



# 2002

A N N U A L R E P O R T



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### **CORPORATE PROFILE**

CryoLife, Inc. was founded in 1984 to provide cardiovascular surgeons with new alternative treatment options for the repair of impaired or damaged heart function. Utilizing the Company's patented 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 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<sup>®</sup>, 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, 2002, without exhibits, as filed with the Securities and Exchange Commission on February 27, 2003. 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

### **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<sup>®</sup>, a subsidiary of the National Association of Securities Dealers, Inc. (NASD<sup>®</sup>), under the symbol CRY.

### **ON THE COVER**

Cryopreserved human cardiovascular tissue provides a significant surgical treatment alternative in correcting congenital heart defects in children. Approximately 59% of all cardiovascular tissue processed by CryoLife is directed to pediatric care.

# President's Letter

## DEAR CRYOLIFE SHAREHOLDERS:

As you know, our financial performance in 2002 was adversely affected due to an order from the U.S. Food and Drug Administration (FDA) on August 13, 2002, for the recall, retention, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissues processed since October 3, 2001. Our preserved human allograft heart valves and BioGlue surgical adhesive were not part of the recall order.

On September 5, 2002 the Company reached an agreement with the FDA amending the original order that provided conditions under which CryoLife could continue to distribute its life- and limb-saving cardiac and vascular tissues throughout the U.S. This modification to the FDA Order was followed by a further clarification on December 31, 2002, which indicated that non-valved cardiac and vascular tissues processed since September 5, 2002 were not required to have special labeling or a prescription from the implanting physician.

Revenues for the year ended December 31, 2002 were \$77.8 million, compared to \$87.7 million in 2001. The net loss for fiscal year 2002 was \$27.8 million, compared to net income of \$9.2 million in 2001. On a fully diluted basis, the loss per common share for 2002 was \$1.43, compared to earnings per common share of \$0.47 in 2001. (All amounts per share are reported on an after-tax basis.) Details of our financial performance are included in the Form 10-K.

I am pleased to report that the Company is working closely with FDA to resolve all outstanding issues. We resumed processing allograft orthopaedic tissues in late February and are currently processing a full range of cardiovascular, vascular, and orthopaedic tissues. We have been fortunate to rehire many of our former experienced technicians to assure successful laboratory operations.

Our work over the past 18 years has helped to improve the quality of life for approximately 100,000 patients. Our technology has revolutionized the way cardiac, vascular, and orthopaedic surgeons practice medicine. CryoLife management is fully committed to building on our success and continuing our innovative contributions in the life sciences.

## BIOGLUE

During 2002 we achieved record BioGlue revenues in both domestic and international markets. For 2003 we anticipate that BioGlue will comprise about 40% of corporate revenues. Industry estimates indicate the U.S. wound closure market is approximately \$875 million annually. We believe BioGlue is one of the most significant advances in cardiovascular surgery of the past 35 years, and we anticipate increased demand for this product. We are well positioned to meet the growing domestic and international demand for BioGlue. Our expanded manufacturing facility, located at our corporate headquarters, has the capacity to produce more than two million units of BioGlue annually.





#### **INTERNATIONAL**

The international arena continues to be an area of significant corporate growth. During 2002, revenues were up 10% compared to 2001, with seven additional marketing approvals. We believe the restructuring of our sales force in the United Kingdom to direct sales representatives has made a significant impact, resulting in an increase in sales in the U.K. of 94% during 2002. The U.K. sales and marketing effort is augmented by 44 distributors throughout Europe, Canada, the Middle East, South Africa, Latin America and Asia. In February 2003, Health Canada, the state ministry that oversees Canadian healthcare, significantly expanded its approved indications for BioGlue when it approved its use as an adjunct method to repair most human soft tissues. This expanded approval was CE marked in Europe in January of 2002, which also contributed to the increase in sales by CryoLife Europa, Ltd. In Japan, the BioGlue clinical trial has been completed and a post clinical trial follow up review of patients has begun.

Since 1984, CryoLife has been a pioneer in developing the technology for preserving human tissues and also innovative life-science-based products. Our goal is to re-establish CryoLife as the industry leader by focusing on our broad range of processed human tissues and our BioGlue family of products. We will continue to build a diversified implantable medical device company that is focused on the development of life-science-based products directed at markets not sufficiently addressed by larger medical device companies. As research shows, these market niches are generally too small to be profitably addressed by those companies.

In February 2003, we augmented our soft tissue preservation business with an exclusive U.S. distribution agreement for a synthetic bone product, Cerasorb™, manufactured by curasan AG. This represents the latest addition to our product and service pipeline, which is full of proprietary bioadhesive, cardiovascular, vascular and orthopaedic products and services. We believe all of these elements will bode well for a revitalization of the Company.

On behalf of the employees of CryoLife and its Board of Directors, I would like to thank you for your continued interest in CryoLife, Inc.

Very truly yours,



Steven G. Anderson  
President and Chief Executive Officer  
April 11, 2003

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**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

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**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2002

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 #1-13165

**CRYOLIFE, INC.**

(Exact name of registrant as specified in its charter)

Florida

(State or other jurisdiction of incorporation or organization)

59-2417093

(IRS Employer Identification No.)

1655 Roberts Boulevard N.W.

Kennesaw, GA 30144

(Address of principal executive offices)

(770) 419-3355

(Telephone No.)

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

<b>Common Stock, \$.01 par value</b>	<b>Registered on the New York Stock Exchange</b>
<b>Preferred Share Purchase Rights</b>	<b>Registered on the New York Stock Exchange</b>

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

None

(Title of Class)

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

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

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

As of June 30, 2002, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was \$272,880,824 computed using the closing price of \$16.06 per share of Common Stock on June 28, 2002, 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, 2003 the number of outstanding shares of Common Stock of the registrant was 19,573,970.

**DOCUMENTS INCORPORATED BY REFERENCE**

Document

Part of Form 10-K

Portions of Registrant's Proxy Statement relating to the Annual Meeting of Shareholders to be filed not later than April 30, 2003.

Part III

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## 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, glutaraldehyde-fixed stentless porcine heart valves, 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 expansion 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, see Note 20 of Notes 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 has applied its proprietary SynerGraft antigen reduction technology to enhance the performance of certain human cardiovascular and vascular tissues. (See “Recent Events” below). The Company estimates that the potential U.S. market for implantable products targeting indications addressed by the preserved tissues processed by the Company, including orthopaedic tissue, the processing of which had been suspended due to factors discussed below, was in excess of \$1 billion in 2001. 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, reported tissue infections, and the resulting adverse publicity, as discussed below, the Company’s market share declined in 2002. The Company seeks to expand the availability of human tissue through its established relationships with approximately 84 tissue banks and organ procurement agencies nationwide.

Historically, CryoLife has 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 of 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 processing orthopaedic tissue in late February 2003. The Company has historically relied on independent orthopaedic sales representatives to market its preservation services and intends to continue using independent sales representatives once it resumes processing orthopaedic tissue.

CryoLife has developed implantable biomaterials for use as surgical adhesives and sealants. The Company’s proprietary BioGlue Surgical Adhesive, designed for cardiovascular, vascular, pulmonary, and general surgical applications, is a polymer based on bovine serum albumin and a cross-linking agent. The Company received a Conformité Européenne (“CE”) Mark (product certification) in 1997 for use of its BioGlue Surgical Adhesive in vascular applications and began marketing this product in April 1998 in the European Economic Area (“EEA”). In March 1999 the Company was awarded a second CE Mark allowing the use of BioGlue in pulmonary indications, including the repair of air leaks in lungs. In December 1999 the Company received FDA approval to distribute BioGlue Surgical Adhesive under a Humanitarian Device Exemption (“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. The Company estimates that the annual worldwide market for surgical sutures and staples in 2002 was in excess of \$2.5 billion. In January 2002 BioGlue was awarded a third CE Mark for use in soft tissue repair procedures. An additional six marketing approvals were granted in the Czech Republic, Colombia, Mexico, Peru, South Korea and Singapore 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 only, to soft tissue repair.

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 August of 2001 the Company received CE Mark approval for its SynerGraft Model 100 vascular graft 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 and 50 cm and can be stored at room temperature until use. The SynerGraft Model 100 vascular graft is marketed in the EEA, Switzerland, and Israel. 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 they eliminate the risk of patient non-compliance with long-term anti-coagulation drug therapy associated with mechanical valves, are less expensive than human heart valves, and their shorter longevity is more appropriately matched with these patients' life expectancies. Glutaraldehyde-fixed porcine and bovine heart valves address a worldwide target market estimated to have been \$400 million in 2002. Unlike most other available porcine heart valves, the Company's stentless porcine heart valves contain 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 of Notes to the Consolidated Financial Statements.

Previously, the Company developed and marketed, outside of the U.S., SynerGraft processed porcine heart valves. During 2002 the Company decided to cease future expenditures on the development and commercialization of these valves. This decision was made to allow the Company to maintain its focus on its preservation services business and its BioGlue and SynerGraft bovine vascular graft product lines.

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. Internationally, preserved human tissues, bioprosthetic cardiovascular and vascular devices, including SynerGraft, and BioGlue Surgical Adhesive are distributed through independent representatives located throughout Europe, the Middle East, Canada, South America, Australia, and Asia. The Company also uses direct technical service representatives in the United Kingdom to market its preservation services, bioprosthetic devices, and BioGlue Surgical Adhesive.

## Recent Events

On February 5, 2003 the Company announced that it had signed an exclusive agreement with curasan AG, located in Germany, for U.S. distribution of Cerasorb<sup>®</sup> Ortho, curasan's resorbable bone graft substitute. The five-year agreement gives CryoLife exclusive rights to market Cerasorb Ortho for all non-spine, non-dental orthopaedic indications such as trauma, general, and sports medicine. Cerasorb, a resorbable, beta-tricalcium phosphate bone regeneration material, was first introduced in Germany in 1998 for dental use. The product captured approximately 60% of the synthetic dental bone regeneration market in Germany within four years. In 2001 curasan received CE Mark certification for Cerasorb's use in general orthopaedics, and in 2002 received FDA 510(k) approval for orthopaedic use. The Company anticipates that the U.S. market for bone grafts and substitutes for which it can distribute Cerasorb is approximately \$140 million annually.

On February 20, 2003 the Company received a letter from the FDA that stated 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 used for arteriovenous ("A-V") access. 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 femoral veins used for A-V access are medical devices that require premarket approval. CryoLife will be providing the agency with information to demonstrate that femoral veins used for A-V access should continue to be regulated as human tissue under Parts 1270 and 1271 of the FDA's regulations. The FDA letter did not question the safety or efficacy of the SynerGraft process or the CryoVein A-V access implant.

The Company has advised the FDA that it will voluntarily suspend use of the 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 FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SG tissue 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.

## FDA Order on Human Tissue Preservation

On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissue processed by the Company since October 3, 2001 (the "FDA Order"). The FDA Order followed an April 2002 FDA Form 483 Notice of Observations ("FDA 483") and an FDA Warning Letter dated June 17, 2002, ("Warning Letter"). Subsequently, the Company responded to the 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 ending 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 contains the following principal provisions:

- The FDA alleges 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. The rule 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 alleges that the Company has 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 must be retained until it is recalled, destroyed, the safety is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.



- The FDA strongly recommends that the Company perform a retrospective review of all tissue in inventory (i.e. currently in storage at the Company) that is 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, is evaluating whether there are similar risks that may be posed by the Company’s allograft heart valves, and will 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. The Company appealed the FDA Order on August 14, 2002 and requested a hearing with the FDA, which was originally set for December 12, 2002. Due to the Agreement discussed below, the Company withdrew its request for a hearing with the FDA. After the FDA issued its order regarding the recall, Health Canada also issued a recall on the same types of tissue and other countries have inquired about the circumstances surrounding the FDA Order.

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 are not subject to the FDA Order. On August 21, 2002 the FDA publicly stated that allograft heart valves have not been included in the FDA Order as these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA also publicly stated that it then still had serious concerns regarding the Company’s processing and handling of allograft heart valves. The FDA also recommended that surgeons carefully consider using processed allografts from alternative sources, that surgeons inform prospective patients of the FDA’s concerns regarding the Company’s allograft heart valves, and that patients be carefully monitored for both fungal and bacterial infections.

On September 5, 2002 the Company reached an agreement with the FDA (the “Agreement”) that supplements the FDA Order and allows the tissues subject to recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company completes steps to assure that the tissue is used for approved purposes and that patients are notified of risks associated with tissue use. Specifically, the Company must obtain physician prescriptions, and tissue packaging must contain specified warning labels. The Agreement calls for the Company to undertake to identify third-party records of donor tissue testing, and to destroy tissue from donors in whom microorganisms associated with an infection are found. The Agreement allowing distribution of tissues subject to the recall had a 45-business day term and was renewed on November 8, 2002 and on January 8, 2003. This most recent renewal expires on March 20, 2003. The Company is unable to predict if the FDA will grant further renewals of the Agreement. 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 Agreement contained the requirement that tissues subject to the FDA Order be replaced with tissues processed under validated methods. 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.

As a result of the adverse publicity surrounding the FDA Warning Letter, FDA Order, and the reported tissue infections, the Company’s procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, decreased 25% in the fourth quarter of 2002 as compared to the fourth quarter of 2001. Although the Company expects to be able to maintain the current level of cardiac tissue procurement, there is no guarantee that sufficient tissue will be available. The Company has continued to process and distribute heart valves since the receipt of the FDA Order, as these tissues are not subject to the FDA Order.

On September 17, 2002 the Company resumed the procurement and processing of vascular tissues. The Company limited its vascular procurement until it addressed the observations detailed in the FDA 483 and had

fully evaluated the demand for the vascular tissues. The Company's procurement of vascular tissue decreased 65% in the fourth quarter of 2002 as compared to the fourth quarter of 2001. The Company expects that vascular procurement will increase significantly following the close out of the FDA 483.

On December 31, 2002 the FDA clarified the Agreement noting that non-valved cardiac and vascular tissues processed since September 5, 2002 are 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. A renewal of the Agreement that expires on March 20, 2003 is therefore not needed in order for the Company to continue to distribute non-valved cardiovascular and vascular tissues processed since September 5, 2002.

On February 14, 2003 the FDA confirmed that the Company has completed the corrective actions necessary to close out the April 2002 FDA 483 Notice of Observations that preceded the Warning Letter and FDA Order. The close out of the 483 followed a two-week inspection of the Company's processing operations. As a result of the close out of the 483, the Company believes it can resume processing and distributing orthopaedic tissues but has not received confirmation of this from the FDA. The Company resumed processing orthopaedic tissues in late February 2003. Prior to shipment of orthopaedic tissues, the Company will confirm with the FDA that they do not disagree with the Company regarding its interpretation of the close out of the FDA 483. The Company will continue to process vascular tissues on a limited basis until it can fully evaluate the demand level for its vascular tissue preservation services.

A new FDA 483 Notice of Observations was issued in connection with the inspection, but 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.

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 for retention levels under the Company's product liability and directors' and officers' insurance policies of \$1.2 million (see Note 9), and for estimated expenses of \$75,000 for packaging and handling for the return of affected tissues under the FDA Order. 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 many 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 \$0.5 million 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. The Company did not record any further write-downs of deferred preservation costs in the fourth quarter of 2002. As of December 31, 2002 the balance of deferred preservation costs were \$2.0 million for allograft heart valve tissues, \$620,000 for non-valved cardiac tissues, \$1.7 million for vascular tissues, and zero for orthopaedic 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. Upon destruction or shipment of the remaining tissues associated with the deferred preservation costs write-down, the deferred tax asset will become deductible in the Company's tax return. An expected refund of approximately \$8.5 million will be generated through a carry back of operating losses and write-downs of deferred preservation costs. In addition, the Company recorded \$2.5 million in income tax receivables related to estimated tax payments for 2002. The Company received payment of the \$2.5 million in January of 2003.

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. As of September 30, 2002, in applying SFAS 144, the Company determined that the asset groups consisted of the long-lived assets related to the Company's two reporting segments, as these asset groups represent the lowest level at which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. 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 September 30, 2002 and December 31, 2002 and therefore management has concluded that there is not an impairment of the Company's long-lived intangible assets, except for goodwill as discussed below, 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, the outcome of discussions with the FDA regarding the shipping of orthopaedic tissues, and the future effects of adverse publicity surrounding the FDA Order and reported infections on preservation revenues, 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 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. Management does not believe an impairment exists related to the other intangible assets that were assessed in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144").

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. As of December 31, 2002 the remaining balance of accrued restructuring costs was \$110,000.

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

## Strategy

The Company's primary objective is to consistently grow revenue and 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 84 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 for antigen reduction properties with the potential for recipient cell repopulation.
- *Expand Distribution of Preserved Human Vascular Tissue and Resume 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 to resume 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) resuming and expanding its product offerings by applying its SynerGraft technology to human grafts for antigen reduction properties with the potential for recipient cell repopulation.
- *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. In 1997 the Company began providing cryopreserved human vascular tissue to be used as dialysis access replacement grafts

for patients undergoing chronic dialysis, and separately, as venous valve replacements for patients suffering from chronic venous insufficiency. In 1997 and 1998 in addition to patellar and Achilles tendons, the Company began providing semi-t/gracilis tendons and cryopreserved posterior and anterior tibialis tendons, respectively, for use in knee repairs, and in 1999 began providing preserved human osteochondral grafts to repair articular defects and aortoiliac grafts to replace infected abdominal aortic grafts. The Company is also investigating the use of other orthopaedic tissues in various surgical applications. As discussed in the section on the FDA Order on Human Tissue Preservation, the Company resumed orthopaedic processing in late February 2003.

- *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. The Company has since been successful in broadening the scope for approved uses 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 for dialysis access.
- *Develop and Commercialize Bioprosthetic Cardiovascular Devices.* The Company intends to leverage its expertise with stentless human heart valves to expand commercialization of its stentless porcine heart valve.
- *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, such as Cerasorb.

## **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, and vascular tissue. In addition, the Company has historically preserved orthopaedic tissue and resumed processing orthopaedic tissue in late February 2003.

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 55,400 cryopreserved human heart valves and conduits from 1984 through 2002. Revenues from human heart valve and conduit preservation services accounted for 39%, 33%, and 30% of total revenues, respectively, in 2000, 2001, and 2002. 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. 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, which effectively removes cells from the heart valve leaving the collagen matrix intact. The CryoValve® SG valve is especially designed to benefit patients, both children and adults, who have had a minor immune response to transplanted tissues. Early clinical data indicates that the new SynerGraft processing method mitigates the increase of panel reactive antibodies ("PRA") experienced by some of the patients who receive allograft heart valves. The absence of a significant immunologic response to the decellularized allograft has the potential of improved long-term function of the allograft heart valves. Animal studies and explants from human recipients have documented that allograft heart valves treated with the SynerGraft process have repopulated *in vivo* with the recipient's own cells. The Company's data shows a majority of the cardiac allografts processed with standard cryopreservation methods do not repopulate *in vivo*. As discussed at "Recent Events", 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 heart valve and non-valved conduit replacement market in the U.S. in 2002 was approximately \$400 million. Management believes that approximately 80,000 heart valve and non-valved conduit surgeries were conducted in the U.S. in 2002. Of the total number of heart valve and conduit surgeries, approximately 27,000, or 34%, involved mechanical heart valves, and approximately 53,000, or 66%, involved tissue heart valves or conduits, including porcine, bovine, and cryopreserved human tissues. Approximately 3,800 human heart valves and conduits cryopreserved by the Company were shipped for implantation in 2002.

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	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	high 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
Average Estimated Valve Cost in U.S.:	\$7,300	\$4,700	\$5,500	\$4,000(3)	\$4,700

(1) Limited long-term clinical data is available since stentless porcine heart valves only recently became commercially available.

(2) Pressure measured in mm/Hg.

(3) Mechanical valves also require chronic anti-coagulation drug therapy at a cost of approximately \$450 per year.

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 dialysis access and aortoiliac arteries for the reconstruction of infected abdominal synthetic grafts. The Company shipped approximately 33,300 human vascular tissues from 1986 through 2002, which includes 4,400 shipments in 2002. Revenues from human vascular preservation services accounted for 28%, 28%, and 23% of total revenues, respectively, in 2000, 2001, and 2002.

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. The Company's cryopreserved human vascular tissues are used for coronary artery bypass surgeries, peripheral vascular reconstruction, dialysis access graft replacement, venous valve transplantation, and infected abdominal aortic graft replacement.

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 2002. The Company estimates that approximately 30% of these are re-operations, which may require the use of preserved vascular tissue.

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 2002 approximately 78,000 peripheral vascular reconstruction surgeries were performed in the U.S. in which its cryopreserved human vascular tissues could have been used.

In 1997 the Company began a program for the preservation of human superficial femoral veins and arteries for use in dialysis access graft replacement as an alternative for synthetic grafts, which have a higher risk of infection and thrombosis than human tissue. The Company estimates that in 2002 there were approximately 300,000 end stage renal failure patients receiving dialysis in the U.S., and a majority of these patients rely on hemo-dialysis requiring either a native fistula or synthetic graft for arterial-venous access. There are approximately 87,000 synthetic grafts placed annually for arterial-venous access.

*Human Orthopaedic Tissue.* As discussed at "FDA Order on Human Tissue Preservation", the Company suspended processing orthopaedic tissues between August 2002 and late February 2003. The Company has historically provided preservation services for surgical replacements for the meniscus and the anterior and posterior cruciate ligaments, which are critical to the proper operation of the human knee, as well as osteochondral grafts used for the repair of cartilage defects in the knee. CryoLife shipped approximately 27,500 human connective tissues for the knee through the end of 2002, which includes 4,200 shipments in 2002. Revenues from human orthopaedic preservation services accounted for 21%, 26%, and 18% of total revenues, respectively, in 2000, 2001, and 2002.

Human menisci, historically cryopreserved by the Company prior to the issuance of the FDA Order, 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 2002 approximately 725,000 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, historically cryopreserved by the Company prior to the issuance of the FDA Order, 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 2002 approximately 200,000 cruciate ligament reconstruction surgeries were performed in the U.S.

In 1999 the Company began preserving osteochondral 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 success of transplanted osteochondral grafts is attributed to the presence of viable chondrocytes (cells of the cartilage). The Company estimates that in 2002 approximately 450,000 articular cartilage repair procedures were performed in the U.S. and that approximately 10–15% of these repairs will be amenable to fresh osteochondral (OA) resurfacing replacement within 5 years.

#### *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. World wide 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 worldwide market for surgical sutures and staples in 2002 was in excess of \$2.5 billion. The Company began shipping BioGlue Surgical Adhesive for distribution in the 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 an 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 the Company received a third CE Mark for BioGlue for 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 only to soft tissue repair. Revenues from BioGlue Surgical Adhesive represented 8%, 12%, and 27% of total revenues, respectively, in 2000, 2001, and 2002.

#### *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 heart valves, the Company's stentless porcine heart valve has minimal synthetic materials, which decrease the risk of endocarditis, a debilitating and potentially deadly infection. Revenues from bioprosthetic cardiovascular and vascular devices represented 1% of total revenues in 2000, 2001, and 2002.

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 a worldwide target market estimated to have been \$400 million in 2002.

The CryoLife-O'Brien aortic valve is a stentless porcine valve with design features which management believes provides 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 technology involves the removal of cells from the structure of animal or human 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 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 between 25 and 50 cm in 5 cm increments. The SynerGraft Model 100 vascular graft can be stored at room temperature until use.

#### *Other Implantable Devices*

On February 5, 2003 the Company announced that it has signed an exclusive agreement with curasan AG, located in Germany, for U.S. distribution on Cerasorb® Ortho, curasan's resorbable bone graft substitute. The five-year agreement gives CryoLife exclusive rights to market Cerasorb Ortho for all non-spine, non-dental orthopaedic indications such as trauma, general, and sports medicine. Cerasorb, a resorbable, beta-tricalcium phosphate bone regeneration material, was first introduced in Germany in 1998 for dental use. The product captured approximately 60% of the synthetic dental bone regeneration market in Germany within four years. In 2001 curasan received CE Mark certification for Cerasorb's use in general orthopaedics, and in 2002 received FDA 510(k) approval for orthopaedic use. The Company anticipates that the U.S. market for bone grafts and substitutes for which it can distribute Cerasorb is approximately \$140 million.



### *Single-Use Medical Devices*

On October 9, 2000 the Company sold substantially all of the remaining assets of Ideas for Medicine, Inc. (“IFM”) to Horizon Medical Products, Inc. See Note 3 of Notes to the Consolidated Financial Statements for a more detailed discussion.

## **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 84 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 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, eight of which are employed as procurement relations managers and 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 may identify characteristics which would disqualify the tissue for preservation or implantation.

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 below  $-135^{\circ}\text{C}$ . Prior to the issuance of the FDA Order, osteochondral grafts were refrigerated in proprietary solutions from  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  for up to 45 days. The entire preservation process is rigidly controlled by guidelines established by the Company.

*Distribution of Tissue to Implanting Physicians.* After preservation, 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 more than 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 delivery 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 4,000 cardiovascular, vascular, and orthopaedic surgeons who have implanted tissues cryopreserved by the Company during the past twelve months. The Company works to maintain relationships with and market to surgeons within these medical specialties. Because the Company markets its preservation services directly to physicians, an important aspect of increasing the distribution of the Company's preservation services is educating physicians on the use of cryopreserved human tissue and on proper implantation techniques. Trained field support personnel provide support to implanting institutions and surgeons. The Company currently employs approximately 35 persons as technical service representatives who deal primarily with cardiovascular and vascular surgeons and provide field support. These representatives receive a base salary with a performance bonus. The Company has over 150 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 has retained the majority of these distributor groups and added a few groups in anticipation of resuming orthopaedic processing and distribution.

The Company sponsors physician training seminars where leading 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 Distribution*

In September 1999 the Company established its European subsidiary, CryoLife Europa, Ltd. ("Europa"), to provide distribution and technical services to the Company's network of European representatives, customers, and surgeons. In February 2000 Europa officially opened its headquarters located near London, England. The Company's European, Middle East, and African sales, marketing, and distribution activities directed through Europa are channeled through approximately 30 independent distributors located throughout Europe, the Middle East, and South Africa. Since 2002 Europa has employed approximately four persons as direct technical representatives who also provide field support for the United Kingdom. Marketing efforts are directed almost exclusively 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, excluding Japan, through Europa and other existing independent representatives. The Company conducts training sessions for doctors with respect to the application and administration of BioGlue Surgical Adhesive.

During 1998 the Company signed a five-year 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, the Middle East, Africa, and Canada. The Company commenced marketing the SynerGraft Model 100 vascular graft in Europe, Switzerland, and Israel during the third quarter of 2001. Marketing efforts are primarily directed toward vascular surgeons to educate them with respect to the uses and benefits of the Company's bovine vascular grafts.

## **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 continue 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 18 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. 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 2000, 2001, and 2002, the Company spent approximately \$5.2 million, \$4.7 million, and \$4.6 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 7%, 5%, and 6% of the

Company's revenues for those respective years. The Company's research and development program is overseen by its medical and scientific advisory boards. 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**

During 2001 the Company completed a 100,000 square foot addition to its corporate headquarters and laboratory facilities located on a 21.5-acre campus-style setting in suburban Atlanta, Georgia. The new addition is to accommodate growth and development of the Company's BioGlue Surgical Adhesive and the SynerGraft family of biologic implantable devices. The total Company U.S. facilities consist of three separate locations totaling approximately 243,000 square feet of leased manufacturing, administrative, laboratory, and warehouse space. Approximately 24,000 square feet are dedicated to forty-five 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, processing, manufacturing, and packaging. Approximately 40 liquid nitrogen storage units maintain cryopreserved tissue at  $-196^{\circ}\text{C}$ . Three 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 23 technicians employed in this area, and the laboratory is staffed for two shifts, 365 days per year. In 2002 the laboratory processed approximately 16,400 human allografts for distribution and transplant. The current processing level is estimated to be at about one-third of total capacity. Increasing this processing level could be accomplished by increasing employees and expanding to three shifts.

### *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 twelve technicians employed in this area.

### *Bioprosthetic Cardiovascular and Vascular Devices*

The bioprosthesis laboratory, which was relocated to the expanded corporate headquarters in 2001, 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 six technicians.

### *Other facilities*

The Company maintains two separate facilities, located in Marietta, Georgia, that total 31,000 square feet. One facility is approximately 20,000 square feet, with about 2,100 square feet of laboratory space and a suite of six clean rooms. The other facility contains approximately 11,000 square feet, including 4,000 square feet of laboratory space and a suite of eight clean rooms. The Company is currently seeking to sublease these facilities.

## **Quality Assurance**

The Company's operations encompass the provision of 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 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, 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 expects to be in compliance with ISO 13485 quality system requirements by the end of 2003. The ISO 13485 requirements are intended to be an enhancement to current quality management 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, and ISO 9001 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.

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 tests to screen for serologic infectious diseases. Samples of some tissues are also sent to independent laboratories for pathology testing. Following dissection of the tissue to be cryopreserved, a separate procedure is begun in which the dissected tissue is treated with proprietary antimicrobial solutions.

The materials and solutions used by the Company in processing tissue are pre-screened to determine if they meet strict quality standards as defined by Company protocols. Only materials and solutions that meet the Company's requirements are approved by quality assurance personnel for use in processing. Throughout tissue processing, detailed records 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 additionally regulated by the FDA and periodically inspected for compliance to Quality System Regulations. Other human tissue processed by the Company is periodically inspected for compliance with the 'CFR Part 1270. CFR 1270 is an FDA regulation which sets forth the requirements with which the Company must comply in determining the suitability of human tissue for implantation.

### *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 procedures are accepted by quality control and utilized in production.

All materials, components and resulting sub-assemblies are traced throughout the manufacturing process to assure that appropriate corrective actions can be implemented, if necessary. Each process is documented along with all inspection results, including final finished product inspection and acceptance. Records are maintained as to the consignee of product to facilitate product removals or corrections, if necessary. 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.

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 39 U.S. patents and 53 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 23 pending U.S. patent applications and in excess of 97 pending foreign applications that relate to areas including heart valve and tissue processing technology and delivery of bioadhesives for anastomosis and other uses. The Company sold the patents related to the IFM product line to Horizon in 1998. 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.

On August 7, 2002 the Company announced the settlement of its ongoing litigation with Colorado State University Research Foundation (“CSURF”) over the ownership of the Company’s SynerGraft technology. The settlement resolved all disputes between the parties and extinguished all CSURF ownership claims to any aspect of the Company’s SynerGraft technology. The settlement includes an unconditional assignment to the Company of CSURF tissue engineering patents, trade secrets, and know-how relating to tissue decellularization and recellularization. The technology assignment supercedes the 1996 technology license, which was terminated by the terms of the settlement. Payment terms include a nonrefundable advance of \$400,000 paid by the Company to CSURF that will be applied to earned royalties as they accrue through March 2011. The Company recorded these amounts as prepaid royalties and will expense the amounts as the royalties accrue. 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 a number of 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 and vascular tissue shipments, and the lack of orthopaedic tissue shipments, the Company’s competitors have been favorably impacted. This interruption in the Company’s services may make it difficult for the Company to regain its 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 are 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. Edwards Life Sciences, Inc. is the leading supplier of bovine 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 three other companies that offer stentless porcine 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.* As discussed at “FDA Order on Human Tissue Preservation”, the Company ceased processing orthopaedic tissue in August 2002. The Company resumed processing orthopaedic tissue in late February 2003. 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 freeze-dried and fresh frozen human connective tissues. These alternative allografts are distributed by Musculoskeletal Transplant Foundation, Lifenet, and others. Prior to the issuance of the FDA Order, tendons cryopreserved by the Company constituted 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 with existing methodologies, including traditional wound closure products such as sutures and staples, marketed by companies such as Johnson & Johnson, Tyco Healthcare Corporation, and others. Other competitors in the surgical sealant market include Baxter Healthcare International, Inc., Angiotech Pharmaceuticals, Inc., and Genzyme Biosurgery. Competitive products may also be under development by other large medical device, pharmaceutical and biopharmaceutical companies, including 3M and Confluent Surgical, Inc. 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. BioGlue Surgical Adhesive is the only FDA approved product with an arterial surgical glue product code designation (MUQ- glue, surgical, arteries).

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 human heart valves and BioGlue surgical bioadhesives 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.

*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. BioGlue Surgical Adhesive is the only FDA approved product with an arterial surgical glue product code designation (MUQ- glue, surgical, arteries).

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

Other than human and porcine heart valves, BioGlue Surgical Adhesive, and SynerGraft processed bovine vascular grafts, none of the Company's other tissue services or tissue-based products are currently subject to regulation under the FDCA or FDA regulation as medical devices. See "Recent Events" 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. The 1998 Final Rule provided clarification of certain provisions in the 1993 Interim Rule and 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 FDA has proposed and is refining three regulations covering registration, expanded donor suitability and testing requirements, and the use of good tissue practices, akin to good manufacturing practices required for medical device manufacturers. In March 2002 the FDA issued a guidance document for implementation without seeking prior comments titled, "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 will expand its regulation of processed human tissue in the future. For example, in November 2000 the FDA published a proposed rule for good tissue manufacturing practices. Moreover, the FDA may determine that the vascular and orthopaedic tissue 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 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 which 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. The CE Mark is awarded by third parties called Notified Bodies. 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 February 19, 2003 the Company had approximately 274 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](http://www.cryolife.com), on the day of filing. All of such filings made on or after November 15, 2002 have been made available on the website.

## **RISK FACTORS**

### **The FDA Order on Human Tissue-Dependence on Preservation of Human Tissue Has Adversely Affected CryoLife's Business**

On August 13, 2002 the Company 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 the Company at its headquarters since at least October 3, 2001 based upon allegations of FDA violations by the Company of its handling of such tissue and alleged contamination through the Company's processing of such tissue that resulted in 14 post-transplant infections including one death. A significant portion of the Company's current revenues is derived from the preservation of human tissues. Revenues of 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 the Company's revenues. Of those revenues, \$26.9 million or 67% were derived from preservation of tissues subject to the FDA Order. Revenues for human tissue preservation services for the year ended 2001 were 86% of the Company's revenues. Of those revenues, 68% were derived from preservation of tissues subject to the FDA Order. During the fourth quarter of 2002, revenues derived from the preservation of tissues were \$6.3 million, a 66% decrease in revenues from the fourth quarter of 2001.

The FDA Order and resulting adverse publicity have had a material adverse effect on the Company's business, financial condition, results of operations and cash flows. As a result of the FDA Order, the Company has experienced, and expects to continue to experience at least through the first half of 2003, decreases in revenues and profits as compared to prior year periods and there is a possibility that the Company may not generate sufficient cash from operations to fund its operations over the long-term. Although the Agreement that supplements the FDA Order has allowed the Company to ship vascular and non-valve cardiac patch tissues subject to the FDA Order with certain restrictions, the Company has continued to experience a reduced demand for such tissues and for tissues processed since the September 5, 2002 Agreement 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 from the Company's competitors. Even though the FDA 483 letter that preceded the FDA Order was closed out on February 14, 2003, demand for such tissue may continue to be reduced by the adverse publicity generated from the FDA Order. Therefore, the Company may still experience significant decreases in revenues and profits and there is a possibility that the Company will not generate sufficient cash from operations to fund its operations in the long-term. In addition, as a result of the FDA Order, the time for processing human tissue and the costs of such processing have increased and are likely to further increase, which could have a material adverse effect on the Company's business, results of operations and financial position.

The success of the Company 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 the Company's growth. The Company 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 uncertainty regarding future tissue processing, some procurement agencies have ceased sending tissue to the Company for processing. If the Company's relationships with procurement agencies continue to be adversely affected or the Company is unable to obtain tissues from procurement agencies that have ceased sending tissue to the Company for processing, the Company may be unable to obtain adequate supplies of donated tissues to operate profitably.

### **The FDA Order Has Had an Adverse Impact on Liquidity and Capital Resources**

Based upon the FDA Order, the Company anticipates a continued decrease in liquidity. Based upon the present and anticipated decrease in revenues and profits from the FDA Order and associated adverse publicity, the Company expects that cash generated by operations will continue to decrease over the near term and working capital could decrease. Although the Company has reduced its level of operations and the number of personnel employed in response to the FDA Order, there is a possibility that the Company may not have sufficient funds to fund its primary capital requirements or to meet its operating and development needs in the long-term.

### **Demand for Our Orthopaedic Tissue Preservation Services is Minimal and May Not Return**

As a result of the FDA Order and related adverse publicity, the Company has received only nominal revenue from the preservation of orthopaedic tissues since August 14, 2002. Revenues since August 14, 2002 have been from shipments of tissues that were processed prior to October 3, 2001. For the year ended December 31, 2001, human tissue preservation services revenues for orthopaedic tissues were \$22.5 million, which represented 26% of the Company'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 tissues were \$11.9 million (prior to the reduction of estimated tissue recall returns), which represented 23% of the Company's revenues. Because orthopaedic tissue is generally not involved in life-saving or limb-saving procedures and due to the adverse publicity, the demand for orthopaedic tissue from the Company may remain minimal and may never return to the levels in existence before the FDA Order, when the Company resumes processing. As a result, this portion of the Company's business may have to be permanently discontinued or may only continue at an extremely reduced level. Any of these occurrences would result in a significant decrease in the Company's revenues and profitability in the future as compared to historical results.

### **Physicians May Be Reluctant To Implant the Company's Preserved Tissues**

Even though the April 2002 483 Notice that preceded the FDA's Warning Letter has been closed out, there is a risk that physicians or implanting institutions will be reluctant to choose the Company'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 the Company's tissues are used. In addition, for similar reasons, hospital risk managers may forbid implanting surgeons to utilize the Company's tissues where alternatives are available. If a significant number of implanting hospitals or physicians refused to use tissues preserved by the Company, the Company's revenues and profits would be materially adversely affected.

### **Heart Valves Processed by the Company May Also be Recalled**

On August 21, 2002 the FDA publicly stated that allograft heart valves have not been included in the FDA recall order as these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA also publicly stated that it still has serious concerns regarding the processing and handling of allograft heart valves. The FDA also recommended that surgeons carefully consider using processed allografts from alternative sources, that surgeons should inform prospective patients of the FDA's concerns with the Company's allograft heart valves, and that patients should be carefully monitored for both fungal and bacterial infections. Any adverse finding by the FDA regarding allograft heart valves, including a recall, would cause further decreases in the Company's revenue base and profits and significantly reduce the Company's potential for growth. If such a recall occurs, the Company may also be required to write-down all or a portion of the deferred preservation costs for allograft heart valves, which could have a material adverse effect on the results of operations and financial condition of the Company.

### **Products Not Included in the FDA Recall May Come Under Increased Scrutiny**

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

### **Demand for Heart Valves Processed by the Company Has Decreased and May Continue to Decrease**

Possibly as a result of the FDA's public statement on August 21, 2002 regarding allograft heart valves, and due to the adverse publicity associated with the FDA Order and reported tissue infections, some physicians and

implanting institutions have been reluctant to choose the Company's allograft heart valves for use in implantation, 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 the Company's preserved tissues are used, especially if alternatives are available. If adverse publicity continues and if the FDA's public statement is not retracted, the demand for Company's allograft heart valves could continue to decrease and may never return to the levels exhibited before the FDA Order. In such an event, the Company's revenues and profits would be materially adversely affected as compared to historical results. Heart valve shipments decreased 33% in the fourth quarter of 2002 as compared to the fourth quarter of 2001.

### **The Costs of Recall and Related Write-Downs Have Adversely Affected the Company**

The Company's financial statements reflect the estimated cost of recalling tissue pursuant to the FDA Order. The Company recorded a write-down of \$32.7 million of deferred preservation costs for tissues subject to the FDA Order. While these estimates are based on the Company's best estimate of the costs associated with the recall and the impairment of deferred preservation costs subject to the FDA Order, there can be no assurance that these costs and write-downs will be limited to the amount estimated.

### **Adverse Publicity May Reduce Demand for Products Not Affected by the FDA Recall**

Even though the Company's BioGlue products and its porcine heart valve products (which are not sold in the U.S.) are 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 the Company's business, results of operations and financial position.

### **We May Be Unable to Address the Concerns Raised by the FDA in Its February 2003 Form 483 Notice of Observations**

In connection with closing out its April 2002 Form 483 Notice of Observations, the FDA issued a new Form 483 Notice of Observations in February 2003. The majority of the observations in the new letter focused on the Company's systems for handling complaints. If the Company is unable to satisfactorily respond to the FDA's observations contained in this notice, 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 position is that femoral veins used for A-V access are medical devices that require premarket approval. If CryoLife is unable to persuade the FDA that its assertions are incorrect, there can be no guarantee that CryoLife will be able to obtain any required approvals on a timely basis or without significant expenditures, if at all. Inability to market either CryoValve or CryoVein could have a material adverse impact on the Company's business, results of operations, financial position or cashflows.

### **Regulatory Action Outside of the U.S. May Also Affect the Company'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 their inquiries are now, to the Company's knowledge, complete. In addition, the Company has not shipped tissue out of the U.S. without following the restrictions set forth in the FDA Order as supplemented by the Agreement. In the event additional regulatory concerns are raised by other countries, the Company may be unable to export tissues outside of the U.S.



### **The Company's Common Stock Is Potentially At Risk Of Being Delisted From The New York Stock Exchange**

Because of the impact of the FDA Order and the recent trading price of the Company's common stock, there is a possibility that the Company's common stock could be delisted from the New York Stock Exchange. If the stock is delisted, there is no guarantee that there will be a liquid market for the stock and the trading price of the stock would likely be adversely affected.

### **The Company Is The Subject of an Ongoing SEC Investigation**

The Company received notice from the Securities and Exchange Commission on August 17, 2002 that it is the subject of an investigation with respect to accounting issues and trades in the Company's stock related to the FDA Order. The Company does not know any details of what the SEC is specifically investigating, but believes that an adverse finding by the SEC could have a material adverse effect on its business financial position, results of operations, and cash flows. The staff of the SEC subsequently confirmed that its investigation is informal in nature, and that it does not have subpoena power at this time. At the present time, the Company is unable to predict the outcome of this matter.

### **As a result of the FDA Recall and Resulting Financial Impact, CryoLife's Lender has Notified It that It is in Default of Certain Provisions of the Company's Credit Facility**

The Term Loan contains 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 has occurred. The lender has determined that the FDA Order and resulting financial impact, as described in Note 2 to the Summary Consolidated Financial Statements, and the inquiries of the Securities and Exchange Commission, as described in Note 12 to the Summary Consolidated Financial Statements, have had a material adverse effect on the Company that constitutes an event of default. Additionally, as of September 30 and December 31, 2002, the Company was in violation of the debt coverage ratio and net worth financial covenants. The lender has advised the Company that it is in default of certain provisions of the Term Loan; however, as of February 24, 2003, the lender has elected not to pursue any of its various remedies provided for in the Term Loan, but reserves the right to exercise any such right under the terms of the Term Loan. There is no assurance the lender will not exercise its rights, which could have a material adverse effect on the Company's liquidity.

Due to cross default provisions included in the Company's debt agreements, as of December 31, 2002 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, 2002. There is no assurance the lender will not exercise its rights under lease agreements, which could have a material adverse effect on the Company's liquidity.

### **The Company's Insurance Coverage May Be Insufficient to Cover Judgments Under Existing or Future Claims**

The Company's products are used by health care providers in connection with the treatment of patients, who will, on occasion, sustain injury or die as a result of their condition or medical treatment. As a result, the use of the Company's products and human tissue processed by the Company involves the possibility of adverse effects that could expose the Company to product liability claims, including the lawsuits filed against the Company relating to implanted tissue described below in Part I, Item 3 "Legal Proceedings." The FDA Order could adversely influence the outcome of current product liability claims relating to tissue processed by the Company. In addition, due to the publicity surrounding the recent FDA Order, more product liability claims relating to tissue processed by the Company could be filed.

In addition, a recent U.S. Supreme Court decision held that product liability may exist despite FDA approval, and future court decisions may also increase the Company's risk of product liability.

Whether or not the Company is ultimately determined to be liable for product liability claims, the Company will incur significant legal expenses. In addition, such litigation could damage the Company's reputation and therefore impair its ability to market its products or obtain product liability insurance and could cause the premiums for such insurance to increase. Although the Company has incurred minimal losses due to product liability claims to date, the Company may incur significant losses in the future. Management believes that the coverage is adequate to cover any losses due to product claims that may be incurred; however, there can be no assurance that such coverage will be adequate. In addition, there can be no assurance that such coverage will continue to be available on terms acceptable to the Company, especially in light of the FDA Order and the number of product liability claims the Company has had made against it. Furthermore, if any product liability claims are successful, it could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

#### **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 and the adverse publicity from the FDA Order, the Company may be unable to obtain insurance coverage in the future, causing the Company 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, which may adversely impact the Company's profitability. The Company has received several notices of non-renewal and/or notices of potential premium increases from its current insurance companies. The Company is in the process of soliciting insurance for the coming renewal period of April 1 and May 1, 2003.

#### **Intense Competition May Affect the Company's Ability to Recover from the FDA Order and Develop its Surgical Adhesive Business**

The Company 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. During the time that the Company has been restricted in its processing and distribution of human tissue due to the FDA Order as supplemented by the Agreement, tissue preservation service customers have been forced to obtain tissue from the Company's competitors, which could lead to permanent substitution.

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 and porcine heart valve markets, including St. Jude Medical, Inc., Medtronic, Inc. and Edwards Life Sciences. The Company is aware that several 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 the Company's competitors have greater financial, technical, manufacturing and marketing resources than the Company and are well established in their markets.

There can be no assurance that the Company's products and services will be able to compete successfully with the products of these or other companies. Any products developed by the Company that gain regulatory clearance or approval would have to compete for market acceptance and market share. Failure of the Company to compete effectively could have a material adverse effect on the Company's business, financial condition, results of operations and cash flows. The FDA Order and related adverse publicity have had an adverse effect on the Company's competitive position, which has had a material adverse effect on the Company's results of operations. The FDA Order and related adverse publicity may continue to have an adverse effect on the

Company's competitive position, which may continue to have a material adverse effect on the Company's results of operations. As a result, the Company's competitors may gain competitive advantages that may be difficult to overcome.

### **Rapid Technological Change Could Cause the Company's Services and Products to Become Obsolete**

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

### **Products in Development May Not be Successful**

The Company's growth and profitability will depend, in part, upon its ability to complete development of and successfully introduce new products, including additional applications of its BioGlue and SynerGraft technologies and its ACT. The Company may be required to undertake time consuming and costly development activities and seek regulatory clearance or approval for new products. The Company has had minimal reduction in its development efforts since the receipt of the FDA Order. The Company may have to further reduce its development efforts in the future because of the impact of the FDA Order, reported tissue infections, and adverse publicity on the Company's financial condition.

Although the Company 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 the Company to obtain any required regulatory approvals or clearances. There can be no assurance that the Company 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 the Company'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, the Company'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 complete successfully the development of a product or application, or a determination by the Company, for financial, technical or other reasons, not to complete development of any product or application, particularly in instances in which the Company has made significant capital expenditures, could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows. The Company'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 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**

The Company may invest in new technology licenses or distribution rights, such as Cerasorb, and may be unable to meet the expected revenue forecast for the licenses or rights. In addition, the Company may not be able to recover its initial investment in the license, distribution right or purchase of initial inventory, which may adversely impact the Company's profitability.

### **Funding for the ACT Technology May Not be Available**

The ACT is a reversible linker technology that has potential uses in the areas of cancer therapy, fibrinolysis (blood clot dissolving) and other drug delivery applications. In February 2001 the Company 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. The Company has been seeking such funding since 1998.

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. 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, the Company 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. Failure to obtain the desired financing, or failure of the ACT to perform as anticipated in future tests, could have a material adverse effect on the Company's future expansion plans and could limit future growth.

### **Uncertainties Regarding the SynerGraft Technology**

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

### **Extensive Government Regulation May Retard the Company'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 the Company's efforts to market and develop its products. The allograft heart valves to which the Company 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 the Company 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 improve 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 the Company 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 the Company 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. There can be no assurance that the Company will be able to 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 the Company maintaining its CE Mark ISO 9001, and ISO 13485 certifications, of which there can be no assurance.

Most of the Company'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 the Company, 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 the Company and adversely affect the Company's competitive position. The FDA may also place conditions on product approvals that could restrict commercial applications of such products. Product marketing approvals or clearances may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Delays imposed by the governmental clearance process may materially reduce the period during which the Company 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 the Company's or its collaborative partners' development focus and disclosure of trial results by competitors.

Even if regulatory approval is obtained for any of the Company'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 the Company 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 the Company's business, financial condition, results of operations, and cash flows. As noted above, the FDA Order has 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 the Company's methods of charging for its preservation



services. The Company'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 the Company's business, financial condition, results of operations and cash flows.

### **Uncertainties Related to Patents and Protection of Proprietary Technology May Affect the Value of our Intellectual Property**

The Company owns several patents, patent applications and licenses relating to its technologies, which it believes provide important competitive advantages. There can be no assurance that the Company'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 the Company, 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 the Company's technologies or design around the patented aspects of the Company's technologies. There can be no assurance that the Company's proposed technologies will not infringe patents or other rights owned by others.

In addition, under certain of the Company's license agreements, if the Company 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 the Company's business, financial condition, results of operations, and cash flows. Additionally, the Company 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 the Company will have adequate remedies for any breach or that the Company's trade secrets will not otherwise become known or independently discovered by competitors, any of which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

### **Uncertainties Regarding Future Health Care Reimbursement May Affect the Amount and Timing of the Company's Revenues**

Even though the Company does not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand for the Company's cryopreserved tissue and other services and products. The Company'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. The Company 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 the Company.

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 the Company and other Company services and products, could have a material adverse effect on the Company. 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 the Company 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 the Company's new products and services, market acceptance of these products would be adversely affected, which could have a material adverse effect on the Company's business, financial condition, results of operations and cash flows.

### **CryoLife is Dependent on its Key Personnel**

The Company's business and future operating results depend in significant part upon the continued contributions of its key technical personnel and senior management, many of who would be difficult to replace. The Company's business and future operating results also depend in significant part upon its ability to attract and retain qualified management, processing, technical, marketing, sales and support personnel for its operation. Competition for such personnel is intense and there can be no assurance that the Company will be successful in attracting and retaining such personnel. The loss of key employees, the failure of any key employee to perform adequately or the Company's inability to attract and retain skilled employees as needed could have a material adverse effect on the Company's business, financial condition, results of operations and cash flows.

### **Our Consolidated Financial Statements as of and for the Two Years Ended December 31, 2001 and 2000 Included in this Form 10-K Were Audited By Arthur Andersen LLP, Which Has Been Found Guilty of Obstruction of Justice and May Be 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 agreed to cease practicing before the SEC. Arthur Andersen LLP may seek to have the conviction overturned, may dissolve or liquidate, may merge with or have its assets sold to a third party and has lost critical personnel. In the event that Arthur Andersen LLP dissolves, liquidates or does not otherwise continue in business, Arthur Andersen LLP 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 two years ended December 31, 2001 and 2000 included in this Form 10-K.

In addition, Arthur Andersen LLP has not consented to the inclusion of their report dated March 27, 2002 in this Form 10-K, 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 this Form 10-K, you 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.

### **Volatility of Securities Prices**

The trading price of the Company'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, quarter to quarter variations in operating results, announcement of technological innovations or new products by the Company 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 the Company's control. If the Company's revenues or operating results in future quarters fall below the expectations of securities analysts and investors, the price of the Company's common stock would likely decline further, perhaps substantially. Changes in the trading price of the Company's common stock may bear no relation to the Company's actual operational or financial results. If the Company's share prices do not meet the requirements of the New York Stock Exchange, the Company's shares may be delisted. The Company's closing stock price in the period January 1, 2002 to February 24, 2003 has ranged from a high of \$31.31 to a low of \$1.89.

**Anti-Takeover Provisions**

The Company'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 the Company, including provisions authorizing the issuance of preferred stock without shareholder approval, restricting the persons who may call a special meeting of the shareholders and prohibiting shareholders from taking action by written consent. In addition, the Company is subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of the Company'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 the Company on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts.

**Absence of Dividends**

The Company has not paid, and does not presently intend to pay, cash dividends. The Company's major credit agreement contains, and 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 the Company 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, adequacy of product liability insurance to defend against lawsuits, the outcome of lawsuits filed against the Company, the impact of the FDA Order and related Agreement on future revenues, profits and business operations, the effect of the FDA Order on sales of BioGlue, future tissue procurement levels resulting from the FDA Order, expected future impact of BioGlue on revenues, the estimates underlying the charges recorded in the second and third quarter due to the FDA Order, the impact of the February 2003 FDA 483, 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 product loss claims incurred but not reported at December 31, 2002, future costs of human tissue preservation services, changes in liquidity and capital resources as a result of the FDA Order, 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 referenced in the SEC Letter, future product development plans as a result of the FDA Order, the Company’s competitive position, the successful development of the Company’s SynerGraft porcine heart valves, 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 arrangements, 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 facility consists of three separate locations totaling approximately 243,000 square feet of leased office, manufacturing, laboratory and warehouse space. Approximately 30,000 square feet are dedicated to clean room work areas. The primary facility has five main laboratory facilities: human tissue processing, BioGlue manufacturing, bioprosthesis manufacturing, research and development, and microbiology. 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 which provides a near-sterile environment. The human tissue processing laboratory contains approximately 13,500 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 14,500 square feet with a suite of eight clean rooms. The microbiology laboratory is approximately 6,600 square feet with a suite of three clean rooms. Two additional facilities contain approximately 11,000 square feet, including approximately 4,000 square feet of laboratory space with a suite of eight clean rooms and 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 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 Vascutech, 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.***

In the normal course of business as a medical device and services company the Company has product liability complaints filed against it. As of February 24, 2003 21 cases had been filed against the Company between May 18, 2000 and January 30, 2003. The cases are currently in the pre-discovery or discovery stages. Of these cases, 14 allege product liability claims arising out of the Company's orthopaedic tissue services, six 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.

Included in these cases is the complaint filed against the Company in the Superior Court of Cobb County, Georgia, on July 12, 2002 by Steve Lykins, as Trustee for the benefit of next of kin of Brian Lykins. This complaint alleges strict liability, negligence, professional negligence, and breach of warranties related to tissue implanted in November of 2001. The plaintiff seeks unspecified compensatory and punitive damages.

The Company maintains claims-made insurance policies, which the Company believes to be adequate to defend against these suits. The Company's insurance company has been notified of these actions. The Company intends to vigorously defend against these claims. Nonetheless, an adverse judgment or judgments imposing aggregate liabilities in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

Claims-made insurance policies 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 represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier. 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. As of December 31, 2002 the Company accrued \$3.6 million in estimated costs for unreported product liability claims related to services performed and products sold during 2002 and prior years. 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 Sheets.

Several punitive class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company alleging that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated there under. During the third quarter of 2002 the U.S. District Court for the Northern District of Georgia consolidated the suits, and on November 14 2002, lead plaintiffs were named. A consolidated complaint was filed on January 15, 2003, seeking the Court's certification of the litigation as a class action on behalf of all purchasers of the Company's stock between April 2, 2001 and August 14, 2002. The consolidated complaint also seeks recovery of compensatory damages in an unspecified amount and various fees and expenses of litigation, including attorneys' fees. The principal allegations of the



consolidated complaint are that the Company failed to disclose its alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. Although the Company considers all of the claims in the consolidated complaint to be without merit and intends to defend against them vigorously, the Company is unable to predict at this time the final outcome of these claims. The Company carries directors' and officers' liability insurance policies, which the Company currently believes should be adequate to address these claims. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

The Company received notice in October 2002 that a complaint had been filed instituting a shareholder derivative action against the Company and Company officers and directors 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. The suit was filed in the Superior Court of Gwinnett County, Georgia, by Rosemary Lichtenberger. The suit alleges the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in practices that caused the Company to suffer damages by being out of compliance with FDA guidelines, and by causing the Company to issue press releases that erroneously portrayed CryoLife's products, operations, financial results, and future prospects. The complainant seeks undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of the Company as a nominal defendant. By an order entered on January 21, 2003, the lawsuit was stayed until discovery commences in the consolidated complaint of the class action lawsuit. In January 2003 the Company received notice that another shareholder derivative lawsuit was filed in the Superior Court of Fulton County, Georgia by Robert F. Frailey against the Company as a nominal defendant, and Company officers and directors Steven G. Anderson, Bruce J. Van Dyne, John W. Cook, Ronald D. McCall, Ronald C. Elkins, Virginia C. Lacy, and Alexander C. Schwartz. The complaint asserts claims for breach of fiduciary duty, abuse of control, gross mismanagement, and waste of corporate assets. As in the Lichtenberger action, the Frailey action alleges that the defendant officers and directors caused the Company to suffer damages by not being in compliance with FDA guidelines, and by causing the Company to issue press releases that erroneously portrayed CryoLife's products, operations, financial results, and future prospects. The complaint also alleges improper insider trading by certain Company officers and directors. The complainant seeks declaratory relief, damages of unspecified amount, litigation expenses including attorneys' and experts' fees, and unspecified equitable or injunctive relief against the individual defendants derivatively on behalf of the Company as a nominal defendant.

The Company's Board of Directors has established a committee that is independent of management to investigate the claims asserted in the Lichtenberger and Frailey complaints and report back to the Board with its recommendations for action in response to the shareholders' demands. The independent committee has engaged independent legal counsel to assist in the investigation. The committee is in the process of its investigation of the claims.

The Company has concluded that it is probable that it will incur losses relating to claims and litigation of at least \$1.2 million, which represents the aggregate amount of the Company's deductibles under its product liability and directors' and officers' insurance policies. Therefore the Company has recorded an accrual of \$1.2 million as of December 31, 2002.

**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.

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Date First Elected to Present Office</u>
Steven G. Anderson	64	President, Chief Executive Officer, and Chairman	February, 1984
Sidney B. Ashmore	44	Vice President, Marketing	March, 2001
Kirby S. Black, PhD	48	Senior Vice President, Research and Development	July, 1995
David M. Fronk	39	Vice President, Clinical Research	December, 1998
Albert E. Heacox, PhD	52	Senior Vice President, Laboratory Operations	June, 1989
D. Ashley Lee, CPA	38	Vice President Finance, Chief Financial Officer, and Treasurer	December, 2002
James C. Vander Wyk, PhD	58	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 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.

**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 and Related Stockholder Matters.*

#### 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.

	<u>High</u>	<u>Low</u>
<b>2002</b>		
<b>First quarter</b> .....	<b>30.74</b>	<b>20.05</b>
<b>Second quarter</b> .....	<b>32.00</b>	<b>14.90</b>
<b>Third quarter</b> .....	<b>16.06</b>	<b>1.40</b>
<b>Fourth quarter</b> .....	<b>7.92</b>	<b>2.12</b>
	<u>High</u>	<u>Low</u>
<b>2001</b>		
First quarter .....	30.25	20.00
Second quarter .....	42.00	23.80
Third quarter .....	44.82	29.00
Fourth quarter .....	40.32	23.00

The Company has never declared or paid any cash dividends on its Common Stock. The Company currently intends to retain any future earnings for funding growth and, therefore, does not anticipate paying any cash dividends on its Common Stock in the foreseeable future. The holders of any shares of Preferred Stock issued by the Company 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. The Company's Credit Facility contains, and future credit agreements may contain, financial covenants, including covenants to maintain certain levels of net worth and certain leverage ratios, which have the effect of restricting the amount of dividends that the Company can pay.

As of February 20, 2003 the Company had 408 shareholders of record.

### Item 6. *Selected Financial Data.*

The following Selected Consolidated 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 year ended December 31, 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 as of and for each of the years in the three-year period ended December 31, 2001, are derived from the Company's Consolidated Financial Statements that have been audited by Arthur Andersen LLP, independent auditors. The data set forth below with respect to the Company's Consolidated Balance Sheet and Statement of Operations as of and for the year ended December 31, 1998 are derived from the Company's Consolidated Financial Statements that have been audited by Ernst & Young LLP, independent auditors. The historical results are not necessarily indicative of future results of operations.

## Selected Financial Information

	December 31,				
	2002	2001	2000	1999	1998
(in thousands, except percentages and per share data)					
<b>Operations</b>					
Revenues .....	\$ 77,795	\$ 87,671	\$ 77,096	\$ 66,722	\$ 60,691
Net (loss)/income .....	(27,761)	9,166	7,817	4,451	6,486
Research and development as a percentage of revenues .....	5.9%	5.4%	6.8%	6.6%	7.8%
<b>(Loss)/Earnings Per Share(1)</b>					
Basic .....	\$ (1.43)	\$ 0.49	\$ 0.42	\$ 0.24	\$ 0.36
Diluted .....	\$ (1.43)	\$ 0.47	\$ 0.41	\$ 0.24	\$ 0.35
<b>Year-End Financial Position</b>					
Total assets .....	\$106,345	\$129,310	\$112,009	\$94,025	\$98,390
Working capital .....	37,816	66,668	69,063	59,597	62,310
Long Term Liabilities .....	2,752	10,071	12,192	6,177	8,577
Shareholder's equity .....	79,800	101,439	89,395	80,226	80,421
Current ratio(2) .....	3:1	5:1	8:1	9:1	8:1
Shareholders' equity per diluted common share(1) .....	\$ 4.11	\$ 5.16	\$ 4.65	\$ 4.27	\$ 4.38

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

(2) Current assets less current liabilities.

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

### Overview

The Company was organized in 1984 to address market opportunities in the area of biological implantable products and materials and today is a leader in preservation of human tissues for cardiovascular and vascular transplant applications. The Company was a leader in orthopaedic transplant applications until it suspended processing orthopaedic tissue from August 2002 following the receipt of the FDA Order until late February 2003. Additionally, the Company develops and commercializes implantable medical devices, including BioGlue Surgical Adhesive, SynerGraft processed bovine vascular grafts, and glutaraldehyde-fixed stentless porcine heart valves. The Company's revenues are primarily generated in the U.S. In 2002, 2001, and 2000, approximately 8%, 7%, and 7%, respectively, of total revenues were derived from international sources.

Prior to December 2001 the Company sold BioGlue Surgical Adhesive in the U.S. as an adjunct in the repair of acute thoracic aortic dissections pursuant to an HDE. In December 2001 the Company received FDA approval 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. As a result, the number of annual procedures in the U.S. in which BioGlue could be potentially used increased from approximately 4,000 procedures to in excess of 700,000 procedures. Due to this approval, the composition of the Company's revenues is expected to change in future years with the anticipated growth in shipments of BioGlue Surgical Adhesive.

### 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 laboratory expenses, tissue procurement fees, fringe benefits, facility allocations, and freight-in charges, and are stated, net of reserve, on a first-in, first-out basis.

As of December 31, 2002 the deferred preservation costs were \$2.0 million for allograft heart valve tissues, \$620,000 for non-valved cardiac tissues, \$1.7 million for vascular tissues, and zero for orthopaedic tissues. 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 at Item 1. Business. "FDA Order on Human Tissue Preservation". The amount of these write-downs reflects management's estimate based on information currently available to it. These estimates may prove inaccurate, as the scope and impact of the FDA Order are determined. Management will continue to evaluate the recoverability of these deferred preservation costs based on the factors discussed in the Recent Events section and record additional write-downs if it becomes clear that additional impairments have occurred. The write-down creates a new cost basis which cannot be written back up if these tissues become saleable. The cost of human tissue preservation services may be favorably impacted depending on the future level of tissue shipments related to previously written-down deferred preservation costs. The shipment levels of these written-down tissues will be affected by the amount and timing of the release of tissues processed after September 5, 2002, as a result of the Agreement with the FDA, since, under the Agreement, written-down tissues may be shipped if tissues processed after September 5, 2002 are not available for shipment.

**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. As of September 30, 2002, in applying SFAS 144, the Company determined that the asset groups consisted of the long-lived assets related to the Company's two reporting segments, as these asset groups represent the lowest level at which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. 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 September 30, 2002 and December 31, 2002 and therefore management has concluded that there is not an impairment of the Company's long-lived intangible assets, except for goodwill discussed below, 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, the outcome of discussions with the FDA regarding the shipping of orthopaedic tissues, and the future effects of adverse publicity surrounding the FDA Order and reported infections on preservation revenues, 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 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. Management does not believe an impairment exists related to the other intangible assets that were assessed in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 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. The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies 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 represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier. 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. As of December 31, 2002 the Company accrued \$3.6 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2002. The Company engaged an independent actuarial firm to perform an analysis of the unreported product claims as of December 31, 2002. The unreported product loss liability was estimated using a frequency-severity approach, whereas, 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 emergence and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The 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.

### **New Accounting Pronouncements**

The Company will be 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 Company has determined that the adoption of SFAS 143 will not have a material effect on the financial position, results of operations, and cash flows of the Company, as the Company does not currently have any relevant transactions.

The Company will be 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 No. 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 Company has determined that the adoption of SFAS 145 will not have a material effect on the financial position, results of operations, and cash flows of the Company, as the Company does not currently have any relevant transactions.

The Company will be 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 Company will adopt SFAS 146 for restructuring plans entered into after December 31, 2002.

## Results of Operations

### *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
	(amounts in thousands)			
Revenues as reported . . . . .	\$12,171	\$21,975	\$77,795	\$87,671
Reduction in revenues due to estimated tissue recall returns . . . . .	—	—	3,466	—
Revenues prior to reduction for estimated tissue recall returns(1) . . . . .	<u>\$12,171</u>	<u>\$21,975</u>	<u>\$81,261</u>	<u>\$87,671</u>

(1) Management has included this information to show the revenue effect of tissue returns resulting from the recall instituted by the FDA Order.

Revenues prior to the reduction for the estimated effect of tissue returns as a result of the FDA Order 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 have been made to the original estimate of recall returns as actual returns to date have approximated the original estimate of recall returns. The Company expects the final recall returns to be received in the first quarter of 2003, at which time the estimate may change depending on final actual recall returns.

Management believes that a decrease in revenues as compared to prior periods will continue at least through the first half of 2003, although, the close out of the April 2002 FDA 483 should assist the Company in rebuilding demand for its preservation services. In the event the Company is not successful in rebuilding demand for its preservation services, future revenues can be expected to decrease significantly as compared to prior year periods. As discussed at Item 1, Business “Recent Events”, the outcome of the discussions with the FDA regarding the use of the SynerGraft process on human tissue could result in a reduction in SynerGraft processed cardiovascular and vascular tissue which would reduce revenue and the gross margins with respect to cardiovascular and vascular tissues.

### 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
Percentage of total revenue as reported . . . . .	46%	14%	27%	12%
Percentage of total revenue prior to reduction for estimated tissue recall returns . . . . .	46%	14%	26%	12%

Revenues 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.

Although BioGlue revenue increased as compared to the prior year and BioGlue was not included in the FDA Order, future sales of BioGlue could be adversely affected due to the adverse publicity surrounding the FDA’s review of and correspondence with the Company. Additionally, there is a possibility the Company’s BioGlue manufacturing operations could come under increased scrutiny from the FDA as a result of their review of the Company’s tissue processing laboratories.

### 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
Percentage of total revenue as reported . . . . .	27%	29%	30%	33%
Revenues prior to reduction for estimated tissue recall returns . . . . .	\$3,283	\$6,304	\$23,924	\$28,606
Percentage of total revenue prior to reduction for estimated tissue recall returns . . . . .	27%	29%	29%	33%

Revenues from cardiovascular preservation services prior to the reduction for estimated returns of tissue subject to the FDA Order 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.

The Company anticipates a future decrease in cardiovascular preservation revenues as compared to prior year periods for at least the first half of 2003 as a result of the FDA Warning Letter, the FDA Order, the FDA letter posted on its website, certain reported tissue infections, and the related adverse publicity. The Company anticipates that the clarification received from the FDA on December 31, 2002 that non-valve conduit tissues processed after September 5, 2002 are not subject to the FDA Order and that the Company is able to ship these tissues without obtaining physician prescriptions, labeling the tissue as subject to a recall, or requiring special steps regarding procurement agency records of donor screening and testing beyond those required for all processors of human tissue will enable the Company to increase its shipments of non-valve conduit tissue as compared to the fourth quarter of 2002. If the Company is unable to rebuild demand for its preservation services for these tissues, future non-valved cardiac preservation revenue could continue to decrease. The clarification from the FDA does not affect heart valve tissues, as these tissues are not subject to the FDA Order.

### 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
Percentage of total revenues as reported . . . . .	24%	27%	23%	28%
Revenues prior to reduction for estimated tissue recall returns . . . . .	\$2,908	\$5,865	\$20,373	\$24,488
Percentage of total revenue prior to reduction for estimated tissue recall returns . . . . .	24%	27%	25%	28%

Revenues from human vascular tissue preservation services prior to reduction for estimated returns of tissue subject to the FDA Order 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.

The Company anticipates a future decrease in vascular preservation revenues as compared to prior year periods for at least the first half of 2003 as a result of the adverse publicity surrounding the FDA Warning Letter, FDA Order, and certain reported tissue infections. The Company anticipates that the clarification received from the FDA on December 31, 2002 that vascular tissues processed after September 5, 2002 are not subject to the FDA Order and that the Company is able to ship these tissues without obtaining physician prescriptions, labeling the tissue as subject to a recall, or requiring special steps regarding procurement agency records of donor screening and testing beyond those required for all processors of human tissue will enable the Company to increase its shipments of vascular tissue as compared to the fourth quarter of 2002. If the Company is unable to rebuild demand for its preservation services for these tissues, future vascular preservation revenue could continue to decrease.



## Orthopaedic Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2002	2001	2002	2001
Revenues as reported . . . . .	<b>\$108</b>	\$6,314	<b>\$14,134</b>	\$22,458
Percentage of total revenue as reported . . . . .	<b>1%</b>	29%	<b>18%</b>	26%
Revenues prior to reduction for estimated tissue recall returns . . . . .	<b>\$108</b>	\$6,314	<b>\$14,542</b>	\$22,458
Percentage of total revenue prior to reduction for estimated tissue recall returns . . . . .	<b>1%</b>	29%	<b>18%</b>	26%

Revenues from human orthopaedic tissue preservation services prior to reduction for estimated returns of tissue subject to the FDA Order 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.

The Company anticipates a substantial decrease in the orthopaedic preservation revenues as compared to prior year periods for at least the first half of 2003 due to the Company's inability to ship orthopaedic grafts processed between October 3, 2001 and September 5, 2002 pursuant to the FDA Order, the adverse publicity resulting from the FDA Warning Letter and FDA Order, and the reported infections in some orthopaedic allograft recipients. The Company resumed processing orthopaedic tissues in late February 2003 following the close out of the April FDA 483 as discussed in Item 1. Business – "FDA Order on Human Tissue Preservation Services". If the Company is unable to rebuild demand for its preservation services for orthopaedic tissues or if it is unable to confirm that the FDA does not disagree with the Company's interpretation that following the close out of the April 2002 FDA 483 the Company can resume distribution of orthopaedic tissue, future orthopaedic preservation revenue, if any, may be minimal.

## 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.

## Costs and Expenses

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. The Company anticipates a reduction in the cost of human tissue preservation services due to a reduction in shipments of tissues as a result of the FDA Order; however, the cost of human tissue preservation services as a percent of revenue is likely to increase as a result of lower tissue processing volumes, especially if the decline in demand continues. Additionally, the cost of human tissue preservation services may be favorably impacted, depending on the future level of tissue shipments related to previously written-down deferred preservation costs, because the write-down creates a new cost basis which cannot be written back up if these tissues become saleable. The shipment levels of these written-down tissues will be affected by the amount and timing of the release of tissues processed after September 5, 2002, pursuant to the Agreement with the FDA, since written-down tissues may be shipped if tissues processed after the Agreement are not available for shipment.

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 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 (see Legal Proceedings at Part I, Item 3), 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. The Company expects to continue to incur significant legal costs and professional fees to defend the lawsuits filed against the Company and to address FDA compliance requirements. Additional marketing expenses may also be incurred to address the effects of the adverse publicity surrounding the FDA Order

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.

As discussed in New Accounting Pronouncements, the Company recorded a \$1.4 million write-down of its goodwill, which is shown as a separate line on the Consolidated Income Statements 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.

***Year Ended December 31, 2001 Compared to Year Ended December 31, 2000***

**Revenues**

Revenues increased 14% to \$87.7 million in 2001 from \$77.1 million in 2000. The increase in revenues was primarily due to increased sales of BioGlue Surgical Adhesive and growth in the Company's human vascular and orthopaedic tissue preservation services. The increases were primarily attributable to a greater acceptance of these products by the surgical community and the Company's ability to procure greater amounts of tissue. These increases in revenues have been offset by decreases in other revenues. Year over year statistics presented for tissues procured and processed for human tissue preservation services are from the period beginning in November of the prior year through October of the current year, as such procurement and processing of tissues received during this time period is the primary generator of calendar year revenues.

**BioGlue Surgical Adhesive**

	Twelve Months Ended December 31,	
	2001	2000
Revenues . . . . .	\$10,595	\$6,405
Percentage of total revenue . . . . .	12%	8%

Revenues from the sale of BioGlue Surgical Adhesive increased 65% for the year ended December 31, 2001. The increase in revenues was due to a 56% increase in the number of milliliter shipments of BioGlue. The increase in shipments was primarily due to increased acceptance of BioGlue since its introduction in domestic markets in January of 2000 pursuant to a HDE and its introduction in international markets in April 1998. Additionally, BioGlue shipments increased in 2001 as a result of subsequent domestic and international regulatory approvals for use of BioGlue for certain indications. Domestic revenues were 66% and 59% of total BioGlue revenues in 2001 and 2000, respectively.

**Cardiovascular Preservation Services**

	Twelve Months Ended December 31,	
	2001	2000
Revenues . . . . .	\$28,606	\$29,685
Percentage of total revenue . . . . .	33%	39%

Revenues from cardiovascular preservation services decreased 4% for the year ended December 31, 2001. This decrease in revenues resulted from a 4% decrease in the number of cardiovascular allograft shipments as a result of a 4% decrease in cardiovascular tissues procured and processed year over year. Although cardiovascular tissues procured and processed decreased year over year, cardiovascular tissues procured and processed improved during the course of 2001 resulting in a 5% increase in cardiovascular tissue processed during the fourth quarter of 2001 as compared to fourth quarter of 2000.

## Vascular Preservation Services

	Twelve Months Ended December 31,	
	2001	2000
Revenues .....	\$24,488	\$21,279
Percentage of total revenue .....	28%	28%

Revenues from human vascular tissue preservation services increased 15% for the year ended December 31, 2001. This increase in revenues was primarily due to a 17% increase in the number of vascular allograft shipments resulting from an 11% increase in vascular tissues procured and processed year over year and an increase in demand for all vascular tissue types.

## Orthopaedic Preservation Services

	Twelve Months Ended December 31,	
	2001	2000
Revenues .....	\$22,458	\$16,132
Percentage of total revenue .....	26%	21%

Revenues from human orthopaedic tissue preservation services increased 39% for the year ended December 31, 2001. This increase in revenues was primarily due to a 27% increase in the number of allograft shipments. The increase in orthopaedic shipments, primarily osteochondral grafts and non-bone tendons, was due to a 14% increase in orthopaedic allograft tissues procured and processed year over year and an increasing acceptance of these tissues in the orthopaedic surgeon community. Shipments of non-bone tendons and osteochondral grafts increased 51% and 80%, respectively, in 2001 resulting in a \$4.9 million and \$1.5 million increase, respectively, in revenues in 2001 as compared to 2000. Additional increases in revenues were due to a more favorable product mix, with increased shipments of osteochondral grafts, which carry higher average selling prices than other orthopaedic tissues. These increases were partially offset by a decrease in boned tendon shipments resulting in a \$900,000 decrease in revenues in 2001 as compared to 2000.

## Bioprosthetic Devices

Revenues from bioprosthetic cardiovascular devices decreased 31% to \$535,000 in 2001 from \$771,000 in 2000, representing 1% of total revenues during such periods. This decrease in revenues was primarily due to the Company's on-going focus on development and start-up of production of the Company's SynerGraft line of bioprosthetic heart valves and vascular grafts which adversely impacted its ability to manufacture other bioprosthetic cardiovascular devices during the first half of 2001.

## Single Use Medical Devices

Revenues from single use medical devices manufactured by the Company's former wholly-owned subsidiary Ideas for Medicine, Inc. ("IFM") decreased to zero in 2001 from \$2.2 million in 2000. The decrease in revenues was due to the October 9, 2000 sale of substantially all of the remaining assets of IFM to Horizon Medical Products, Inc. ("HMP"). See further discussion of the sale of the IFM assets in Note 3 to the consolidated financial statements.

## Distribution and Grant Revenues

Grant revenues increased to \$989,000 in 2001 from \$616,000 in 2000. Grant revenues in both years are primarily attributable to the SynerGraft research and development programs.

## **Costs and Expenses**

Cost of human tissue preservation services aggregated \$31.2 million in 2001 compared to \$27.5 million in 2000, representing 41% of total human tissue preservation service revenues during each period. Cost of products aggregated \$5.5 million in 2001 compared to \$5.8 million in 2000, representing 49% and 62%, respectively, of total product revenues during such periods. The decrease in the 2001 cost of products as a percentage of total product revenues was due to a more favorable product mix during 2001. The product mix was impacted by an increase in revenues from BioGlue Surgical Adhesive, which carries higher gross margins than bioprosthetic devices, and the termination of the IFM OEM contract with HMP, which had significantly lower margins than BioGlue Surgical Adhesive.

General, administrative, and marketing expenses increased 18% to \$33.8 million in 2001, compared to \$28.7 million in 2000, representing 39% and 37%, respectively, of total revenues during such periods. The increase in expenditures in 2001 was primarily due to an increase of \$500,000 resulting from a full year of operations of CryoLife Europa, Ltd., the Company's European headquarters established in early 2000, an increase in marketing and general expenses to support revenue growth, and \$684,000 of non-recurring charges. The non-recurring charges consist primarily of \$375,000 associated with the termination of certain international distributor agreements and \$160,000 of costs previously capitalized in connection with uncompleted licensing transactions.

Research and development expenses decreased 9% to \$4.7 million in 2001, compared to \$5.2 million in 2000, representing 5% and 7%, respectively, of total revenues during such periods. Research and development spending in 2001 related principally to the Company's human clinical trials for its BioGlue Surgical Adhesive and to its focus on its SynerGraft and Protein Hydrogel Technologies. Total research and development expenses decreased in 2001 due to the wrap-up of the BioGlue clinical trial and the lack of active enrollment expenses from this trial in 2001 as compared to 2000.

Interest income, net of interest expense, was \$1.9 million and \$1.7 million in 2001 and 2000, respectively. The 2001 increase in net interest income and expense was due primarily to the interest expense capitalized in 2001 in connection with the expansion of the corporate headquarters and manufacturing facility.

Other expense was \$852,000 in 2001 as compared to other income of \$169,000 in 2000. Other expense in 2001 primarily consisted of a \$1.6 million loss related to an other than temporary decline in the market value of marketable securities previously recorded in comprehensive income as a component of shareholder's equity, partially offset by a non-recurring gain of \$713,000 related to the reversal of the previously established reserve against the note receivable from the sale of the IFM assets and product line.

The effective income tax rate was 32% and 33% for the years ended December 31, 2001 and 2000, 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 when younger patients are out of school for the summer break and also due to a greater availability of tissue as donation is often higher in the summer months. However, the demand for the Company's human vascular and orthopaedic tissue preservation services, BioGlue Surgical Adhesive, and bioprosthetic cardiovascular and vascular devices does not appear to experience seasonal trends.

## **Liquidity and Capital Resources**

At December 31, 2002 net working capital (current assets less current liabilities) was \$37.8 million, with a current ratio (current assets divided by current liabilities) of 3 to 1, compared to \$66.7 million at December 31, 2001. 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. The Company funded these requirements through cash generated by operations, equity offerings, and bank credit facilities. Based on the decrease in revenues resulting from the FDA Order and associated adverse publicity, the Company expects that its cash generated by operations will decrease significantly over the near term, and that net working capital will decrease. It is possible that the Company will not have sufficient funds to meet its primary capital requirements over the long term.

Net cash used in operating activities was \$2.1 million in 2002, as compared to cash provided of \$6.5 million in 2001. The \$2.1 million of cash used in 2002 was primarily due to an increase in working capital requirements, which resulted in a \$12.2 million decrease in cash, partially offset by \$10.1 million in net income before depreciation, taxes, and excluding non-cash items. Working capital needs were largely driven by a \$12.8 million increase in deferred preservation costs, excluding the effect of the non-cash write-down. Non-cash adjustments to net income for 2002 include a \$32.7 million write-down for the impairment of deferred preservation costs resulting from the FDA Order as discussed in Recent Events, a \$3.1 million write-down for the impairment of inventory as discussed in Costs and Expenses, and a \$1.4 million write-down of goodwill as discussed in Critical Accounting Policies.

Net cash provided by investing activities was \$6.3 million for 2002, as compared to cash used of \$18.1 million for 2001. The \$6.3 million in current year cash provided was primarily due to a net \$11.8 million increase in cash from sales and maturities of marketable securities, primarily due to the maturity of debt securities, and \$1.2 million in proceeds from notes receivable, partially offset by a \$4.1 million decrease due to capital expenditures in 2002, as the expansion and renovation of the Company's corporate headquarters and manufacturing facilities approached completion, and a decrease due to spending on patents of \$2.6 million, primarily relating to costs incurred to defend the SynerGraft technology patents.

Net cash used in financing activities was \$1.4 million for 2002, as compared to cash provided of \$1.3 million for 2001. The \$1.4 million in cash used in 2002 was primarily due to \$1.6 million in principal payments on the Term Loan, \$663,000 for the purchase of treasury stock, and \$609,000 in principal payments on capital leases, offset by a \$1.5 million increase due to proceeds from stock option exercises.

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

	<u>Total</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>Thereafter</u>
Debt .....	\$ 5,600	\$1,600	\$1,600	\$1,600	\$ 800
Capital Lease Obligations .....	3,637	843	843	843	1,108
Operating Leases .....	27,280	2,294	2,115	2,091	20,780
Purchase Commitments .....	650	300	350	—	—
Total Contractual Obligations .....	<u>\$37,167</u>	<u>\$5,037</u>	<u>\$4,908</u>	<u>\$4,534</u>	<u>\$22,688</u>

On March 4, 2002 the \$4.4 million convertible debenture due on March 5, 2002 was converted into approximately 546,000 shares of common stock at \$8.05 per common share.

The Company's Term Loan, of which the principal balance was \$5.3 million as of February 24, 2003, contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios and a minimum tangible net worth requirement, and the requirement that no materially adverse event has occurred. The lender has determined that the FDA Order, as described in Note 2 to the Consolidated Financial Statements, and the inquiries of the Securities and Exchange Commission, as described in Note 9 to the Consolidated Financial Statements, have a material adverse effect on the Company that constitutes an event of default. Additionally, as of December 31, 2002, the Company is in violation of the debt coverage ratio and net worth financial covenants. As of February 24, 2003 the lender has elected not to declare an event of default, but reserves the right to exercise any such right under the terms of the Term Loan. Therefore, all amounts due under the Term Loan as of December 31, 2002 are reflected as a current liability on the Consolidated Balance Sheet. In the event the lender

calls the Term Loan, the Company at present has adequate funds to pay the principal amount outstanding. The Term Loan is secured by substantially all of the Company's assets. Due to cross default provisions included in the Company's debt agreements, as of December 31, 2002 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, 2002.

The Company's Term Loan, which accrues interest computed at Adjusted LIBOR plus 1.5%, exposes the Company to changes in interest rates going forward. On March 16, 2000, the Company entered into a \$4 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and expires 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 involves 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 is recognized in the period in which it accrues as an adjustment to interest expense on the Term Loan.

On January 1, 2001 the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") as amended. SFAS 133 requires the Company to recognize all derivative instruments on the balance sheet at fair value, and changes in the derivative's fair value must be recognized currently in earnings or other comprehensive income, as applicable. The adoption of SFAS 133 impacts the accounting for the Company's forward-starting interest rate swap agreement. Upon adoption of SFAS 133, the Company recorded an unrealized loss of approximately \$175,000 related to the interest rate swap, which was recorded as part of long-term liabilities and accumulated other comprehensive income within the Statement of Shareholders' Equity.

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 Income Statements, and is amortizing the amounts previously recorded in other comprehensive income of \$292,000 into other expense/income over the remaining life of the agreement through June 2006. If the lender accelerates the payments due under the term loan by declaring an event of default, any remaining balance in other comprehensive income will be reclassified into other expense/income during that period.

On December 31, 2002 the notional amount of this swap agreement was \$2.8 million, and the fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$280,000. The fair value of the swap agreement is recorded as part of long-term liabilities. The Company recorded a loss of \$20,000 on the interest rate swap in 2002. The unamortized value of the swap agreement, recorded in the accumulated other comprehensive income account of shareholders' equity, was \$260,000 at December 31, 2002.

On July 18, 2002 the Company's Board of Directors authorized the purchase of up to \$10 million of its common stock. As of August 13, 2002 the Company had repurchased 68,000 shares of its common stock for \$663,000. No further purchases have been made or are anticipated in the near term.

On July 30, 2002 the Company entered into a line of credit agreement with the lender that made the Term Loan, permitting the Company to borrow up to \$10 million. Any borrowings under the line of credit agreement would accrue interest equal to Adjusted LIBOR plus 1.25% adjusted monthly. This loan is secured by substantially all of the Company's assets. As a result of the financial impact of the FDA Order, see Item 1, Business—FDA Order on Human Tissue Preservation, the Company is not in compliance with the lender's requirements for advances of funds under the line of credit. On August 21, 2002 the lender notified the Company that 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.

Since October 1998 management has been seeking to enter into a corporate collaboration or to complete a potential private placement of equity or equity-oriented securities to fund the commercial development of its Activation Control Technology (“ACT”). This technology is now held by the Company’s wholly owned subsidiary AuraZyme Pharmaceutical, Inc.®, (“AuraZyme”) which was formed on February 26, 2001. This strategy, if successful, will allow an affiliated entity to fund the ACT and should expedite the commercial development of its oncology, fibrinolysis (blood clot dissolving), and surgical sealant product applications without additional research and development expenditures by the Company (other than through the affiliated company). This strategy could favorably impact the Company’s liquidity going forward. However, if the Company is unable to obtain funds for the commercial development of the ACT and/or if the Company decides to fund the technology itself, the expenses required to fund the ACT could adversely impact the Company’s liquidity going forward. The Company has reduced its efforts to fund the commercial development of ACT in the near term until it has resolved the financial impact of the recent FDA Order.

The Company expects that its capital expenditures in 2003 will be less than its expenditures in 2002, which were approximately \$4.1 million. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to resume normal operating levels once it has addressed the observations in the FDA Warning Letter. The Company does not currently anticipate any major purchase of equipment as a result of the FDA re-inspection of its facilities.

Century Medical, Inc. has completed the Japanese BioGlue clinical trial and is performing a post clinical trial follow up of patients who have received the product. The Company does not know when to expect a final decision on the approval of the BioGlue application from the Japanese Ministry of Health and Welfare. If approval is received, the Company believes it could have a positive impact on its BioGlue business.

On February 14, 2003 the FDA confirmed that the Company has completed the corrective actions necessary to close out the April 2002 FDA 483 Notice of Observations that preceded the Warning Letter and FDA Order. The close out of the 483 followed a two-week inspection of the Company’s processing operations. As a result of the close out of the 483, the Company believes it can resume processing and distributing orthopaedic tissues but has not received confirmation of this from the FDA. The Company resumed processing orthopaedic tissues in late February 2003. Prior to shipment of orthopaedic tissues, the Company will confirm with the FDA that they do not disagree with the Company regarding its interpretation of the close out of the April 2002 FDA 483.

A new FDA 483 Notice of Observations was issued in connection with the inspection, but 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. If the Company is unable to satisfactorily respond to the FDA’s observations contained in this notice, the FDA could take further action, which could have a material adverse effect on the Company’s business, results of operations, financial position or cash flows.

On February 20, 2003 the Company received a letter from the FDA that stated 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 used for arteriovenous (“A-V”) access. 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 femoral veins used for A-V access are medical devices that require premarket approval. CryoLife will be providing the agency with information to demonstrate that femoral veins used for A-V access should continue to be regulated as human tissue under Parts 1270 and 1271 of the FDA’s regulations. The FDA letter did not question the safety or efficacy of the SynerGraft process or the CryoVein A-V access implant.

The Company has advised the FDA that it will voluntarily suspend use of the 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 FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SG tissue 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 outcome of the discussions with the FDA regarding the use of the SynerGraft process on human tissue could result in a reduction in SynerGraft processed cardiovascular and vascular tissue which would reduce the revenues and gross margins with respect to cardiovascular and vascular tissues. Considering additional costs associated with processing SynerGraft cardiac and vascular tissues, the potential net financial impact from not utilizing the SynerGraft technology in cardiac and vascular tissue processing is estimated to be approximately 10% of the cardiac and vascular revenues derived from SynerGraft processing.

The Company expects its liquidity to decrease significantly over the next year due to the anticipated significant decrease in revenues throughout at least the first half of 2003 as compared to the prior year period, as a result of the FDA Order and associated adverse publicity, and an expected decrease in cash due to the anticipated increased legal and professional costs relating to the defense of lawsuits and the FDA Order. On September 3, 2002 the Company announced a reduction in employee force of approximately 105 employees. Severance and related costs were approximately \$690,000 and were recorded in the third quarter of 2002. As a result of the employee reduction, management anticipated personnel costs would be reduced by approximately \$385,000 per month. Although the Company has rehired certain employees, due to other turnover, the net change has remained approximately 105 employees as of mid-February 2003 and the savings per month has approximated that expected. The Company intends to increase its hiring in 2003 as a result of receiving the close out of the April 2002 FDA 483. The Company believes that anticipated revenue generation, expense management including the cessation of the development of the bioprosthetic valves, savings resulting from the reduction in the number of employees to reflect the reduction in revenues, tax refunds expected to be at least \$11 million (\$2.5 million of estimated tax payments remitted for the 2002 tax year that were refunded to the Company in January of 2003, and approximately \$8.5 million of loss carrybacks generated from operating losses and write-downs of deferred preservation costs and inventory), and the Company's existing cash and cash equivalents and marketable securities will enable the Company to meet its liquidity needs through at least December 31, 2003, even if the term loan is called in its entirety. There is no assurance that the Company will be able to return to the level of demand for its tissue services that existed prior to the FDA Order as a result of the adverse publicity or as a result of customers and tissue banks switching to competitors. Failure of the Company to maintain sufficient demand for its services, would have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including continued acceptance of BioGlue, the ability to extend the Agreement with the FDA, the extent of the anticipated revenue decreases, the costs associated with compliance with FDA requirements, the outcome of litigation against the Company as described in Part I Item 3 of this Form 10-K, the level of demand for cardiovascular and vascular tissue, the continuing effect of adverse publicity, the Company's ability to resolve the February 2003 FDA 483 and the informal February FDA letter, the ability to regain orthopaedic demand, the actual outcomes of product liability claims that have been incurred but not reported as of December 31, 2002 of which \$3.6 million has been accrued, the timing of the Company's receipt of FDA approvals to begin clinical trials for its products currently in development, the availability of resources required to further develop its marketing and sales capabilities if and when those products gain approval, the extent to which the Company's products generate market acceptance and demand, and the resolution of the "Risk Factors" discussed in Item 1 above. There can be no assurance the Company will not require additional financing or will not be required to seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet future requirements. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

### **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, successful development of its SynerGraft

bioprosthetic devices, funding to continue development of the ACT, expectations regarding the adequacy of financing, expectations regarding the outcome of the February 2003 FDA 483 and informal February FDA letter, product demand and market growth, 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 \$10.3 million and short-term investments in municipal obligations of \$14.6 million as of December 31, 2002, as well as interest paid on its debt. 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 2002.

The Company manages interest rate risk through the use of fixed debt and an interest rate swap agreement. At December 31, 2002 approximately \$2.8 million of the Company's \$5.6 million in debt charged interest at a fixed rate. This fixed rate debt includes a portion of the Company's outstanding term loan balance that has been effectively converted to fixed rate debt through an interest rate swap agreement. A 10% increase in interest rates affecting the Company's variable rate debt, net of the effect of the interest rate swap agreement, would not have a material increase in the Company's financial position, results of operations, and cash flows for 2002.

**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.***

Information concerning a change in accountants is included in the Company's Form 8-K dated April 11, 2002.



### PART III

**Item 10. *Directors and Executive Officers of the Registrant.***

The response to Item 10, applicable to the Directors of the Company, is incorporated herein by reference to the information set forth under the caption "Election of Directors" in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 30, 2003. Information concerning executive officers is included in Part I, Item 4A of this Form 10-K.

The response to Item 10, applicable to Section 16(a) of the Securities Exchange Act of 1934, as amended, is incorporated herein by reference to the information set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 30, 2003.

**Item 11. *Executive Compensation.***

The response to Item 11 is incorporated herein by reference to the information set forth under the caption "Executive Compensation" in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 30, 2003.

**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 under the captions "Executive Compensation", "Ownership of Principal Shareholders and Certain Executive Officers", and "Election of Directors" in the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Commission not later than April 30, 2003.

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

The response to Item 13 is incorporated herein by reference to the information set forth under the caption "Executive Compensation" in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission not later than April 30, 2003.

**Item 14. *Controls and Procedures.***

With the participation of management, the Company's President and Chief Executive Officer along with the Company's Vice President of Finance and Chief Financial Officer evaluated the Company's disclosure controls and procedures within 90 days of the filing date of this annual report. Based upon this evaluation, the Company's President and Chief Executive Officer along with the Company's Vice President of Finance and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective in ensuring that material information required to be disclosed is included on a timely basis in the reports that it files with the Securities and Exchange Commission.

There have been no significant changes in the Company's internal controls or, to the knowledge of the management of the Company, in other factors that could significantly affect these controls subsequent to the evaluation date.

## 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, 2002 and 2001, Consolidated Statements of Operations as of December 31, 2002, 2001 and 2000, Consolidated Statements of Cash Flows as of December 31, 2002, 2001 and 2000, Consolidated Statements of Shareholders' Equity for the years ended December 31, 2002, 2001, 2000, and 1999, 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:

<u>Exhibit Number</u>	<u>Description</u>
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|------|--|
| 2.1  | —Asset Purchase Agreement among the Company and United Cryopreservation Foundation, Inc., United Transplant Foundation, Inc. and QV, Inc. dated September 11, 1996. (Incorporated by reference to Exhibit 2.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)   |
| 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. (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)   |
| 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).   |

<u>Exhibit Number</u>	<u>Description</u>
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| 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.)  |
| 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    | Lease by and between Newmarket Partners I, Laing Properties, Inc. and Laing Management Company, General Partner, as Landlord, and the Company as Tenant, dated July 23, 1993. (Incorporated by reference to Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)   |
| 10.2(a) | First Amendment to Lease dated July 23, 1993, by and between Newmarket Partners I, Laing Properties, Inc. and Laing Management Company, General Partner, as Landlord, and the Company as Tenant dated June 9, 1994. (Incorporated by reference to Exhibit 10.15 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)  |
| 10.2(b) | Second Amendment to Lease dated July 23, 1993, by and between Newmarket Partners I, Laing Properties, Inc. and Laing Management Company, General Partner, as Landlord, and the Company as Tenant dated June 6, 1998. (Incorporated by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)   |
| 10.2(c) | Third Amendment to Lease dated July 23, 1993, by and between Newmarket Partners I, Laing Properties, Inc. and Laing Management Company, General Partner, as Landlord, and the Company as Tenant dated August 3, 2001. (Incorporated by reference to Exhibit 10.17 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)  |

<u>Exhibit Number</u>	<u>Description</u>
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| 10.2(d) | —Fourth Amendment to Lease dated July 23, 1993, by and between Newmarket Partners I, Laing Properties, Inc. and Laing Management Company, General Partner, as Landlord, and the Company as Tenant dated June 25, 2002. (Incorporated by reference to Exhibit 10.18 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)                       |
| 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.)   |

<u>Exhibit Number</u>	<u>Description</u>
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.)
10.10	—Form of Secrecy and Noncompete Agreement, by and between the Company and it’s 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 Amlı 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 Amlı 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 Amlı 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.)



<u>Exhibit Number</u>	<u>Description</u>
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	Noncompetition Agreement between the Company and United Cryopreservation Foundation, Inc. dated September 11, 1996. (Incorporated by reference to Exhibit 10.1 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
10.20	Noncompetition Agreement between the Company and QV, Inc. dated September 11, 1996. (Incorporated by reference to Exhibit 10.3 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
10.21	Revolving Term Loan Facility between the Company and NationsBank N.A., dated August 30, 1996. (Incorporated by reference to Exhibit 10.4 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
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	Noncompetition Agreement between the Company and United Transplant Foundation, Inc. dated September 11, 1996. (Incorporated by reference to Exhibit 10.2 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
10.24(a)	First Amendment of Third Amended and Restated Loan Agreement between CryoLife, Inc., as Borrower and NationsBank, N.A. (South), as Lender, dated April 14, 1997. (Incorporated by reference to Exhibit 10.1 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.)
10.24(b)	Second Modification of Third Amended and Restated Loan Agreement dated December 16, 1997 by and between the Registrant and NationsBank, N.A. (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.)
10.24(c)	Fourth Modification of Third Amended and Restated Loan Agreement dated December 16, 1997 by and between the Company and Bank of America, N.A. and First Modification of Revolving Note dated December 31, 1999. (Incorporated by reference to Exhibit 10.24 to the Registrant’s Annual Report on Form 10-K for the fiscal year ended December 31, 1999)
10.25	Reserved.
10.26	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.)
10.27	Consulting Agreement dated March 5, 1997 between CryoLife Acquisition Corporation and J. Crayton Pruitt, Sr., M.D. (Incorporated by reference to Exhibit 10.2 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended March 31, 1997.)
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.)

<u>Exhibit Number</u>	<u>Description</u>
10.31	—Form of Non-Competition Agreement dated March 5, 1997 between the Company and 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. (Incorporated by reference to Exhibit 10.6 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended March 31, 1997.)
10.32	—Standard Form of Agreements Between Owner and Design/Builder by and between the Company and Choate Design and Build Company dated January 19, 2000. (Incorporated by reference to Exhibit 10.32 to the Registrant’s Annual Report on Form 10-K for the fiscal year ended December 31, 1999)
10.33	—Construction Loan and Permanent Financing Agreement with Bank of America dated April 25, 2000. (Incorporated by reference to Exhibit 10.1 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.)
10.33(a)	—Second Amendment to Construction Loan and Permanent Financing Agreement, dated July 30, 2002 by and between the Company and Bank of America. (Incorporated by reference to Exhibit 10.1 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.33(b)	—Promissory Note by and between the Company and Bank of America, dated July 30, 2002. (Incorporated by reference to Exhibit 10.2 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
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	—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.)
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).

**Exhibit  
Number    Description**

- 10.44\*—Letter Agreement between the Company and FDA, dated November 8, 2002.  
10.45\*—Letter Agreement between the Company and FDA, dated January 8, 2003.  
21.1\*—Subsidiaries of CryoLife, Inc.  
23.1\*—Consent of Deloitte & Touche LLP.  
23.2\*—Notice regarding consent of Arthur Andersen LLP.  
99.1\*—Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002.

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\* Filed herewith.

† 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.)

(b) Reports on Form 8-K

1. NONE.



## 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.

February 26, 2003

CRYOLIFE, INC.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ STEVEN G. ANDERSON</u> <b>Steven G. Anderson</b>	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	February 26, 2003
<u>/s/ D. ASHLEY LEE</u> <b>D. Ashley Lee</b>	Vice President, Treasurer, and Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2003
<u>/s/ JOHN M. COOK</u> <b>John M. Cook</b>	Director	February 26, 2003
<u>/s/ RONALD CHARLES ELKINS, M.D.</u> <b>Ronald Charles Elkins, M.D.</b>	Director	February 26, 2003
<u>/s/ VIRGINIA C. LACY</u> <b>Virginia C. Lacy</b>	Director	February 26, 2003
<u>/s/ RONALD D. MCCALL</u> <b>Ronald D. McCall</b>	Director	February 26, 2003
<u>/s/ BRUCE J. VAN DYNE, M.D.</u> <b>Bruce J. Van Dyne, M.D.</b>	Director	February 26, 2003

## CERTIFICATIONS

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 annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures 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 annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; 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; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ STEVEN G. ANDERSON

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

Date: February 26, 2003

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 annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures 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 annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; 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; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ DAVID ASHLEY LEE

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**David Ashley Lee**  
**Vice President, Treasurer, and Chief Financial Officer**

Date: February 26, 2003

## INDEPENDENT AUDITORS' REPORT

To the Board of Directors  
CryoLife, Inc.

We have audited, the accompanying consolidated balance sheet of CRYOLIFE, INC. (a Florida corporation) AND SUBSIDIARIES ("the Company") as of December 31, 2002 and the related consolidated statement of operations, shareholders' equity, and cash flows for the year ended December 31, 2002. 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 audit. The financial statements of the Company as of December 31, 2001 and for each of the two years then ended were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated March 27, 2002.

We conducted our audit 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 audit provides 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 as of December 31, 2002 and the results of their operations and their cash flows for the year ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

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  
February 24, 2003

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**

		December 31,	
		2002	2001
		(in thousands, except per share data)	
<b>ASSETS</b>			
<b>Current assets:</b>			
Cash and cash equivalents . . . . .		\$ 10,277	\$ 7,204
Marketable securities, at market . . . . .		14,583	26,483
Receivables:			
Trade accounts, less allowance for doubtful accounts of \$75 in 2002 and \$100 in 2001 . . . . .		6,930	13,305
Note receivable, less allowance of \$250 in 2001 . . . . .		—	1,169
Income taxes . . . . .		11,312	1,557
Other . . . . .		512	1,263
Total receivables . . . . .		18,754	17,294
Deferred preservation costs, net . . . . .		4,332	24,199
Inventories . . . . .		4,585	6,259
Prepaid expenses . . . . .		2,413	2,341
Deferred income taxes . . . . .		6,734	688
Total current assets . . . . .		61,678	84,468
<b>Property and equipment:</b>			
Land . . . . .		1,009	1,009
Equipment . . . . .		22,403	18,998
Furniture and fixtures . . . . .		5,275	5,347
Leasehold improvements . . . . .		32,971	24,990
Construction in progress . . . . .		189	7,767
		61,847	58,111
Less accumulated depreciation and amortization . . . . .		23,717	18,865
Net property and equipment . . . . .		38,130	39,246
<b>Other assets:</b>			
Goodwill, less accumulated amortization of \$501 in 2001 . . . . .		—	1,399
Patents, less accumulated amortization of \$1,014 in 2002 and \$1,102 in 2001 . . . . .		5,324	2,919
Other, less accumulated amortization of \$397 in 2002 and \$135 in 2001 . . . . .		1,282	1,278
Total assets . . . . .		\$106,414	\$129,310

See accompanying notes to consolidated financial statements.

**CRYOLIFE, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2002	2001
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable . . . . .	\$ 3,874	\$ 555
Accrued expenses and other current liabilities . . . . .	6,823	1,491
Accrued compensation . . . . .	1,627	2,560
Accrued procurement fees . . . . .	3,769	6,592
Current maturities of capital lease obligation . . . . .	2,169	609
Current maturities of long-term debt . . . . .	5,600	1,600
Convertible debenture . . . . .	—	4,393
Total current liabilities . . . . .	23,862	17,800
Capital lease obligations, less current maturities . . . . .	971	3,140
Bank line of credit, less current maturities . . . . .	—	5,600
Deferred income taxes . . . . .	986	449
Other long-term liabilities . . . . .	795	882
Total liabilities . . . . .	26,614	27,871
<b>Shareholders' equity:</b>		
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 20,935 in 2002 and 20,172 shares in 2001 . . . . .	209	202
Additional paid-in capital . . . . .	73,630	66,828
Retained earnings . . . . .	12,786	40,547
Deferred compensation . . . . .	(21)	(33)
Accumulated other comprehensive income, net of tax . . . . .	282	(145)
Treasury stock; 1,361 shares in 2002 and 1,286 shares in 2001, at cost . . . . .	(7,086)	(5,960)
Total shareholders' equity . . . . .	79,800	101,439
Total liabilities and shareholders' equity . . . . .	\$106,414	\$129,310

See accompanying notes to consolidated financial statements.

**CRYOLIFE, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2002	2001	2000
	(in thousands, except per share data)		
<b>Revenues:</b>			
Human tissue preservation services .....	\$ 55,373	\$75,552	\$67,096
Products .....	21,597	11,130	9,384
Research grants and distribution revenue .....	825	989	616
Total revenues .....	<u>77,795</u>	<u>87,671</u>	<u>77,096</u>
<b>Costs and expenses:</b>			
Human tissue preservation services .....	55,363	31,165	27,500
(including write-down of \$32,715 in 2002)			
Products .....	10,270	5,464	5,847
General, administrative, and marketing .....	47,530	33,844	28,731
Research and development .....	4,597	4,737	5,207
Nonrecurring charges .....	1,399	—	—
Interest expense .....	692	96	299
Interest income .....	(895)	(1,967)	(1,952)
Other expense (income), net .....	273	852	(169)
Total costs and expenses .....	<u>119,229</u>	<u>74,191</u>	<u>65,463</u>
(Loss) income before income taxes .....	(41,434)	13,480	11,633
Income tax (benefit) expense .....	(13,673)	4,314	3,816
Net (loss) income .....	<u>\$ (27,761)</u>	<u>\$ 9,166</u>	<u>\$ 7,817</u>
<b>(Loss) earnings per share:</b>			
Basic .....	<u>\$ (1.43)</u>	<u>\$ 0.49</u>	<u>\$ 0.42</u>
Diluted .....	<u>\$ (1.43)</u>	<u>\$ 0.47</u>	<u>\$ 0.41</u>
<b>Weighted average shares outstanding:</b>			
Basic .....	<u>19,432</u>	<u>18,808</u>	<u>18,541</u>
Diluted .....	<u>19,432</u>	<u>19,660</u>	<u>19,229</u>

See accompanying notes to consolidated financial statements.

**CRYOLIFE, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>		
	<b>2002</b>	<b>2001</b>	<b>2000</b>
	(in thousands)		
<b>Net cash flows from operating activities:</b>			
Net (loss) income	\$(27,761)	\$ 9,166	\$ 7,817
Adjustments to reconcile net (loss) income to net cash flows (used by) provided by operating activities:			
Loss (gain) on sale of marketable equity securities	240	(9)	—
Depreciation of property and equipment	5,222	4,203	3,023
Amortization	201	404	199
Provision for doubtful accounts	50	304	21
Write-down of deferred preservation costs and inventories	35,816	—	—
Other non-cash adjustments to income	1,419	348	—
Deferred income taxes	(5,568)	624	1,658
Tax effect of non-qualified option exercises	481	421	595
Changes in operating assets and liabilities:			
Trade and other receivables	7,076	(2,707)	469
Income taxes	(9,755)	(983)	(543)
Deferred preservation costs	(12,848)	(3,888)	(2,659)
Inventories	(1,427)	(2,265)	(1,433)
Prepaid expenses and other assets	(59)	(1,121)	234
Accounts payable	3,313	(1,814)	535
Accrued expenses and other liabilities	1,489	3,796	367
Net cash flows (used by) provided by operating activities	<u>(2,111)</u>	<u>6,479</u>	<u>10,283</u>
<b>Net cash flows from investing activities:</b>			
Capital expenditures	(4,100)	(14,329)	(9,491)
Other assets	(2,598)	(689)	39
Purchases of marketable securities	(9,970)	(29,336)	(5,729)
Sales and maturities of marketable securities	21,780	24,235	8,542
Proceeds from notes receivable	1,169	2,020	360
Net cash flows provided by (used in) investing activities	<u>6,281</u>	<u>(18,099)</u>	<u>(6,279)</u>
<b>Net cash flows from financing activities:</b>			
Principal payments of debt	(1,600)	(1,050)	(287)
Proceeds from debt issuance	—	1,165	6,835
Principal payments on obligations under capital leases	(609)	(291)	(180)
Proceeds from exercise of options and issuance of stock	1,472	1,502	1,660
Purchase of treasury stock	(663)	—	(612)
Net cash flows (used in) provided by financing activities	<u>(1,400)</u>	<u>1,326</u>	<u>7,416</u>
Increase (decrease) in cash	2,770	(10,294)	11,420
Effect of exchange rate changes on cash	303	18	(68)
Cash and cash equivalents, beginning of year	7,204	17,480	6,128
Cash and cash equivalents, end of year	<u>\$ 10,277</u>	<u>\$ 7,204</u>	<u>\$17,480</u>
<b>Supplemental disclosures of cash flow information—cash paid during the year for:</b>			
Interest	\$ 636	\$ 896	\$ 471
Income taxes	2,874	4,996	2,215
<b>Non-cash investing and financing activities:</b>			
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	\$ 203	\$ 844

See accompanying notes to consolidated financial statements.

**CRYOLIFE, INC.**

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**

	Common Shares Outstanding		Additional Paid-In Capital	Retained Earnings	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Shareholders' Equity
	Shares	Amount					Shares	Amount	
	(in thousands)								
<b>Balance at December 31, 1999</b> . . . . .	20,041	\$200	\$64,359	\$ 23,564	\$ (57)	\$ (785)	(1,701)	\$(7,055)	\$80,226
Net income . . . . .	—	—	—	7,817	—	—	—	—	7,817
Other comprehensive loss, net of taxes . . . . .	—	—	—	—	—	(303)	—	—	(303)
Comprehensive income . . . . .									7,514
Exercise of options . . . . .	36	1	338	—	—	—	356	1,389	1,728
Employee stock purchase plan . . . . .	—	—	239	—	—	—	67	288	527
Amortization of deferred compensation . . . . .	—	—	—	—	12	—	—	—	12
Purchase of treasury stock . . . . .	—	—	—	—	—	—	(78)	(612)	(612)
<b>Balance at December 31, 2000</b> . . . . .	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
<b>Balance at December 31, 2001</b> . . . . .	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)
<b>Balance at December 31, 2002</b> . . . . .	20,935	\$209	\$73,630	\$ 12,786	\$ (21)	\$ 282	(1,361)	\$(7,086)	\$79,800

See accompanying notes to consolidated financial statements.



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

**1. Summary of Significant Accounting Policies**

*Nature of Business*

Founded in 1984, CryoLife, Inc. (the “Company”) is a leader in the development and commercialization of implantable living human tissues for use in cardiovascular and vascular surgeries throughout the U.S. and Canada. Historically, the Company has been a leader in the development and commercialization of implantable living human tissues for use in orthopaedic surgeries throughout the U.S. and Canada. The Company suspended processing of orthopaedic tissue from August 2002 until late February 2003 as a result of a recall order from the FDA. (See Note 2 for further discussion). The Company’s human tissue cryopreservation services are marketed in North America, Europe, South America, and Asia. The Company’s BioGlue® Surgical Adhesive is FDA approved in the U.S. as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels, is CE marked in the European Community and is approved in Canada, Australia and certain countries within the Middle East, South America, Asia, and South Africa for use in cardiovascular, vascular, pulmonary, and soft tissue repair. The Company’s bioprosthetic implantable devices include stentless porcine heart valves marketed in Europe, South America, the Middle East, Canada, and South Africa, and SynerGraft® processed bovine vascular grafts, which are CE marked in the European Community. Until October 9, 2000 the Company served as an original equipment manufacturer for single-use medical devices for use in vascular surgical procedures.

In February 2001 the Company formed a wholly owned subsidiary, AuraZyme Pharmaceuticals, Inc., to foster the commercial development of the Company’s light-activated drug delivery systems that have potential application in cancer treatment and fibrinolysis (blood clot dissolving) and other drug delivery applications.

*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, write-downs of deferred preservation costs, valuation of long-lived tangible and intangible assets, commitments and contingencies, disclosure of the fair value of stock based compensation, and the related pro-forma expense and income taxes.

*Revenue Recognition*

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin No. 101, “Revenue Recognition in Financial Statements” (“SAB 101”), 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 delivered to the customer. The Company has recorded the estimated amount of credits issued and to be issued for tissues recalled pursuant to the FDA Order as a service revenue return. 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 and delivery occurs upon shipment. Revenues from research grants are recognized in the period the associated costs are incurred. 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.

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### *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.

#### *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, 2002 and 2001 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 hospital. Deferred preservation costs consist primarily of laboratory expenses, tissue procurement fees, fringe and facility allocations, and freight-in charges, and are stated, net of reserve, on a first-in, first-out basis.

As of December 31, 2002 the deferred preservation costs were \$2.0 million for allograft heart valve tissues, \$620,000 for non-valved cardiac tissues, \$1.7 million for vascular tissues, and zero for orthopaedic tissues. For the year ended December 31, 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 matters discussed in Note 2, FDA Order on Human Tissue Preservation. The amount of these write-downs reflects management's estimate based on information currently available to it. These estimates may prove inaccurate, as the scope and impact of the FDA Order are determined. Management will continue to evaluate the recoverability of these deferred preservation costs based on the factors discussed in Note 2 and record additional write-downs if it becomes clear that additional impairments have occurred. The write-down creates a new cost basis which cannot be written back up if these tissues become saleable. The cost of human tissue preservation services may be favorably impacted depending on the future level of tissue shipments related to previously written-down deferred preservation costs. The shipment levels of these written-down tissues will be affected by

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

the amount and timing of the release of tissues processed after September 5, 2002, as a result of the Agreement with the FDA, since written-down tissues may be shipped if tissues processed after the Agreement are not available for shipment.

#### *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 is capitalized in connection with the expansion of the corporate headquarters and manufacturing facility.

#### *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 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. Management does not believe an impairment exists related to the other intangible assets that were assessed in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144").

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

2003	\$180
2004	150
2005	150
2006	136
2007	109
	<u>\$725</u>

#### *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. As of September 30, 2002, in applying SFAS 144, the Company determined that the asset groups consisted of the long-lived assets related to the Company's two reporting

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

segments, as these asset groups represent the lowest level at which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. 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 September 30, 2002 and December 31, 2002 and therefore management has concluded that there is not an impairment of the Company's long-lived intangible, except for goodwill discussed above, 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, the outcome of discussions with the FDA regarding the shipping of orthopaedic tissues, and the future effects of adverse publicity surrounding the FDA Order and reported infections on preservation revenues, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

#### *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. The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies 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 represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier. 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. As of December 31, 2002 the Company accrued \$3.6 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2002. The Company engaged an independent actuarial firm to perform an analysis of the unreported product claims as of December 31, 2002. The unreported product loss liability was estimated using a frequency-severity approach; whereas, 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 emergence and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The 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.

#### *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.

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 SFAS 148 will not have a material effect on the financial position, results of operations, and 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:

	2002	2001	2000
Expected dividend yield .....	0%	0%	0%
Expected stock price volatility .....	.630	.600	.540
Risk-free interest rate .....	3.67%	4.73%	6.39%
Expected life of options .....	5.3 Years	4.2 Years	4.3 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.

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
<b>Net (loss) income—as reported</b> .....	<b>\$(27,761)</b>	\$9,166	\$7,817
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of tax .....	<b>1,287</b>	2,232	1,183
Net (loss) income—pro forma .....	<b><u>\$(29,048)</u></b>	<u>\$6,934</u>	<u>\$6,634</u>
<b>(Loss) earnings per share—as reported:</b>			
Basic .....	\$ (1.43)	\$ 0.49	\$ 0.42
Diluted .....	\$ (1.43)	\$ 0.47	\$ 0.41
<b>(Loss) earnings per share—pro forma:</b>			
Basic .....	\$ (1.49)	\$ 0.37	\$ 0.36
Diluted .....	\$ (1.49)	\$ 0.35	\$ 0.35

#### *Stock Split*

On November 27, 2000 the Board of Directors declared a three-for-two stock split, effected in the form of a stock dividend, payable on December 27, 2000, to shareholders of record on December 8, 2000. All share and per share information in the accompanying consolidated financial statements has been adjusted to reflect this split.

#### *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 will be 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 Company has determined that the adoption of SFAS 143 will not have a material effect on the results of operations or financial position of the Company, as the Company does not currently have any relevant transactions.



## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company will be 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 No. 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 Company has determined that the adoption of SFAS 145 will not have a material effect on the results of operations or financial position of the Company, as the Company does not currently have any relevant transactions.

The Company will be 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 Company will adopt SFAS 146 for restructuring plans entered into after December 31, 2002.

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

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

- The FDA alleges 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. The rule 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 alleges that the Company has 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 must be retained until it is recalled, destroyed, the safety is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.
- The FDA strongly recommends that the Company perform a retrospective review of all tissue in inventory (i.e. currently in storage at the Company) that is 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, is evaluating whether there are similar risks that may be posed by the Company’s allograft heart valves, and will take further regulatory action if appropriate.

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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. The Company appealed the FDA Order on August 14, 2002 and requested a hearing with the FDA, which was originally set for December 12, 2002. Due to the Agreement discussed below, the Company withdrew its request for a hearing with the FDA. After the FDA issued its order regarding the recall, Health Canada also issued a recall on the same types of tissue and other countries have inquired about the circumstances surrounding the FDA Order.

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 are not subject to the FDA Order. On August 21, 2002 the FDA publicly stated that allograft heart valves have not been included in the FDA Order as these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA also publicly stated that it then still had serious concerns regarding the Company's processing and handling of allograft heart valves. The FDA also recommended that surgeons carefully consider using processed allografts from alternative sources, that surgeons inform prospective patients of the FDA's concerns regarding the Company's allograft heart valves, and that patients be carefully monitored for both fungal and bacterial infections.

On September 5, 2002 the Company reached an agreement with the FDA (the "Agreement") that supplements the FDA Order and allows the tissues subject to recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company completes steps to assure that the tissue is used for approved purposes and that patients are notified of risks associated with tissue use. Specifically, the Company must obtain physician prescriptions, and tissue packaging must contain specified warning labels. The Agreement calls for the Company to undertake to identify third-party records of donor tissue testing, and to destroy tissue from donors in whom microorganisms associated with an infection are found. The Agreement allowing distribution of tissues subject to the recall had a 45-business day term and was renewed on November 8, 2002 and on January 8, 2003. This most recent renewal expires on March 20, 2003. The Company is unable to predict whether or not the FDA will grant further renewals of the Agreement. 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 Agreement contained the requirement that tissues subject to the FDA Order be replaced with tissues processed under validated methods. 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.

As a result of the adverse publicity surrounding the FDA Warning Letter and FDA Order and related tissue infections, the Company's procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, decreased 25% in the fourth quarter of 2002 as compared to the fourth quarter of 2001. Although the Company expects to be able to maintain the current level of cardiac tissue procurement, there is no guarantee that sufficient tissue will be available. The Company has continued to process and distribute heart valves since the receipt of the FDA Order, as these tissues are not subject to the FDA Order.

On September 17, 2002 the Company resumed the procurement and processing of vascular tissues. The Company limited its vascular procurement until it addressed the observations detailed in the FDA 483 and had fully evaluated the demand for the vascular tissues. The Company's procurement of vascular tissue decreased

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

65% in the fourth quarter of 2002 as compared to the fourth quarter of 2001. The Company expects that vascular procurement will increase significantly following the close out of the FDA 483.

On December 31, 2002 the FDA clarified the Agreement noting that non-valved cardiac and vascular tissues processed since September 5, 2002 are 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. A renewal of the Agreement that expires on March 20, 2003 is therefore not needed in order for the Company to continue to distribute non-valved cardiovascular and vascular tissues processed since September 5, 2002.

On February 14, 2003 the FDA confirmed that the Company has completed the corrective actions necessary to close out the April 2002 FDA 483 that preceded the Warning Letter and FDA Order. The close out of the 483 followed a two-week inspection of the Company's processing operations. As a result of the close out of the 483, the Company believes it can resume processing and distributing orthopaedic tissues but has not received confirmation of this from the FDA. The Company resumed processing orthopaedic tissues in late February 2003. Prior to shipment of orthopaedic tissues, the Company will confirm with the FDA that they do not disagree with the Company regarding its interpretation of the close out of the FDA 483. The Company will continue to process vascular tissues on a limited basis until it can fully evaluate the demand level for its vascular tissue preservation services.

A new FDA 483 was issued in connection with the inspection, but 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.

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 for retention levels under the Company's product liability and directors' and officers' insurance policies of \$1.2 million (see Note 9), and for estimated expenses of \$75,000 for packaging and handling for the return of affected tissues under the FDA Order. 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 many 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.

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 \$0.5 million 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. The Company did not record any further write-downs of deferred preservation costs in the fourth quarter of 2002. As of December 31, 2002 the balance of deferred preservation costs were \$2.0 million for allograft heart valve tissues, \$620,000 for non-valved cardiac tissues, \$1.7 million for vascular tissues, and zero for orthopaedic 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. Upon destruction or shipment of the remaining tissues associated with the deferred preservation costs write-down, the deferred tax asset will become deductible in the Company's tax return. An expected refund of approximately \$8.5 million will be generated through a carry back of operating losses and write-downs of deferred preservation costs. In addition, the Company recorded \$2.5 million in income tax receivables related to estimated tax payments for 2002. The Company received payment of the \$2.5 million in January of 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. As of December 31, 2002, the remaining balance of accrued restructuring costs was \$110,000.

The Company expects its liquidity to decrease significantly over the next year due to the anticipated significant decrease in revenues throughout at least the first half of 2003 as compared to the prior year period, as a result of the reported tissue infections, the FDA Order and associated adverse publicity, and an expected decrease in cash due to the anticipated increased legal and professional costs relating to the defense of lawsuits (discussed in Note 9) and ongoing FDA compliance. The Company believes that anticipated revenue generation,

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

expense management including the cessation of the development of the bioprosthetic valves, savings resulting from the reduction in the number of employees to reflect the reduction in revenues, tax refunds expected to be at least \$11 million (\$2.5 million of estimated tax payments remitted for the 2002 tax year which were received in January of 2003, and approximately \$8.5 million of loss carrybacks generated from operating losses and write-downs of deferred preservation costs), and the Company's existing cash and marketable securities will enable the Company to meet its liquidity needs through at least December 31, 2003, even if the term loan is called in its entirety. There is no assurance that the Company will be able to return to the level of demand for its tissue services that existed prior to the FDA Order due to the adverse publicity or as a result of customers and to tissue banks switching to competitors. Failure of the Company to maintain sufficient demand for its services, would have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

**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):

	<u>Cost Basis</u>	<u>Adjustments to Cost Basis</u>	<u>Adjusted Cost Basis</u>	<u>Unrealized Holding Gains/(Losses)</u>	<u>Estimated Market Value</u>
<b>December 31, 2002</b>					
Cash equivalents:					
Money market funds .....	\$ 52	\$ —	\$ 52	\$ —	\$ 52
Municipal obligations .....	7,175	—	7,175	—	7,175
	<u>\$ 7,227</u>	<u>\$ —</u>	<u>\$ 7,227</u>	<u>\$ —</u>	<u>\$ 7,227</u>
Marketable securities:					
Municipal obligations .....	<u>\$14,276</u>	<u>\$ —</u>	<u>\$14,276</u>	<u>\$307</u>	<u>\$14,583</u>
	<u>Cost Basis</u>	<u>Adjustments to Cost Basis</u>	<u>Adjusted Cost Basis</u>	<u>Unrealized Holding Gains/(Losses)</u>	<u>Estimated Market Value</u>
<b>December 31, 2001</b>					
Cash equivalents:					
Money market funds .....	\$ 1,301	\$ —	\$ 1,301	\$ —	\$ 1,301
Municipal obligations .....	500	—	500	—	500
	<u>\$ 1,801</u>	<u>—</u>	<u>\$ 1,801</u>	<u>—</u>	<u>\$ 1,801</u>
Marketable securities:					
Municipal obligations .....	17,696	—	17,696	147	17,843
Debt securities .....	6,227	(1,217)	5,010	—	5,010
Equity securities .....	3,900	(343)	3,557	10	3,567
Certificates of deposit .....	63	—	63	—	63
	<u>\$27,886</u>	<u>(1,560)</u>	<u>\$26,326</u>	<u>\$157</u>	<u>\$26,483</u>

The Adjustments to Cost Basis column includes a \$1.6 million loss recorded in 2001 for an other than temporary decline in the market value of debt and equity securities. Gross realized losses on sales of available-for-sale securities totaled \$240,000 in 2002 and gross realized gains on sales of available-for-sale securities totaled \$9,000 in 2001. Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of \$104,000 and \$50,000, at December 31, 2002 and 2001, respectively, are included as a separate component of other comprehensive income in shareholders' equity.



## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

At December 31, 2002 and 2001 approximately \$1.2 million and zero, respectively, of marketable securities had a maturity date of less than 90 days, approximately \$8.0 million and \$3.4 million, respectively, had a maturity date between 90 days and 1 year, and approximately \$5.4 million and \$14.5 million, respectively, had a maturity date between 1 and 5 years, and approximately zero and \$8.6 million, respectively, matured in more than 5 years or did not have a maturity date.

#### 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. The cash portion of the purchase price was financed by borrowings under the Company’s revolving term loan agreement. Pursuant to the purchase agreement, an additional consideration of \$700,000 was paid in January 2000. In connection with this acquisition, the Company also entered into a consulting agreement with the former majority shareholder of IFM requiring monthly payments to such shareholder of approximately \$17,000 until March 2002.

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. Concurrently, IFM and HMP signed a Manufacturing Agreement (the “Agreement”) that provided for the manufacture by IFM of specified minimum dollar amounts of IFM products to be purchased exclusively by HMP over each of the four years following the sale. Thereafter, responsibility for such manufacturing was to be assumed by HMP.

The Company recorded deferred income at the transaction date totaling \$2.9 million, representing the selling price less the net book value of the assets sold, which included \$7.7 million of goodwill, net of accumulated amortization, and the costs related to the sale. The income was deferred because the sale and manufacturing agreements represented, in the aggregate, a single transaction for which the related income should be recognized over the term of the manufacturing agreement. Accordingly, the deferred income was reflected in cost of goods sold during 1999 to maintain margins that would have been approximately equal over the four-year period of the Agreement on the products manufactured and sold by IFM to HMP. During 1999 amortization of deferred income totaled \$1.2 million.

On June 22, 1999 IFM notified HMP that it was in default of certain provisions of the Agreement. Specifically, HMP was in violation of the payment provisions contained within the Agreement, which called for inventory purchases to be paid for within 45 days of delivery. Additionally, HMP was in violation due to nonpayment of interest related to such past due accounts receivable.

After notification of the default, HMP indicated to the Company that it would not be able to meet and did not meet the minimum purchase requirements outlined in the Agreement. At December 31, 1999, the Company determined that it had incurred an impairment loss on its IFM assets due to the significant uncertainties related to the Company’s ability to realize its investment in IFM. In calculating the amount of the impairment loss, management used its best estimate to determine the realizable value of its increase in working capital due to the HMP default and the recoverability of IFM’s long-lived assets, consisting primarily of leasehold improvements and equipment. As a result, management recorded a \$2.1 million impairment loss on working capital and a \$2.6 million impairment loss on leasehold improvements. Additionally, the Company offset the above charges with \$2.5 million of deferred income recorded in connection with the sale of the IFM product line to HMP. The net



## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

pretax effect of the above nonrecurring charges was \$2.2 million and has been included under the caption “Nonrecurring charges” in the 1999 Consolidated Statement of Operations.

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 consists of a portion, approximately \$3.8 million, which bears 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 will be forgiven and the note will 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 is deferred until the full amount of the note is 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 have become 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. During 2002, the Company reduced the reserve on the note receivable to zero, and recorded 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):

	<b>2002</b>	<b>2001</b>
Raw materials .....	<b>\$2,341</b>	\$1,987
Work in process .....	<b>306</b>	1,183
Finished goods .....	<b>1,938</b>	3,089
	<b>\$4,585</b>	\$6,259

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**6. Long-Term Debt**

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

	<b>2002</b>	<b>2001</b>
5-year term loan, bearing interest equal to the Adjusted LIBOR plus 1.5%, to be adjusted monthly . . . . .	<b>\$5,600</b>	\$ 7,200
7% convertible debenture, due in March 2002 . . . . .	<u>—</u>	<u>4,393</u>
Total debt . . . . .	<b>5,600</b>	11,593
Less current maturities . . . . .	<u><b>5,600</b></u>	<u>5,993</u>
Total long-term debt . . . . .	<u><b>\$ —</b></u>	<u><b>\$ 5,600</b></u>

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% (2.94% at December 31, 2002). At December 31, 2002 the principal balance of the Term Loan was \$5.6 million. The Term Loan is secured by substantially all of the Company's assets. The Term Loan contains 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 has occurred. The lender has notified the Company that the FDA Order, as described in Note 2, and the inquiries of the SEC, as described in Note 9, have had a material adverse effect on the Company that constitutes an event of default. Additionally, as of December 31, 2002, the Company is in violation of the debt coverage ratio and net worth financial covenants. As of February 24, 2003 the lender has elected not to declare an event of default, but reserves the right to exercise any such right under the terms of the Term Loan. Therefore, all amounts due under the Term Loan as of December 31, 2002 are reflected as a current liability on the Consolidated Balance Sheets.

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.

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.

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Scheduled maturities of long-term debt for the next five years are as follows (in thousands):

2003 .....	\$1,600
2004 .....	1,600
2005 .....	1,600
2006 .....	800
2007 .....	—
Thereafter .....	—
	<u>\$5,600</u>

Total interest costs were \$692,000, and \$915,000, and \$528,000, in 2002, and 2001, and 2000 which included zero, \$819,000, and \$229,000, respectively, of interest capitalized in connection with the expansion of the corporate headquarters and manufacturing facilities.

#### 7. Derivatives

The Company's Term Loan, which accrues interest computed at Adjusted LIBOR plus 1.5%, exposes 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 expires 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 involves 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 is recognized in the period in which it accrues as an adjustment to interest expense on the Term Loan.

On January 1, 2001 the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") as amended. SFAS 133 requires the Company to recognize all derivative instruments on the balance sheet at fair value, and changes in the derivative's fair value must be recognized currently in earnings or other comprehensive income, as applicable. The adoption of SFAS 133 impacts the accounting for the Company's forward-starting interest rate swap agreement. Upon adoption of SFAS 133, the Company recorded an unrealized loss of approximately \$175,000 related to the interest rate swap, which was recorded as part of long-term liabilities and accumulated other comprehensive income as the cumulative effect of adopting SFAS 133 within the Statement of Shareholders' Equity.

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 is amortizing the amounts previously recorded in other comprehensive income of \$292,000 into other expense/income over the remaining life of the swap agreement through June 2006. If the lender accelerates the payments due under the term loan by declaring an event of default, any remaining balance in other comprehensive income will be reclassified into other expense/income during that period.

At December 31, 2002 the notional amount of this swap agreement was \$2.8 million, and the fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$280,000. The fair value of the swap agreement is recorded as part of short-term liabilities. For the year ended

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

December 31, 2002 the Company recorded a loss of \$20,000 on the interest rate swap. The unamortized value of the swap agreement, recorded in the accumulated other comprehensive income account of shareholders' equity, was \$260,000 at December 31, 2002.

**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, 2002 and 2001.

**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, 2002 are as follows (in thousands):

	<u>Capitalized Leases</u>	<u>Operating Leases</u>
2003 .....	\$ 843	\$ 2,294
2004 .....	843	2,115
2005 .....	843	2,091
2006 .....	843	1,943
2007 .....	265	1,981
Thereafter .....	<u>—</u>	<u>16,856</u>
Total minimum lease payments .....	3,637	<u>\$27,280</u>
Less amount representing interest .....	<u>497</u>	
Present value of net minimum lease payments .....	3,140	
Less current portion .....	<u>2,169</u>	
Capital lease obligation, less current portion .....	<u>\$ 971</u>	

Property acquired under capital leases through December 31, 2002 consists of the following (in thousands):

Equipment .....	\$ 403
Furniture and fixtures .....	890
Leasehold improvements .....	3,199
Accumulated depreciation .....	(907)
	<u>\$3,585</u>

Total rental expense for operating leases amounted to \$2,470,000, \$2,243,000, and \$1,478,000, for 2002, 2001, and 2000, respectively. Total rental income under the sublease was \$310,000 in 2002, \$310,000 in 2001, and \$95,000 in 2000.

Due to cross default provisions included in the Company's debt agreements, as of December 31, 2002 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, 2002.

### *Litigation, Claims, and Assessments*

In the normal course of business as a medical device and services company the Company has product liability complaints filed against it. As of February 24, 2003 21 cases had been filed against the Company between May 18, 2000 and January 30, 2003. The cases are currently in the pre-discovery or discovery stages. Of these cases, 14 allege product liability claims arising out of the Company's orthopaedic tissue services, six 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.

Included in these cases is the complaint filed against the Company in the Superior Court of Cobb County, Georgia, on July 12, 2002 by Steve Lykins, as Trustee for the benefit of next of kin of Brian Lykins. This complaint alleges strict liability, negligence, professional negligence, and breach of warranties related to tissue implanted in November of 2001. The plaintiff seeks unspecified compensatory and punitive damages.

The Company maintains claims-made insurance policies, which the Company believes to be adequate to defend against these suits. The Company's insurance company has been notified of these actions. The Company intends to vigorously defend against these claims. Nonetheless, an adverse judgment or judgments imposing aggregate liabilities in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

Claims-made insurance policies 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 represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier. 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 the year ended December 31, 2002 the Company accrued \$3.6 million in estimated costs for unreported product liability claims related to services performed and products sold during 2002 and prior years. 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 Sheets.

Several punitive class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company alleging that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated there under. During the third quarter of 2002 the U.S. District Court for the Northern District of Georgia consolidated the suits, and on November 14, 2002 lead plaintiffs were named. A consolidated complaint was filed on January 15, 2003, seeking the Court's certification of the litigation as a class action on behalf of all purchasers of the Company's stock between April 2, 2001 and

August 14, 2002. The consolidated complaint also seeks recovery of compensatory damages in an unspecified amount and various fees and expenses of litigation, including attorneys' fees. The principal allegations of the consolidated complaint are that the Company failed to disclose its alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. Although the Company considers all of the claims in the consolidated complaint to be without merit and intends to defend against them vigorously, the Company is unable to predict at this time the final outcome of these claims. The Company carries directors' and officers' liability insurance policies, which the Company currently believes should be adequate to address these claims. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

The Company received notice in October 2002 that a complaint had been filed instituting a shareholder derivative action against the Company and Company officers and directors 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. The suit was filed in the Superior Court of Gwinnett County, Georgia, by Rosemary Lichtenberger. The suit alleges the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in practices that caused the Company to suffer damages by being out of compliance with FDA guidelines, and by causing the Company to issue press releases that erroneously portrayed CryoLife's products, operations, financial results, and future prospects. The complainant seeks undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of the Company as a nominal defendant. By an order entered on January 21, 2003, the lawsuit was stayed until discovery commences in the consolidated complaint of the class action lawsuit. In January 2003 the Company received notice that another shareholder derivative lawsuit was filed in the Superior Court of Fulton County, Georgia by Robert F. Frailey against the Company as a nominal defendant, and Company officers and directors Steven G. Anderson, Bruce J. Van Dyne, John W. Cook, Ronald D. McCall, Ronald C. Elkins, Virginia C. Lacy and Alexander C. Schwartz. The complaint asserts claims for breach of fiduciary duty, abuse of control, gross mismanagement, and waste of corporate assets. As in the Lichtenberger action, the Frailey action alleges that the defendant officers and directors caused the Company to suffer damages by being out of compliance with FDA guidelines, and by causing the Company to issue press releases that erroneously portrayed CryoLife's products, operations, financial results, and future prospects. The complaint also alleges improper insider trading by certain Company officers and directors. The complainant seeks declaratory relief, damages of unspecified amount, litigation expenses including attorneys' and experts' fees, and unspecified equitable or injunctive relief against the individual defendants derivatively on behalf of the Company as a nominal defendant. The Frailey complaint has not yet been served on any of the named defendants.

The Company's Board of Directors has established a committee that is independent of management to investigate the Claims asserted in the Lichtenberger and Frailey complaints and report back to the Board with its recommendations for action in response to the shareholders' demands. The independent committee has engaged independent legal counsel to assist in the investigation. The committee is in the process of its investigation.

On August 7, 2002 the Company announced the settlement of its ongoing litigation with Colorado State University Research Foundation ("CSURF") over the ownership of the Company's SynerGraft technology. The settlement resolves all disputes between the parties and extinguishes all CSURF ownership claims to any aspect of the Company's SynerGraft technology. The settlement includes an unconditional assignment to the Company of CSURF tissue engineering patents, trade secrets and know-how relating to tissue decellularization and recellularization. The technology assignment supercedes the 1996 technology license, which was terminated by the terms of the settlement. Payment terms include a nonrefundable advance of \$400,000 paid by the Company to CSURF that will be applied to earned royalties as they accrue through March 2011. The Company recorded these amounts as prepaid royalties and will expense the amounts as the royalties accrue. The earned royalty rate is a maximum of 0.75% of net revenues from products or tissue services utilizing the SynerGraft technology. Royalties earned under the agreement for revenues through December 31, 2002 were approximately \$37,000.



**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

On August 17, 2002 the Company received a letter from the U.S. Securities and Exchange Commission (the “SEC Letter”) that stated that the Company was subject to an investigation related to the Company’s August 14, 2002 announcement of the FDA Order and requesting information from the Company from the period between September 1, 2001 through the date of the Company’s response to the SEC Letter. The SEC Letter stated, in part, that “We are trying to determine whether there have been any violations of the federal securities laws. The investigation and the subpoena do not mean that we have concluded that anyone has broken the law. Also, the investigation does not mean that we have a negative opinion of any person, entity or security.” The staff of the SEC subsequently confirmed that its investigation was informal in nature, and that it did not have subpoena power. At the present time, the Company is unable to predict the outcome of this matter.

The Company has concluded that it is probable that it will incur losses relating to claims and litigation of at least \$1.2 million, which represents the aggregate amount of the Company’s deductibles under its product liability and directors’ and officers’ insurance policies. Therefore the Company has recorded an accrual of \$1.2 million as of December 31, 2002.

**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 generally 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, 2002 and 2001, there were 427,000 and 128,000, 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:

	<u>Shares</u>	<u>Exercise Price</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 1999 .....	1,519,000	\$ 2.33-11.50	\$ 7.67
Granted .....	492,000	11.50-29.15	13.99
Exercised .....	(416,000)	2.33-9.00	3.85
Canceled .....	(45,000)	6.83-9.00	8.64
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 .....	<u>2,386,000</u>	<u>\$ 2.20-31.99</u>	<u>\$12.10</u>

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Weighted Average Number Outstanding	Remaining Contract Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 2.20-2.20	644,000	5.02	\$ 2.20	180,000	\$ 2.20
6.59-8.50	551,000	3.14	7.75	269,000	8.22
9.00-11.63	635,000	2.45	11.38	466,000	11.32
12.92-30.86	425,000	4.34	27.65	157,000	27.04
31.99-31.99	131,000	3.48	31.99	103,000	31.99
\$ 2.20-31.9	<u>2,386,000</u>	3.70	\$12.10	<u>1,175,000</u>	\$13.12

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:

	2002	2001	2000
Weighted average fair value of options granted during the year . . .	\$ 4.23	\$ 15.20	\$ 6.97
Number of shares as to which options are exercisable at end of year . . . . .	<b>1,175,000</b>	915,000	791,000

**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 shall become outstanding between December 11, 1995 and the earliest of the Right's exercise date or expiration date. Each Right entitles the registered holder to purchase from the Company one-thirtieth of a share of a newly created Series A Junior Participating Preferred Stock at an exercise 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, at the Right's then current exercise price, that number of shares of Common Stock with a market value equal to twice the exercise price times the number of one-tenth's of a share of Series A Junior Participating Preferred Stock for which the Right is then exercisable. 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.

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**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. No further purchases are anticipated in the near term.

On October 14, 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, and 2000, the Company had purchased an aggregate of 1,159,000 and 1,159,000 shares, respectively, of its common stock for an aggregate purchase price of \$8,258,000 and \$8,258,000, respectively. No further purchases are anticipated under this authorization.

**13. Accumulated Other Comprehensive Income**

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

	December 31,	
	2002	2001
Net (loss) income . . . . .	\$(27,761)	\$ 9,166
Unrealized gain on investments . . . . .	95	1,124
Change in fair value of interest rate swap (including cumulative effect of adopting SFAS 133 in 2001) . . . . .	30	(200)
Translation adjustment . . . . .	303	18
Comprehensive income . . . . .	\$(27,333)	\$10,108

The tax effect on the change in unrealized gain/loss on investments is \$55,000 and \$575,000 for the years ended December 31, 2002 and 2001, respectively. The tax effect on the change in fair value of the interest rate swap is \$4,000 and \$93,000 for the years ended December 31, 2002 and 2001, respectively. The translation adjustment is not currently adjusted for income taxes, as it relates to a permanent investment in a foreign subsidiary.

**14. Employee Benefit Plans**

The Company has a 401(k) savings plan (the "Plan") providing retirement benefits to all employees who have completed at least three months of service. The Company makes matching contributions of 50% of each participant's contribution up to 5% of each participant's salary. Total company contributions approximated \$404,000, \$384,000, and \$355,000, for 2002, 2001, and 2000, 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 2002, 2001, or 2000.

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, 2002 and 2001 there were 543,000 and 657,000, respectively, shares of common stock reserved under the ESPP and there had been 357,000 and 243,000, respectively, shares issued under the plan.

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**15. Earnings Per Share**

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

	<b>2002</b>	<b>2001</b>	<b>2000</b>
Numerator for basic and diluted earnings per share: (loss) income available to common shareholders .....	<u><b>\$(27,761)</b></u>	<u>\$ 9,166</u>	<u>\$ 7,817</u>
Denominator for basic earnings per share: weighted-average shares . . .	<u><b>19,432</b></u>	<u>18,808</u>	<u>18,541</u>
Effect of dilutive stock options .....	<u>—</u>	<u>852</u>	<u>688</u>
Denominator for diluted earnings per share: adjusted weighted-average shares .....	<u><b>19,432</b></u>	<u>19,660</u>	<u>19,229</u>
(Loss) earnings per share:			
Basic .....	<u><b>\$ (1.43)</b></u>	<u>\$ 0.49</u>	<u>\$ 0.42</u>
Diluted .....	<u><b>\$ (1.43)</b></u>	<u>\$ 0.47</u>	<u>\$ 0.41</u>

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

On July 23, 2002 the Company's Board of Directors authorized the purchase of up to \$10 million of its common stock. As of February 24, 2003 the Company had repurchased 68,000 shares of its common stock for \$663,000. No further purchases are anticipated in the near term.

**16. Income Taxes**

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

	<b>2002</b>	<b>2001</b>	<b>2000</b>
Current:			
Federal .....	<u><b>\$ (8,000)</b></u>	<u>\$4,680</u>	<u>\$2,272</u>
State .....	<u><b>(164)</b></u>	<u>115</u>	<u>(114)</u>
	<u><b>(8,164)</b></u>	<u>4,795</u>	<u>2,158</u>
Deferred .....	<u><b>(5,509)</b></u>	<u>(481)</u>	<u>1,658</u>
	<u><b>\$(13,673)</b></u>	<u>\$4,314</u>	<u>\$3,816</u>

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Such amounts differ from the amounts computed by applying the U.S. federal and state income tax rate of 34% in 2002, 35% in 2001, and 34% in 2000 to pretax income as a result of the following (in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Tax (benefit) expense at statutory rate .....	<b>\$(14,088)</b>	\$4,718	\$3,955
Increase (reduction) in income taxes resulting from:			
Entertainment expenses .....	<b>83</b>	50	47
State income taxes, net of federal benefit .....	<b>(167)</b>	108	231
Nontaxable interest income .....	<b>(202)</b>	(242)	(264)
Research and development credits .....	<b>—</b>	(200)	(125)
Foreign sales corporation .....	<b>(27)</b>	(60)	—
Other .....	<b>728</b>	(60)	(28)
	<b>\$(13,673)</b>	\$4,314	\$3,816

For the year ended December 31, 2002, the Company generated federal income tax losses of approximately \$27 million. These losses will be carried back to prior years to offset income taxes paid and should result in approximately \$8.5 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):

	<u>2002</u>	<u>2001</u>
Long-term deferred tax (liabilities) assets:		
Property .....	<b>\$ (865)</b>	\$(550)
Intangible assets .....	<b>(210)</b>	153
Impairment of IFM long-lived assets .....	<b>—</b>	(52)
Other .....	<b>89</b>	—
	<b>(986)</b>	(449)
Current deferred tax assets (liabilities):		
Unrealized loss on interest rate swap .....	<b>88</b>	93
Unrealized loss on marketable securities .....	<b>(104)</b>	449
Allowance for bad debts .....	<b>26</b>	32
Accrued expenses .....	<b>1,875</b>	13
Prepaid items .....	<b>(56)</b>	—
Deferred preservation costs and inventory reserves .....	<b>4,845</b>	96
Other .....	<b>60</b>	5
	<b>6,734</b>	688
Net deferred tax assets .....	<b>\$5,748</b>	\$ 239

At December 31, 2002 the Company has recorded a net deferred tax asset of \$5.7 million. If the temporary differences that generated the net deferred tax asset become fully deductible in 2003, the Company will have sufficient pre-tax earnings in 2001 to carryback these losses and realize the deferred tax asset. If some of the temporary differences become deductible in future years, the realization of the deferred tax asset may be dependent on generating sufficient taxable income in future periods. Although realization is not ensured, the Company believes that it is more likely than not that the deferred tax asset will be realized.

## CRYOLIFE, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

#### 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 aggregate premium contributions under this program were \$74,000, \$75,000, and \$53,000, for 2002, 2001, and 2000, 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, 2002 freezers with a total cost of approximately \$2.3 million and related accumulated depreciation of approximately \$1.5 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 \$90,000, \$87,000, and \$78,000 during 2002, 2001, and 2000, 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 \$100,000, \$100,000, and \$102,000 in 2002, 2001 and 2000, 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 \$240,000, \$473,000 and \$44,000 in 2002, 2001, and 2000, respectively, relating to research performed by the university where the same Director and shareholder holds a significant position. The Company expensed \$4,500, zero, and zero in 2002, 2001 and 2000, respectively, relating to consulting services performed by a member of the Company's Board of Directors and a shareholder of the Company. The Company paid \$35,000, \$210,000 and \$210,000, in 2002, 2001, and 2000, 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. There are no intersegment sales.

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.



**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

	<u>Revenue</u>	<u>Cost of Preservation Services and Products</u>	<u>Gross Margin</u>
<b>2002:</b>			
Human Tissue Preservation Services .....	\$55,373	\$55,363	\$ 10
Implantable Medical Devices .....	21,597	10,270	11,327
All Other <sup>(a)</sup> .....	825	—	825
	<u>\$77,795</u>	<u>\$65,633</u>	<u>\$12,162</u>
<b>2001:</b>			
Human Tissue Preservation Services .....	\$75,552	\$31,165	\$44,387
Implantable Medical Devices .....	11,130	5,464	5,666
All Other <sup>(a)</sup> .....	989	—	989
	<u>\$87,671</u>	<u>\$36,629</u>	<u>\$51,042</u>
<b>2000:</b>			
Human Tissue Preservation Services .....	\$67,096	\$27,500	\$39,596
Implantable Medical Devices .....	7,176	4,068	3,108
All Other <sup>(a)</sup> .....	2,824	1,779	1,045
	<u>\$77,096</u>	<u>\$33,347</u>	<u>\$43,749</u>

(a) The All Other designation includes 1) grant revenue and 2) distribution revenues and 3) revenues and cost of sales of IFM, a single-use medical device business, through October 9, 2000, the date of the sale of substantially all of the remaining assets of IFM.

Net revenues by product for the years ended December 31, 2002, 2001 and 2000 were as follows (in thousands):

<u>Revenue</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
Human tissue preservation services:			
Cardiovascular tissue .....	\$23,413	\$28,606	\$29,685
Vascular tissue .....	17,826	24,488	21,279
Orthopaedic tissue .....	14,134	22,458	16,132
Total preservation services .....	<u>55,373</u>	75,552	67,096
BioGlue surgical adhesive .....	20,898	10,595	6,405
Bioprosthetic devices .....	699	535	771
Single-use medical devices .....	—	—	2,208
Grant and distribution revenue .....	825	989	616
	<u>\$77,795</u>	<u>\$87,671</u>	<u>\$77,096</u>

**CRYOLIFE, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Net revenues by geographic location for the years ended December 31, 2002, 2001 and 2000 were as follows (in thousands):

<u>Revenue<sup>(b)</sup></u>	<u>2002</u>	<u>2001</u>	<u>2000</u>
U.S. ....	<b>\$71,188</b>	\$81,657	\$72,010
International .....	<b>6,607</b>	6,014	5,086
	<u><b>\$77,795</b></u>	<u>\$87,671</u>	<u>\$77,096</u>

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

At December 31, 2002, 2001, and 2000, 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.

**20. Subsequent Events**

On February 20, 2003 the Company received a letter from the FDA that stated 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 used for arteriovenous ("A-V") access. 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 femoral veins used for A-V access are medical devices that require premarket approval. CryoLife will be providing the agency with information to demonstrate that femoral veins used for A-V access should continue to be regulated as human tissue under Parts 1270 and 1271 of the FDA's regulations. The FDA letter did not question the safety or efficacy of the SynerGraft process or the CryoVein A-V access implant.

The Company has advised the FDA that it will voluntarily suspend use of the 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 FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SG tissue 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 outcome of the discussions with the FDA regarding the use of the SynerGraft process on human tissue could result in a reduction in SynerGraft processed cardiovascular and vascular tissue which would reduce the revenues and gross margins with respect to cardiovascular and vascular tissues.

## **INDEPENDENT AUDITORS' REPORT**

To the Board of Directors and Stockholders of  
CryoLife, Inc.

We have audited the consolidated financial statements of CryoLife, Inc. and Subsidiaries as of and for the year ended December 31, 2002 and have issued our report thereon dated February 24, 2003 which report includes an explanatory paragraph because 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; such report is included elsewhere in this Form 10-K. Our audit also included the 2002 financial statement schedules of CryoLife, Inc., listed in Item 14. These financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion based on our audit. The financial statements of the Company as of December 31, 2001 and 2000 and for the years then ended were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on the 2001 and 2000 financial statements in their report dated March 29, 2002. Those auditors also audited the 2001 and 2000 financial statement schedules listed in Item 14, and their report dated March 29, 2002 expressed an unqualified opinion on those financial statement schedules.

In our opinion, such 2002 financial statement schedules, when considered in relation to the basic 2002 financial statements taken as a whole, present fairly in all material respects the information set forth therein.

### **DELOITTE & TOUCHE LLP**

Atlanta, Georgia  
February 24, 2003

**SCHEDULE II****CRYOLIFE, INC. AND SUBSIDIARIES****VALUATION AND QUALIFYING ACCOUNTS****Years ended December 31, 2002, 2001, and 2000**

<u>Description</u>	<u>Balance beginning of period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance end of Period</u>
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
Year ended December 31, 2000				
Allowance for doubtful accounts .....	\$528,000	\$ 21,000	\$464,000	\$ 85,000
Deferred preservation costs .....	151,000	230,000	152,000	229,000

## 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 Form 10-K 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

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## BOARD OF DIRECTORS

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CryoLife, Inc.  
Kennesaw, Georgia

**John M. Cook**<sup>1</sup>  
Chairman of the Board and  
Chief Executive Officer  
PRG-Schultz International, Inc.  
(An international, publicly-held  
audit recovery firm)  
Atlanta, Georgia

**Ronald C. Elkins, M.D.**<sup>1</sup>  
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Health Sciences Center  
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**Virginia C. Lacy**<sup>1,2</sup>  
Administrator  
The Jeannette & John Cruikshank  
Memorial Foundation  
(A charitable foundation)  
and President,  
Precision Devices Corporation  
(A distributor of small medical  
products to hospitals)  
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**Bruce J. Van Dyne, M.D.**<sup>2</sup>  
Board Certified Neurologist  
Private Practice  
Minneapolis, Minnesota

<sup>1</sup> Audit Committee

<sup>2</sup> Compensation Committee





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Biotechnologies for Medicine<sup>SM</sup>

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