0.10

The second quarter of 2002 includes an increase to pretax losses related to the accounting treatment of the FDA Order of $12.6 million, consisting of a net $8.9 million increase to cost of human tissue preservation services, a $2.4 million reduction to revenues, and a $1.3 million accrual for retention levels under the Company's insurance policies and for estimated expenses for the return of affected tissues under the FDA Order. The third quarter of 2002 includes an increase to pretax losses related to the accounting treatment of the FDA Order of $24.6 million, consisting 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 an increase to pretax losses related to the write-down of bioprosthetic valves of $3.1 million. The fourth quarter of 2002 includes an increase to pretax losses related to product liability claims of $3.6 million and for an employee force reduction of $690,000.

The first quarter of 2003 includes a decrease in pretax losses related to a revenue adjustment for estimated tissue recall returns under the FDA Order of $848,000 and the effect of shipments of tissue with a zero cost basis of $2.3 million, and an increase in pretax losses related to the adjustment of the value of certain deferred tissue preservation costs that exceeded market value of $297,000. The second quarter of 2003 includes an increase in pretax losses related to product liability claims of $12.5 million and the adjustment of the value of certain deferred tissue preservation costs that exceeded market value of $1.0 million, and a decrease in pretax losses related to the effect of shipments of tissue with a zero cost basis of $1.0 million. The second quarter of 2003 also included the establishment of a valuation allowance against the Company's deferred tax assets of $9.0 million. The third quarter of 2003 includes a decrease in pretax losses related to a revenue adjustment for estimated tissue recall returns under the FDA Order of $52,000 and the effect of shipments of tissue with a zero cost basis of $791,000, and an increase in pretax losses related to the adjustment of the value of certain deferred tissue preservation costs that exceeded market value of $1.8 million and for product liability claims of $213,000. The third quarter of 2003 also included an increase to the valuation allowance against the Company's deferred tax assets of $1.9 million. The fourth quarter of 2003 includes a decrease in pretax losses related to a reduction in product liability claims accruals of $1.8 million and the effect of shipments of tissue with a zero cost basis of $114,000, and an increase in pretax losses to adjust the value of certain deferred tissue preservation costs that exceeded market value of $3.7 million. The fourth quarter of 2003 also included an increase to the valuation allowance against the Company's deferred tax assets of $2.8 million.

SCHEDULE I

CRYOLIFE, INC. AND SUBSIDIARIES
VALUATION AND QUALIFYING ACCOUNTS
Years ended December 31, 2003, 2002, and 2001

Description	Balance beginning of period	Additions	Deductions	Balance end of Period
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
Year ended December 31, 2001				
Allowance for doubtful accounts	$ 85,000	$ 338,000	$ 323,000	$ 100,000
Deferred preservation costs	229,000	280,000	209,000	300,000

Exhibit 21.1

SUBSIDIARIES OF CRYOLIFE, INC.

Subsidiary	Jurisdiction
CryoLife Acquisition Corp.	Florida
CryoLife Technology, Inc.	Nevada
CryoLife Europa, LTD.	United Kingdom
AuraZyme Pharmaceuticals, Inc.	Florida
CryoLife International, Inc.	Florida

Exhibit 23.1

INDEPENDENT AUDITORS' CONSENT

We consent to the incorporation by reference in Registration Statement Nos. 333-16581, 33-83996, 33-84048, 333-03513, 333-59853, 333-59849, 333-06141, 333-34025, 333-75535, 333-47310, 333-10463, and 333-112673 of CryoLife, Inc., on Form S-8 of our report dated February 24, 2004, (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) appearing in this Annual Report on Form 10-K of CryoLife, Inc., for the year ended December 31, 2003.

/s/Deloitte & Touche LLP

Atlanta, Georgia

March 1, 2004

Exhibit 23.2

NOTICE REGARDING CONSENT OF ARTHUR ANDERSEN LLP

Section 11(a) of the Securities Act of 1933, as amended (the "Securities Act"), provides that if any part of a registration statement, at the time such part becomes effective, contains an untrue statement of a material fact or an omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, any person acquiring a security pursuant to such registration statement (unless it is proved that at the time of such acquisition such person knew of such untruth or omission) may sue, among others, every accountant who has consented to be named as having prepared or certified any part of the registration statement, or as having prepared or certified any report or valuation which is used in connection with the registration statement, with respect to the statement in such registration statement, report or valuation which purports to have been prepared or certified by the accountant.

This Annual Report on Form 10-K is incorporated by reference into Registration Statement File Nos. 333-16581, 33-83996, 33-84048, 333-03513, 333-59853, 333-59849, 333-06141, 333-34025, 333-75535, 333-47310, 333-104637, and 333-112673 (collectively, the "Registration Statements") of CryoLife, Inc. ("CryoLife") and, for purposes of determining any liability under the Securities Act, is deemed to be a new registration statement for each Registration Statement into which it is incorporated by reference.

As recommended by CryoLife's Audit Committee, CryoLife's Board of Directors dismissed Arthur Andersen LLP ("Andersen") on April 8, 2002, effective April 9, 2002, as CryoLife's independent accountants. See CryoLife's Current Report on Form 8-K filed April 11, 2002 for more information. After reasonable efforts, CryoLife has been unable to obtain Andersen's written consent to the incorporation by reference into the Registration Statements of its audit reports with respect to CryoLife's financial statements as of and for the fiscal year ended December 31, 2001.

Under these circumstances, Rule 437a under the Securities Act permits CryoLife to file this Form 10-K without a written consent from Andersen. However, as a result, with respect to transactions in CryoLife securities pursuant to the Registration Statements that occur subsequent to the date this Annual Report on Form 10-K is filed with the Securities and Exchange Commission, Andersen may not have any liability under Section 11(a) of the Securities Act for any untrue statements of a material fact contained in the financial statements audited by Andersen or any omissions of a material fact required to be stated therein. Accordingly, you might be unable to assert a claim against Andersen under Section 11(a) of the Securities Act because it has not consented to the incorporation by reference into the Registration Statements of the copies of its audit reports for the period ending December 31, 2001 which are reproduced herein. To the extent provided in Section 11(b)(3)(C) of the Securities Act, however, other persons who are potentially subject to liability under Section 11(a) of the Securities Act, including CryoLife's officers and directors, may still rely on Andersen's original audit reports as being made by an expert for purposes of establishing a due diligence defense under Section 11(b) of the Securities Act. These facts may have the effect of limiting the ability of CryoLife investors to recover any losses suffered in connection with the purchase or sale of CryoLife securities due to material inaccuracies or omissions contained in the financial statements reproduced herein for the periods ending December 31, 2001.

Exhibit 31.1

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

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 1, 2004

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

Exhibit 31.2

I, David Ashley Lee, Vice President, Treasurer, and Chief Financial Officer, 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)) 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;

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 1, 2004

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

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, 2003, 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 Vice President, Treasurer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN G. ANDERSON

STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer
March 2, 2004

/s/ DAVID ASHLEY LEE

DAVID ASHLEY LEE
Vice President, Treasurer, and
Chief Financial Officer
March 2, 2004

FORWARD-LOOKING STATEMENT

The Company's statements herein addressing events or developments that will or may occur in the future 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 of the attached 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 Annual Report are qualified by these cautionary statements.

TRANSFER AGENT

Communications regarding change of address, transfer of stock ownership or lost stock certificates should be directed to:

American Stock Transfer & Trust Company
59 Maiden Lane, Plaza Level
New York, NY 10038
800-937-5449

LEGAL COUNSEL

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Attorneys at Law
2800 One Atlantic Center
1201 West Peachtree Street
Atlanta, GA 30309-3450

INDEPENDENT AUDITORS

Deloitte & Touche LLP
Suite 1500
191 Peachtree Street N.E.
Atlanta, GA 30303-1924

BOARD OF DIRECTORS

Steven G. Anderson
Chairman, President and
Chief Executive Officer
CryoLife, Inc.
Kennesaw, Georgia

Thomas F. Ackerman[1]
Senior Vice President and
Chief Financial Officer
Charles River Laboratories
International, Inc.
(research tools and services for drug
and medical device development)
Wilmington, Massachusetts

Daniel J. Bevevino[2]
Vice President and Chief Financial Officer
Respironics, Inc.
(medical devices)
Murrysville, Pennsylvania

John M. Cook[1, 2, 3]
Chairman, President and
Chief Executive Officer
PRG-Schultz International, Inc.
(An international, publicly-held
audit recovery firm)
Atlanta, Georgia

Ronald C. Elkins, M.D.[1, 2, 3]
Professor Emeritus, Section of
Thoracic and Cardiovascular Surgery
University of Oklahoma,
Health Sciences Center
Oklahoma City, Oklahoma

Virginia C. Lacy[2, 3]
Administrator
The Jeannette & John Cruikshank
Memorial Foundation
(A charitable foundation)
and President,
Precision Devices Corporation
(A distributor of small medical
products to hospitals)
Naperville, Illinois

Ronald D. McCall, Esq.[1, 3, 4]
Attorney at Law
Tampa, Florida

Bruce J. Van Dyne, M.D.[1, 3]
Board Certified Neurologist
Private Practice
Minneapolis, Minnesota

[1] Compensation Committee
[2] Audit Committee
[3] Nominating and Corporate Governance Committee
[4] Presiding Director

CryoLife, Inc.
Biotechnologies for Medicine™

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CryoLife®, Inc.

Biotechnologies for Medicine℠