

FORM 10-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

(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, 2001  
OR

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

For the transition period from to

Commission file number 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

TITLE OF EACH CLASS	NAME OF EACH EXCHANGE ON WHICH REGISTERED
Common Stock, \$.01 par value	New York Stock Exchange
Preferred Share Purchase Rights	New York Stock Exchange

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

None

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. [ ]

The aggregate market value of voting stock held by nonaffiliates of the registrant was approximately \$369,802,655 at March 26, 2002 (16,885,966 shares). The number of common shares outstanding at March 26, 2002 was 19,484,931 (exclusive of treasury shares).

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of Registrant's Proxy Statement relating to the Annual Meeting of Shareholders to be filed not later than April 30, 2002.

PART I

ITEM 1. BUSINESS.

## OVERVIEW

CryoLife, Inc. ("CryoLife" or the "Company") is the leader in the preservation of human tissues for cardiovascular, vascular and orthopaedic transplant applications. Additionally, the Company develops and commercializes implantable medical devices, including BioGlue(R) Surgical Adhesive, glutaraldehyde-fixed stentless porcine heart valves, and tissue-engineered SynerGraft(R) porcine heart valves and 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 business 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 19 of notes to the consolidated financial statements.

CryoLife processes and distributes for transplantation preserved human cardiovascular, vascular and orthopaedic 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 applies its proprietary SynerGraft technology to enhance the preservation of certain human cardiovascular and vascular tissues. The Company estimates that it provided in excess of 70% of the preserved human heart valve tissue implanted in the U.S. in 2001. The Company also provides preservation services for surgical replacements for the meniscus and the anterior and posterior cruciate ligaments, which are critical to the proper operation of the human knee, as well as osteochondral grafts used for the repair of cartilage defects in the knee. The Company estimates that the potential U.S. market for implantable products targeting indications addressed by the preserved tissues processed by the Company was in excess of \$1 billion in 2001. The Company seeks to expand the availability of human tissue through its established relationships with approximately 100 tissue banks and organ procurement agencies nationwide.

CryoLife has developed implantable biomaterials for use as surgical adhesives and sealants. The Company's patent protected BioGlue Surgical Adhesive, designed for cardiovascular, vascular, pulmonary, and general surgical applications, is a polymer based on a derivative of an animal blood protein and a cross-linking agent. The Company estimates that the annual worldwide market for surgical sutures and staples in 2001 was in excess of \$2 billion. The Company received a Conformite Europeene ("CE") Mark (product certification) in 1998 for use of its BioGlue Surgical Adhesive in vascular applications and began marketing this product in April 1998 in the European Community ("EC"). 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 U.S. Food and Drug Administration ("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. In December 2001 the Company received FDA approval for BioGlue as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. In February 2002 BioGlue was awarded a third CE Mark for use in general surgical repair procedures.

CryoLife has developed and markets outside of the U.S. bioprosthetic cardiovascular and vascular devices for implantation, consisting of tissue-engineered SynerGraft porcine heart valves, SynerGraft bovine vascular grafts, and glutaraldehyde-fixed stentless porcine heart valves: the CryoLife-O'Brien(R) aortic heart valve and the CryoLife-Ross(R) pulmonary heart valve. The Company has applied its proprietary SynerGraft technology to the processing of the Company's stentless porcine heart valves and bovine ureters used as vascular grafts. SynerGraft involves the depopulation of cells from animal tissue leaving a collagen matrix that has the potential to be repopulated with the implant recipient's cells. This process is designed to increase longevity, and to improve the biocompatibility and functionality of such tissue. In November 2000 the Company received CE Mark approval for its SynerGraft Model 500 heart valve which allowed the Company to begin commercial distribution into the EC for use in implantation into either the aortic or pulmonary position. In

April of 2001 the Company received CE Mark approval for its SynerGraft Model 700 heart valve for use in implantation into the pulmonary position. The Company believes that its porcine heart valves, treated with the SynerGraft technology, will expand its opportunity to address the broader international and U.S. heart valve markets, estimated to have been \$390 million and \$400 million, respectively, in 2001. In August of 2001 the Company received CE Mark approval for its SynerGraft Model 100 vascular graft for dialysis access, peripheral vascular bypass, and vascular patching. 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. Glutaraldehyde-fixed porcine heart valves are 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 \$325 million in 2001. Unlike most other available porcine heart valves, the Company's stentless porcine heart valves do not contain synthetic materials which increase the risk of endocarditis, a debilitating and potentially fatal infection. The Company's CryoLife-O'Brien heart valve, currently marketed in the EC 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. The Company's CryoLife-Ross pulmonary heart valve is also marketed in the EC and certain countries outside the U.S. For information regarding international revenues, see Note 19 of notes to the consolidated financial statements.

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, fibrin lysis (blood clot dissolving) and other drug delivery applications. AuraZyme seeks to advance the development of drug delivery therapies through 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, and relies on independent orthopaedic sales representatives to market its preservation services for human orthopaedic tissue. 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 and bioprosthetic devices and in Canada to market its preservation services and implantable medical devices.

#### GROWTH STRATEGY

The Company's primary objective is to continue its consistent revenue growth and profitability. The Company's strategy to generate continued 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:

- o Continue Leadership in 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 100 tissue banks and procurement agencies across the U.S. which recover and send tissue to the Company for preservation, (iii) expanding its physician training activities and (iv) expanding its product offerings by

applying its SynerGraft technology to human heart valves and conduits for antigen reduction properties with the potential for recipient cell repopulation.

- o Expand Distribution of Preserved Human Vascular Tissue and Orthopaedic Tissue. Using the same strategy it has successfully employed to expand its preservation services for cardiovascular tissue, the Company intends to increase its preservation revenues from human vascular tissue and orthopaedic tissue by (i) continuing educational efforts directed to vascular and orthopaedic surgeons about the clinical advantages of preserved vascular and orthopaedic tissue, (ii) expanding its relationships with tissue banks and procurement agencies, (iii) expanding its programs for training physicians in the use of tissue preserved by the Company and (iv) expanding its product offerings by applying its SynerGraft technology to human vascular grafts for antigen reduction properties with the potential for recipient cell repopulation.
- o Broaden Application of Preservation Services. The Company will continue to collect, monitor and evaluate implant data to (i) develop expanded uses for the human tissues currently cryopreserved by the Company and (ii) identify new human tissues as candidates for 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 1998 in addition to patellar and Achilles tendons, the Company began providing cryopreserved posterior and anterior tibialis and semi-t/gracilis tendons 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 cryopreserved peripheral nerves and other orthopaedic tissues in various surgical applications.
- o Expand Distribution of Biomaterials for Surgical Adhesive and Sealant Applications. The Company began commercial marketing of its patent protected BioGlue Surgical Adhesive in the EC through its independent representatives for vascular and pulmonary applications upon receipt of a CE Mark in 1998 and 1999, respectively. In December 1999 the Company received FDA approval to distribute BioGlue Surgical Adhesive under an HDE for use as an adjunct in the repair of acute thoracic aortic dissections. 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 February 2002 BioGlue was awarded a third CE Mark for use in general surgical procedures. The Company has commenced aggressive marketing programs to promote the FDA approved expanded uses of BioGlue by (i) contacting the more than 600 hospitals and medical centers in North America whose Institutional Review Boards ("IRBs") had previously approved the use of BioGlue for aortic dissections to inform them that the product is approved for vascular repair and that the HDE restrictions have been lifted, (ii) contacting those medical centers that did not have IRB approvals in place for the use of BioGlue for aortic dissections and (iii) contacting vascular surgeons and emergency room physicians who perform central and peripheral vascular repair. In addition to these adhesive and sealant applications of BioGlue, the Company intends to pursue, either directly or through strategic alliances, technologies for replacement for spinal disc nuclei and for delivering bone material for orthopaedic bone repair.
- o 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 valves and to use its stentless porcine heart valves as a platform for the development and commercialization of the Company's SynerGraft technology, which is being developed to expand the target market for the stentless porcine heart valves by minimizing calcification often associated with porcine tissues and thereby increasing their longevity. In November 2000 the Company received a CE Mark allowing

for commercial distribution of the Company's tissue-engineered SynerGraft Model 500 heart valve throughout the EC. In April 2001 the Company received a CE Mark allowing for commercial distribution of the Company's tissue-engineered SynerGraft Model 700 heart valve throughout the EC.

- o 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

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commercialization of its tissue-engineered SynerGraft vascular grafts. In August of 2001 the Company received CE Mark approval for its SynerGraft Model 100 vascular graft for dialysis access and peripheral reconstruction.

- o Leverage Existing Capability across Product Lines. The Company intends to apply its expertise with stentless human heart valves to expand commercialization of its stentless porcine heart valves and to use its human allograft preservation expertise and its stentless porcine heart valves as a platform for the development and commercialization of the Company's SynerGraft technology.

## SERVICES AND PRODUCTS

### Preservation of Human Tissue for Transplant

The Company's proprietary and patent protected preservation process involves the recovery of tissue from deceased human donors by 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 and conduits, vascular tissue and orthopaedic tissue.

CryoLife maintains and collects extensive 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 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 processing techniques and to increase 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 51,600 cryopreserved human heart valves and conduits from 1984 through 2001. Revenues from human heart valve and conduit preservation services accounted for 44%, 39% and 33% of total revenues, respectively, in 1999, 2000 and 2001. 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 as compared to mechanical and porcine heart valve alternatives in certain applications. The Company currently applies its preservation services to human aortic, pulmonary and mitral heart valves for implantation by cardiac surgeons. In addition, the Company provides cryopreserved conduit and patch tissue to surgeons who wish to perform certain specialized cardiac repair procedures. Each of these human heart valves, 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 processing and distributing in the U.S. decellularized cryopreserved human heart valves and conduits utilizing its SynerGraft technology which effectively removes cells from the heart valve leaving the collagen matrix intact. The CryoValve(R) 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 PRA (panel reactive antibodies) experienced by some of the patients who receive allograft heart valves. The absence of an immunologic response to the decellularized allograft has the potential of improved long-term function of the allograft heart valves. Advanced animal studies of both allograft and porcine heart valves that have been treated with the SynerGraft process show that these valves have the potential to repopulate themselves in vivo with the patient's own cells.

The Company estimates that the total heart valve and conduit replacement market in the U.S. in 2001 was approximately \$400 million. Management believes that approximately 107,000 heart valve and conduit surgeries were conducted in the U.S. in 2001. Of the total number of heart valve and conduit surgeries, approximately 53,000, or 50%, involved mechanical heart valves, and approximately 54,000, or 50%, involved tissue heart valves or conduits, including porcine and cryopreserved human tissues. Approximately 5,200 human heart valves and conduits cryopreserved by the Company were shipped for implantation in 2001.

Management believes cryopreserved human heart valves and conduits have characteristics that make them the preferred replacement 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 and mechanical heart valves. Human heart valves are not as susceptible to progressive calcification, or hardening, as are glutaraldehyde-fixed porcine heart valves, and do not require anti-coagulation drug therapy, as do mechanical valves. The synthetic sewing rings contained in mechanical and stented porcine valves may harbor bacteria leading to endocarditis. Furthermore, endocarditis is 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:

	PORCINE				
	CRYOPRESERVED HUMAN -----	STENTED -----	STENTLESS (1) -----	MECHANICAL -----	BOVINE PERICARDIUM -----
Materials:	human tissue	glutaraldehyde fixed pig tissue and synthetic sewing ring	glutaraldehyde fixed pig tissue	pyrolytic carbon bi-leaflet and synthetic sewing ring	glutaraldehyde fixed cow tissue and synthetic sewing ring
Blood Flow Dynamics	normal	moderate elevation	nearly normal	high elevation	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	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 Valve Cost in U.S.:	\$7,300	\$4,500	\$5,500	\$4,100 (3)	\$4,500

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- (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 16 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 and superficial femoral veins and arteries for use in 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 believes it offers the only available small diameter conduit product for below-the-knee vascular reconstruction. The Company also cryopreserves aortoiliac arteries for the reconstruction of infected abdominal synthetic grafts. The Company shipped approximately 28,900 human vascular tissues from 1986 through 2001, which includes 6,100 shipments in 2001. Revenues from human vascular preservation services accounted for 29%, 28% and 28% of total revenues, respectively, in 1999, 2000 and 2001.

A surgeon's first choice for replacing diseased or damaged vascular tissue is generally the patient's 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 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 2001. The Company estimates that approximately 30% of these are re-operations

which may require the use of preserved vascular tissue.

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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 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 2001, approximately 125,000 to 150,000 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 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 2001, there were approximately 300,000 end stage renal failure patients receiving dialysis in the U.S. and a majority of these patients rely on arterial-venous dialysis grafts for vascular access.

Human Orthopaedic Tissue. The Company provides preservation services for surgical replacements for the meniscus and the anterior and posterior cruciate ligaments, which are critical to the proper operation of the human knee, as well as osteochondral grafts used for the repair of cartilage defects in the knee. CryoLife has shipped approximately 23,300 human connective tissues for the knee through 2001, which includes 6,700 shipments in 2001. Revenues from human orthopaedic preservation services accounted for 17%, 21% and 26% of total revenues, respectively, in 1999, 2000 and 2001.

Human menisci cryopreserved by the Company 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 the Company is the only provider of cryopreserved meniscal tissue and that there are no synthetic menisci on the market. The Company estimates that in 2001 in the U.S. approximately 725,000 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 cryopreserved by the Company are 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. Tendons cryopreserved by the Company 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 2001 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. The orthopaedic surgical community has 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), which provide strength and support of the articular cartilage through transplant of osteochondral grafts onto the end of the patient's femur. The Company estimates that in 2001 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.

Other Allograft Tissue Research and Development. The Company is engaged in research and development on other projects for the use of cryopreserved peripheral nerves and other connective tissues, in various surgical applications.



## 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

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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. The 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. Clinical applications for BioGlue Surgical Adhesive include cardiovascular, vascular, pulmonary, and general surgical repair. Other potential applications for BioGlue Surgical Adhesive include orthopaedic indications, and as a replacement for spinal disc nuclei. A derivative of the BioGlue technology is BioLastic(TM), an implantable biomaterial under development which is capable of exchanging oxygen and carbon dioxide. BioLastic is being developed for use in reinforcing or patching vascular tissue, 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 2001 was in excess of \$2 billion. The Company began shipping BioGlue Surgical Adhesive for distribution in the EC 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. 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 February 2002 the Company received a third CE Mark for BioGlue for use in general surgical repair procedures. Revenues from BioGlue Surgical Adhesive represented 2%, 8% and 12% of total revenues, respectively, in 1999, 2000 and 2001.

## 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 valves are stentless with the valve opening, or annulus, retaining a more natural flexibility. Stented porcine and mechanical heart valves are typically fitted with synthetic sewing rings which are rigid and can impede normal blood flow. Unlike most other available porcine heart valves, the Company's stentless porcine heart valves do not contain synthetic materials which increase the risk of endocarditis, a debilitating and potentially deadly infection. Revenues from bioprosthetic cardiovascular and vascular devices represented 1% of total revenues in 1999, 2000 and 2001.

Glutaraldehyde-fixed porcine 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 \$325 million in 2001.

The Company's SynerGraft technology involves the removal of cells from the structure of animal tissue, leaving a collagen matrix that has the potential to repopulate in vivo with the recipient's own cells. This process is designed to increase longevity, and more generally to improve the biocompatibility and functionality of such tissue. The Company believes that its porcine heart valves, when treated with SynerGraft technology, will expand its opportunity to

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address the broader international and U.S. heart valve markets, estimated to have been \$390 million and \$400 million, respectively, in 2001.

The following table sets forth the bioprosthetic cardiovascular devices currently marketed by the Company, along with the product features and market status for each.

STENTLESS PORCINE VALVES	FEATURES	REGULATORY/MARKET STATUS
SynerGraft 700	depopulated pulmonary valve of non-composite leaflet design; no synthetic material; normal hemodynamics	currently marketed in Europe for pulmonary valve replacement with regulatory approval under CE Mark
SynerGraft 500	depopulated valve of aortic composite leaflet design; no synthetic material; normal hemodynamics	currently marketed in Europe for both aortic and pulmonary valve replacement with regulatory approval under CE Mark
CryoLife-O'Brien	matched composite leaflet design; single suture line implantation technique; no synthetic material; normal hemodynamics	currently marketed in Europe for aortic valve replacement with regulatory approval under CE Mark; currently marketed in Canada with regulatory approval under Therapeutic Products Programme
CryoLife-Ross	pulmonary valve with attached conduit; no synthetic material; normal hemodynamics	currently marketed in Europe with regulatory approval under CE Mark

The SynerGraft heart valves are depopulated stentless porcine heart valves with antigen reduction technology. The Company obtained a CE Mark for the SynerGraft Model 500 heart valve in November 2000 for use in implantation in the aortic and pulmonary position. The Company obtained a CE Mark for the SynerGraft 700 pulmonary heart valve in April 2001. The SynerGraft technology removes cells from animal tissues, thereby reducing the transplant recipient's immune response to the implanted tissue. By removing animal cells from the tissue while maintaining the underlying structural strength of the porcine heart valve, this SynerGraft application is designed to provide a platform for a patient's own cells to potentially repopulate the implant.

The CryoLife-O'Brien aortic valve is a stentless porcine valve with design features which management believes provide significant advantages over other stentless porcine 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 EC 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 CryoLife-Ross pulmonary valve, the patent for which the Company acquired in October 1996, is an advanced design stentless porcine heart valve within an attached conduit of porcine tissue, which mimics the structure of a human heart valve. The Company began manufacturing and distributing the CryoLife-Ross pulmonary heart valve, in the EC in September 1998.

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## 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 100 tissue banks and organ procurement agencies throughout the U.S. Management believes the establishment of these relationships is 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, seven of whom 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 cryopreserved. These procedures are conducted under aseptic conditions in clean rooms. At the same time, additional 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 specimens are transferred to liquid nitrogen freezers for long-term storage at temperatures below -135(Degree)C. Osteochondral grafts are refrigerated in proprietary solutions from 2(Degree)C to 8(Degree)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 maintains active relationships with approximately 3,500 cardiovascular, vascular and orthopaedic surgeons who have active practices implanting cryopreserved human tissues and markets to a broader group of physicians 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 has over 150 independent technical service representatives and sub-representatives (who deal primarily with orthopaedic surgeons and who are paid on a commission basis) as well as 47 persons employed as technical service representatives (who deal primarily with cardiovascular and vascular surgeons and receive a base salary with a performance bonus) all of whom provide field support.

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.

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.

#### 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.

#### 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's European, Middle East and African sales, marketing and distribution activities directed through Europa are channeled through 23 independent distributors located throughout Europe, the Middle East and South Africa. Marketing efforts are directed almost exclusively toward cardiovascular, vascular, thoracic and general surgeons, and 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 and CryoLife-Ross stentless porcine heart valves in Europe, the Middle East and Africa. The CryoLife-O'Brien valve is also marketed in Canada. The Company commenced marketing the SynerGraft Model 500 and Model 700 heart valves and the SynerGraft Model 100 vascular graft in Europe during the fourth quarter of 2000, the first quarter of 2001 and the third quarter of 2001, respectively. Marketing efforts are primarily directed toward cardiac, thoracic and vascular surgeons and the Company conducts educational seminars and conferences to train these surgeons and educate them with respect to the uses and benefits of its porcine stentless heart valves.

#### 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 business 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 22 people in its research and development department, including seven PhDs with specialties in the fields of immunology, molecular biology, protein chemistry, organic chemistry and vascular biology.

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 ("PH") technology (of which BioGlue is the first PH product to be introduced) and its ACT. The PHT is based on a bovine protein that mirrors an array of amino acids that perform complex functions in the human and together with glutaraldehyde forms a hydrogel, a water based bio-material similar to human tissue. Materials and implantable replacement devices created with the 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 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 1999, 2000, and 2001, the Company spent approximately \$4.4 million, \$5.2 million and \$4.7 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 7%, 7% and 5% 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, as situations develop, 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 designed to accommodate growth and development of the Company's BioGlue Surgical Adhesive and the SynerGraft family of biologic implantable devices. The total Company 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 sterile environment for tissue dissection, processing, manufacturing and packaging. Some forty liquid nitrogen storage units maintain cryopreserved tissue at minus 325 degrees Fahrenheit. 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 operating room area, 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, including the processing of certain SynerGraft treated human heart valves and conduits and vascular tissues. This laboratory contains approximately 15,600 square feet with a suite of eight clean rooms. Currently there are 59 technicians employed in this area, and the laboratory is staffed for two shifts, 365 days per year. In 2001 the laboratory processed approximately 19,600 human allografts for distribution and transplant. The current processing level is estimated to be at about half of total capacity. Increasing this capacity 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. This laboratory contains approximately 13,500 square feet, including a suite of six clean rooms. Currently, there are seven 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 and CryoLife-Ross stentless porcine heart valves, as well as for the manufacturing the tissue-engineered SynerGraft porcine heart valves and vascular grafts. This laboratory is approximately 20,000 square feet with a suite of six clean rooms for tissue processing. Currently, this laboratory employs 21 technicians.

#### Other facilities

The Company's pilot production facility and AuraZyme are located in two separate facilities, located in Marietta, Georgia, that total 31,000 square feet. The pilot production facility is approximately 20,000 square feet, with about 2,100 square feet of laboratory space and a suite of six clean rooms. The Company conducts research on its ACT in the AuraZyme laboratory and has four employees at that location, including two research scientists. This laboratory contains approximately 11,000 square feet, including 4,000 square feet of laboratory space and a suite of eight clean rooms.

#### 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

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EC to perform assessments of compliance with ISO 9001 and its derivative standards. LRQA performs semi-annual on-site inspections of the Company's quality systems.

The Company's quality assurance staff is comprised primarily of experienced professionals from the medical device and pharmaceutical manufacturing industries. The quality assurance department, in conjunction with the Company's research and development 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. 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 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 disinfection procedure is begun during which the dissected tissue is treated with proprietary antibiotic solutions. A trained technician then removes samples from the disinfected tissue upon which serial cultures are performed to identify bacterial or fungal growth.

The materials and solutions used by the Company in processing tissue are pre-screened to determine if they are of desired quality 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 Code of Federal Regulation ("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.

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 specifications. The Company maintains a rigorous quality assurance program of measuring devices used for manufacturing and inspection to ensure appropriate accuracy and precision.

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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 37 U.S. patents and 58 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 20 pending U.S. patent applications and in excess of 66 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 all 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 3 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. are maintained in secrecy until patents are issued 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. Furthermore, the Company is involved in litigation relating to its SynerGraft technology. An adverse decision in that case could have a material adverse effect on the Company's business and results of operations.

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 small 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 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 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 other 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 three tissue banks offer preservation services for human heart valves in competition with the Company. The Company presently distributes its stentless porcine heart valves only outside the U.S. These stentless porcine heart valves compete with mechanical valves, human heart valves and processed bovine pericardium. 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 two other providers of cryopreserved human vascular tissue in competition with the Company. Companies offering either synthetic or allograft products may enter this market in the future.

Human Orthopaedic Tissue. The Company's competition in the area of orthopaedic tissue varies according to the tissue involved. When transplant is indicated,

the principal competition for human tissues cryopreserved by the Company are freeze-dried and fresh frozen human connective tissues. These alternative allografts are distributed by distributors of Osteotech, Inc. and various tissue banks, among others. Ligaments and tendons cryopreserved by the Company constitute the principal treatment options for injuries which require anterior cruciate ligament repair.

#### 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, United States Surgical Corporation, Sherwood, Davis & Geck and others. Other products currently being marketed include fibrin glue sold by Baxter International, Inc., Chemo-Sero Therapeutic Research Institute, Hoechst AG and others, and management believes

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other products are under development by Baxter Healthcare International, Inc., Bristol-Myers Squibb Company, V.I. Technologies, Inc. and others. Other competitors in the surgical sealant market include Closure Medical Corporation, B. Braun GmbH, Focal, Inc., Fusion Medical Technologies Inc. and Cohesion, Inc. Competitive products may also be under development by other large medical device, pharmaceutical and biopharmaceutical companies. Many of the Company's current and potential competitors have substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales and personnel resources than the Company.

These competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals, and manufacturing and marketing such products. Certain of these competitors may obtain patent protection, approval or clearance by the FDA or foreign countries or product commercialization earlier than the Company, any of which could materially adversely affect the Company. Furthermore, if the Company commences significant commercial sales of its products, it will also be competing with respect to manufacturing efficiency and marketing capabilities.

Other recently developed technologies or procedures are, or may in the future be, the basis of competitive products. There can be no assurance that the Company's current competitors or other parties will not succeed in developing alternative technologies and products that are more effective, easier to use or more economical than those which have been or are being developed by the Company or that would render the Company's technology and products obsolete and non-competitive in these fields. In such event, the Company's business, financial condition and results of operations could be materially adversely affected. See "Risk Factors--Rapid Technological Change."

#### GOVERNMENT REGULATION

##### U.S. Federal Regulation

Because human heart valves and BioGlue surgical bioadhesives are, and other Company products may be, regulated in the future 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.

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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'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 has 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.

Other Tissue. Other than human and porcine heart valves, BioGlue and SynerGraft devices, none of the Company's other tissue services or tissue-based products are currently subject to regulation as medical devices under the FDCA or FDA regulation. Heart valves are one of a small number of processed human tissues over which the FDA has asserted medical device jurisdiction. In July 1997, the FDA published a final rule, which became effective in January 1998, regulating "human tissue." The rule clarifies and modifies an earlier interim rule and 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. In January 2001 the FDA published a final rule to require establishments that process or produce human tissue and cellular-based products to register with the agency and list the tissue and cellular products they process or manufacture. Human tissue is regulated by the FDA in a manner

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the agency has deemed necessary to protect the public health from the transmission of HIV infection and hepatitis infection through transplantation of tissue from donors with or at risk for these diseases. Unlike certain drugs, biologicals and medical devices, human tissue is not subject to premarket notification or approval by the FDA. It is likely, moreover, 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 veins and connective tissue that are currently processed by the Company are medical devices, or the FDA may determine 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.

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.

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; 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.

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#### 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 EC recognizes a single approval, called a CE Mark, which allows for distribution of an approved product throughout the EC (15 countries) without additional general applications to each country. However, individual EC members reserve the right to require additional data to address particular patient safety issues prior to allowing importation. France and an increasing number of EC members require such additional data 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 EC accept the CE Mark in lieu of clinical data submission as an addendum to that country's application process. The Company has been issued CE Marks for its CryoLife-O'Brien and CryoLife-Ross porcine heart valves, BioGlue Surgical Adhesive, and its SynerGraft Model 500 and 700 heart valves and SynerGraft Model 100 vascular grafts. The Company's porcine heart valves may be exported to specified developed nations, including countries in the EC, Australia, Canada, Israel, New Zealand, South Africa and Switzerland if they comply with the laws of that country and have valid marketing authorization by the appropriate authority in that country. Beginning in July 1998, CE Mark Certification was required to market porcine heart valves and other bioprosthesis in the EC.

#### 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

At March 21, 2002 the Company had approximately 384 employees. These employees included 13 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.

#### RISK FACTORS

##### DEPENDENCE ON PRESERVATION OF HUMAN TISSUE

A significant portion of the Company's current revenues is derived from the preservation of human tissues. The success of this business 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. Based on the Company's experience with cardiovascular, vascular and orthopaedic tissues, management believes that once the use by physicians of a particular transplantable tissue gains acceptance, demand for that tissue will exceed the amount of tissue available from human donors. Failure of the Company to maintain its supply of tissue for preservation could have a material adverse effect on the Company's business, financial condition and results of operations. Furthermore, a reduction in the demand for the Company's cryopreserved human tissue could also have a material adverse effect on the Company's business, financial condition and results of operations. Such reduction could occur if competitors' products were perceived as either functionally superior or more cost effective, if the number of procedures in which cryopreserved tissues are used declines or if hospitals acquire sufficient inventories of cryopreserved tissue to allow a reduction in new orders. See "--Intense Competition" and "--Uncertainties Regarding Future Health Care Reimbursement."

##### INTENSE COMPETITION

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. Management believes that at least three tissue banks offer preservation services for human 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 will 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 and results of operations. See "Business--Competition."

##### RAPID TECHNOLOGICAL CHANGE

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 and results of operations.

#### UNCERTAINTIES REGARDING PRODUCTS IN DEVELOPMENT

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. See "--Extensive Government Regulation." Although the Company has conducted

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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, there can be no assurance that any of the Company's products under development will be successfully developed or manufactured or, if developed and manufactured, that such products will 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 and results of operations.

The Company's porcine heart valve products, including its SynerGraft treated porcine valves, are currently only offered for sale outside of the U.S. The Company's porcine heart valves are subject to the risk that the Company may be unable to obtain regulatory approval necessary to permit commercial distribution of these products in the U.S.

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. Generally, the introduction of new human tissue products requires 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.

#### UNCERTAINTIES REGARDING THE FUNDING OF THE ACT TECHNOLOGY

The ACT is a reversible linker technology that has potential uses in the areas of cancer therapy, fibrin lysis (blood clot dissolving) and other drug delivery applications. The Company has 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. 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. 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 our future expansion plans and could limit future growth.

#### UNCERTAINTIES REGARDING THE SYNERGRAFT TECHNOLOGY

The Company currently processes porcine, bovine and human tissues with the SynerGraft process. In animal studies, explanted porcine heart valves have been shown to repopulate with the hosts' cells. However, should SynerGraft-treated tissues implanted in humans not repopulate with the human host cells, the SynerGraft-treated tissues may not have the longevity that the Company currently expects. This could have a material adverse effect on future expansion plans and could limit future growth.

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#### EXTENSIVE GOVERNMENT REGULATION

Government regulation in the U.S., the EC and other jurisdictions represents a potentially determinative factor in the success of the Company's efforts to market and develop its products. See "Business--Government Regulation." The human 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 recordkeeping requirements. There can be no assurance that changes in regulatory treatment or the adoption of new statutory or regulatory requirements will not 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 recordkeeping relating to these activities and impose certain registration and product listing requirements on establishments that process or distribute human tissue or cellular-based products. Although the Company's other human tissue allografts are not currently regulated as medical devices, such tissue may in the future become subject to more extensive FDA regulation, which could include PMA or product licensing requirements.

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 and ISO 9001 certifications, of which there can be no assurance.

Most of the Company's products 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 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 candidate 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 marketed by the Company pursuant to FDA or foreign oversight or approval are subject to pervasive and 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. For example, the FDA is currently inspecting our facilities in suburban Atlanta, Georgia. 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 any applicable FDA requirements, which may be ambiguous, could result in civil and criminal enforcement actions, warnings,

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citations, product recalls or detentions and other penalties and could have a material adverse effect on the Company's business, financial condition and results of operations. In addition, NOTA prohibits the acquisition or transfer of human organs for "valuable consideration" for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, 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. While management believes that the Company is presently in compliance in all material respects with all such applicable statutes and regulations, there can be no assurance that more restrictive state laws or regulations will not be adopted in the future that could have a material adverse effect on the Company's business, financial condition and results of operations. See "Business--Government Regulation."

#### UNCERTAINTIES RELATED TO PATENTS AND PROTECTION OF PROPRIETARY TECHNOLOGY

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 and results of operations. 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 and results of operations. Furthermore, the Company is involved in litigation relating to its SynerGraft technology. An adverse decision in that case could have a material adverse effect on the Company's business and results of operations.

#### UNCERTAINTIES REGARDING FUTURE HEALTH CARE REIMBURSEMENT

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 may be particularly susceptible to third-party cost containment measures. In particular, the initial cost of a cryopreserved human 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 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

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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 and results of operations.

#### DEPENDENCE ON 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 whom 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 and results of operations.

#### PRODUCT LIABILITY AND INSURANCE

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. 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. From time to time, the Company is involved in legal proceedings based on product liability claims of a nature considered normal to its business. 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. If a lawsuit is filed because of such an occurrence, the Company, along with physicians and nurses, hospitals and other medical suppliers, may be named as a defendant, and whether or not the Company is ultimately determined to be liable, the Company may 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, there can be no assurance that it will not incur significant losses in the future. The Company currently maintains product liability insurance in the aggregate amount of \$23

million per year. There can be no assurance that such coverage will continue to be available on terms acceptable to the Company or will be adequate to cover any losses due to product claims if actually incurred. Furthermore, if any such claim is successful, it could have a material adverse effect on the Company's business, financial condition and results of operations. See "Business--Legal Proceedings."

#### INFECTIOUS DISEASES AND MICROBIAL CONTAMINATION

The Company tests the serum from the donor of preserved human tissue for infectious diseases in compliance with 21 CFR 1270, relating to human tissue intended for transplantation. The Company treats human tissue with antimicrobials to reduce the number of organisms that may be present at the time of procurement, and subsequently, tests a portion of the human tissue for detectable levels of bacterial and fungal microorganisms. Although the Company tests human tissue, there can be no assurance that preserved human tissue is free from all infectious diseases or microbial contamination. In November 2001 and March 2002 a total of 14 post-transplant infections, including one resulting in the death of a patient, were reported to be linked to tissues processed by the Company. Such events could lead to concerns over use of CryoLife's tissue, and a decrease in demand for CryoLife's services and products. Any related changes in the Company's tissue processing procedures could have an adverse effect on the cost of tissue processing services.

#### USE AND DISPOSAL OF HAZARDOUS MATERIAL

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The Company's research, development and processing activities involve the controlled use of small quantities of radioactive compounds, chemical solvents and other hazardous materials. The Company's activities also include the preservation and the processing of human and animal tissue. Although the Company believes that its safety procedures for handling, processing and disposing of hazardous materials and human and animal tissue comply with the standards prescribed by federal, state and local regulations, the risk of accidental contamination, injury or disease transmission from these materials cannot be completely eliminated. In the event of such an accident or transmission, the Company could be held liable for resulting damages and any liability could have a material adverse effect on the Company's business, financial condition and results of operations. Also, any failure to comply with applicable regulations could result in the imposition of penalties, fines and sanctions, which could have a material adverse effect on the Company's business, financial condition and results of operations.

#### VOLATILITY OF SECURITIES PRICES

The trading price of the Company's Common Stock has been subject to wide fluctuations from time to time and may continue to be subject to such volatility in the future. Trading price fluctuations can be caused by a variety of factors, including 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, 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.

#### 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 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 or incorporated by reference in this Form 10-K which address activities, events or developments which the Company expects or anticipates will or may occur in the future, including statements regarding the Company's competitive position, the successful development of its SynerGraft porcine valves, the funding to continue

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development of the ACT, other 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, fibrin lysis (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. The AuraZyme Pharmaceuticals laboratory facility contains approximately 11,000 square feet, including approximately 4,000 square feet of laboratory space with a suite of eight clean rooms. The pilot production laboratory, which contains approximately 20,000 square feet, with about 2,100 square feet of laboratory space and a suite of six clean rooms for tissue processing. 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.

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 designed to accommodate growth and development of the Company's BioGlue Surgical Adhesive and the SynerGraft family of biologic implantable devices.

### ITEM 3. LEGAL PROCEEDINGS.

From time to time, the Company is involved in litigation relating to claims arising out of its operations in the normal course of business. Management believes that, except for the litigation described in the following paragraph, no currently ongoing litigation, if determined adversely to the Company, will have a material adverse effect on the Company's business, financial condition or results of operations.

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On May 23, 2001, Colorado State University Research Foundation ("CSURF") filed an action in United States District Court, District of Colorado, alleging that the Company breached a March 26, 1996 Technology License Agreement between CSURF and the Company (the "TLA"). The TLA grants the Company a sole and exclusive, worldwide, royalty bearing license to certain defined technology owned, developed or acquired by CSURF relating to fibroblast and other cellular in growth into human, animal and bioprosthetic grafts (collectively, the "Licensed Technology") and grants the Company the right to make products using the Licensed Technology. CSURF alleges that the Company uses the Licensed Technology in the Company's SynerGraft process and that the Company has breached the TLA by not paying royalties to CSURF on tissues processed using the SynerGraft process. The Company denies these allegations and asserts that no royalties are due to CSURF under the TLA because the Company's SynerGraft process does not utilize the Licensed Technology. CSURF also alleges that the Company is obliged to assign to CSURF certain Company patents and patent applications relating to the Company's SynerGraft process and that the Company engaged in deceptive conduct by not naming CSURF as owner or its representative Christopher Orton as an inventor on those Company patents and patent applications. The Company denies CSURF's allegations and asserts that CSURF is not entitled to any ownership interest in the Company's patents or patent applications, that the Company has not engaged in any deceptive practice, and that CSURF's assignor is not an inventor of any Company patents or patent applications.

CSURF has asked the Court to order the Company to assign its interest in certain Company patents and patent applications to CSURF to order that the TLA be terminated, to order that the Court revise the names of the inventors on the same Company patents to include CSURF's assignor as an inventor, and to hold that the Company has engaged in deceptive conduct. CSURF has requested that it be awarded actual damages in an amount to be determined at trial, that its damage award be trebled, that a constructive trust be imposed in CSURF's favor on all profits CryoLife obtains from tissue processed using the SynerGraft technology and that CSURF be awarded its attorneys' fees, pre-judgment and post-judgment interest, and such other relief as the Court may deem appropriate.

The case is currently in discovery. Interrogatory responses and documents have been exchanged. The Company believes that CSURF's allegations are false and that the Company will prevail in the action. Nonetheless, an adverse decision by the Court could have a material adverse effect on the Company's business and results of operations.

### ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS.

Inapplicable.

ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT.

Each of the executive officers of the Registrant was elected by the Board of Directors to serve until the Board of Directors' meeting immediately following the next annual meeting of shareholders or until his earlier removal by the Board of Directors or his resignation. The following table lists the executive officers of the Registrant and their ages, positions with the Registrant, and the dates from which they have continually served in their present positions with the Registrant.

NAME	AGE	POSITION	DATE FIRST ELECTED TO PRESENT OFFICE
Steven G. Anderson	63	President, Chief Executive Officer and Chairman	February, 1984
Sidney B. Ashmore	43	Vice President, Marketing	March, 2001
Kirby S. Black, PhD	47	Senior Vice President, Research and Development	July, 1995
David M. Fronk	38	Vice President, Clinical Research	December, 1998
Albert E. Heacox, PhD	51	Senior Vice President, Laboratory Operations	June, 1989
D. Ashley Lee, CPA	37	Vice President and Chief Financial Officer	April, 2000
James C. Vander Wyk, PhD	57	Vice President, Regulatory Affairs and Quality Assurance	February, 1996
Ronald D. McCall, Esq.	65	Director, Secretary and Treasurer	January, 1984

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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 to 1996, and general management positions with Amorient Aquafarms from 1985 - 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. 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 at The Ohio State University in 1985 and his MS in Biomedical Engineering at The Ohio State University in 1986.

ALBERT E. HEACOX, PHD, has served as Vice President, Laboratory Operations since June 1989 and has been with the Company since June of 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 plasm 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 and Chief Financial Officer of the Company since April 2000 and had previously served as controller of the Company since December 1994. 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, 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.

RONALD D. MCCALL has served as a director of the Company and as the Secretary and Treasurer of the Company since January 1984. From 1985 to the present, Mr. McCall has been the proprietor of the law firm of Ronald D. McCall, Attorney At Law, Tampa, Florida. Mr. McCall was admitted to the practice of law in Florida in 1961. Mr. McCall received his BA and JD degrees from the University of Florida.

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.

2001	High	Low
First quarter	28.30	20.35
Second quarter	40.91	24.10
Third quarter	44.20	29.18
Fourth quarter	39.25	24.96
2000	High	Low
First quarter	16.42	7.50
Second quarter	16.25	10.38
Third quarter	23.13	14.88
Fourth quarter	35.88	17.83

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

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 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 could have the effect of restricting the amount of dividends that the Company may pay.

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, each of the years in the three-year period ended December 31, 2001, are derived from the Consolidated Financial Statements of the Company, which Consolidated Financial Statements have been audited by Arthur Andersen 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 data set forth below with respect to the Company's Consolidated Income Statements and Balance Sheets for, and as of the end of, the years ended December 31, 1997 and 1998 are derived from the Company's Consolidated Financial Statements which have been audited by Ernst & Young LLP, independent auditors. The historical results are not necessarily indicative of future results of operations.

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

	December 31,				
OPERATIONS	2001	2000	1999	1998	1997
Revenues	\$ 87,671	\$ 77,096	\$ 66,722	\$ 60,691	\$ 50,571
Net income	9,166	7,817	4,451	6,486	4,725
Research and development as a percentage of revenues	5.4%	6.8%	6.6%	7.8%	7.8%
EARNINGS PER SHARE (1)					
Basic	\$ 0.49	\$ 0.42	\$ 0.24	\$ 0.36	\$ 0.33
Diluted	\$ 0.47	\$ 0.41	\$ 0.24	\$ 0.35	\$ 0.32
YEAR-END FINANCIAL POSITION					
Total assets	\$ 129,310	\$ 112,009	\$ 94,025	\$ 98,390	\$ 54,402
Working capital	66,668	69,063	59,597	62,310	19,478
Long Term Liabilities	10,071	12,192	6,177	8,577	17,846
Shareholder's equity	101,439	89,395	80,226	80,421	30,227
Current ratio	5:1	8:1	9:1	8:1	4:1
Shareholder's equity per diluted common share(1)\$	5.16	\$ 4.65	\$ 4.27	\$ 4.38	\$ 2.03

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

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 the leader in preservation of human tissues for cardiovascular, vascular, and orthopaedic transplant applications. Additionally, the Company develops and commercializes



implantable medical devices, including BioGlue(R) Surgical Adhesive, tissue-engineered SynerGraft treated porcine heart valves and bovine vascular grafts, and glutaraldehyde-fixed stentless porcine heart valves. The Company's revenues are primarily generated in the United States. In 2001, 2000, and 1999, approximately 7%, 7%, and 6%, respectively, of total revenues were derived from international sources.

Prior to December 2001 the Company sold BioGlue Surgical Adhesive in the United States as an adjunct in the repair of acute thoracic aortic dissections pursuant to an HDE. In December 2001, the Company received FDA approval for BioGlue's use as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. As a result, the number of annual procedures 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.

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 fibrin lysis (blood clot dissolving) and other drug delivery applications.

#### 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 the 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 United States, 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.

**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. 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 collection based on a number of factors, including past transaction history with the customer and the credit-worthiness of the customer.

**DEFERRED PRESERVATION COSTS:** Tissue is procured from deceased human donors by organ procurement agencies and tissue banks 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 on a first-in, first-out basis.

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**INTANGIBLE ASSETS:** Goodwill resulting from business acquisitions is amortized on a straight-line basis over 20 years. 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). The Company periodically evaluates the recoverability of noncurrent tangible and intangible assets and measures the amount of impairment, if any. Beginning January 1, 2002 goodwill will no longer be amortized but rather will be subject to periodic impairment testing.

#### NEW ACCOUNTING PRONOUNCEMENTS

On July 1, 2001 the Company was required to adopt Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" (SFAS 141). On

January 1, 2002 the Company was required to adopt SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), and SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"). SFAS 141 prohibits pooling-of-interests accounting for acquisitions. SFAS 142 specifies that goodwill and certain other intangible assets will no longer be amortized but instead will be subject to periodic impairment testing. SFAS 144 clarifies accounting and reporting for assets held for sale, scheduled for abandonment or other disposal, and recognition of impairment loss related to the carrying value of long-lived assets. The adoption of these statements did not have a material effect on the consolidated financial statements of the Company.

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 asset 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.

## RESULTS OF OPERATIONS

### YEAR ENDED DECEMBER 31, 2001 COMPARED TO YEAR ENDED DECEMBER 31, 2000

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 are 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. There is a risk that tissue preservation services revenues in 2002 could be adversely affected by concerns about post-transplant infections. See "Risk Factors - Infectious Diseases and Microbial Contamination."

Revenues from the sale of BioGlue Surgical Adhesive increased 65% to \$10.6 million for 2001 from \$6.4 million in 2000, representing 12% and 8%, respectively, of total revenues during such periods. The increase in revenues is 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.

Revenues from cardiovascular preservation services decreased 4% to \$28.6 million in 2001 from \$29.7 million in 2000, representing 33% and 39%, respectively, of total revenues during such periods. 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.

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Revenues from human vascular tissue preservation services increased 15% to \$24.5 million in 2001 from \$21.3 million in 2000, representing 28% of total revenues during such periods. 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.

Revenues from human orthopaedic tissue preservation services increased 39% to \$22.5 million in 2001 from \$16.1 million in 2000, representing 26% and 21%, respectively, of total revenues during such periods. 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 are 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 are partially offset by a decrease in boned tendon shipments resulting in a \$900,000 decrease in revenues in 2001 as compared to 2000.

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 is 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.

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 is 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.

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.

Cost of human tissue preservation services aggregated \$31.1 million in 2001 compared to \$27.5 million in 2000, representing 41% of total human tissue preservation service revenues during each periods. 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 is 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 relates 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.

Net, interest income and expense was \$1.9 million and \$1.7 million in 2001 and 2000, respectively. The 2001 increase in net interest income and expense is 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 consists 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.

#### YEAR ENDED DECEMBER 31, 2000 COMPARED TO YEAR ENDED DECEMBER 31, 1999

Revenues increased 16% to \$77.1 million in 2000 from \$66.7 million in 1999. The increase in revenues was primarily due to increased acceptance in the medical community of preserved tissues which has resulted in increased demand for the Company's preservation services, the Company's ability to procure greater amounts of tissue, revenues attributable to the Company's introduction of BioGlue Surgical Adhesive in domestic markets in January of 2000, and other reasons discussed below. These increases in revenues were partially offset by decreases in other revenues.

Revenues from the sale of BioGlue Surgical Adhesive increased 287% to \$6.4 million for 2000 from \$1.7 million in 1999, representing 8% and 2%, respectively, of total revenues during such periods. The increase in revenues is due to a 177% increase in the number of milliliter shipments of BioGlue. The increase in shipments was primarily due to the introduction of BioGlue in domestic markets in January of 2000 pursuant to an HDE for the use of BioGlue as an adjunct in the repair of acute thoracic aortic dissections, as well as greater product awareness since the introduction of BioGlue in international markets in April of 1998, increased surgeon training, and the receipt of the CE approval for pulmonary indications in Europe in March 1999.

Revenues from cardiovascular preservation services increased 2% to \$29.7 million in 2000 from \$29.0 million in 1999, representing 39% and 44%, respectively, of total revenues during such periods. This increase in revenues resulted from a 5% increase in the number of cardiovascular tissue shipments due to increased demand.

Revenues from human vascular tissue preservation services increased 10% to \$21.3 million in 2000 from \$19.3 million in 1999, representing 28% and 29%, respectively, of total revenues during such periods. This increase in revenues was primarily due to an 11% increase in the number of vascular allograft shipments due to an increased demand for saphenous vein, a 38% increase in vascular tissues procured and processed year over year, and the growth in demand for the Company's cryopreserved femoral vein and artery for dialysis access.

Revenues from human orthopaedic tissue preservation services increased 44% to \$16.1 million in 2000 from \$11.2 million in 1999, representing 21% and 17%, respectively, of total revenues during such periods. This increase in revenues was primarily due to a 45% increase in the number of allograft shipments due to increased acceptance of osteochondral grafts and non-bone tendons by the orthopaedic surgeon community and a 12% increase in the orthopaedic tissues procured and processed year over year.

Revenues from bioprosthetic cardiovascular devices decreased 19% to \$771,000 in 2000 from \$955,000 in 1999, representing 1% of total revenues during such periods. This decrease in revenues is primarily due to the Company's focus on the start-up of the SynerGraft heart valve manufacturing process, which adversely impacted its ability to manufacture other bioprosthetic cardiovascular devices.

Revenues from IFM decreased 41% to \$2.2 million in 2000 from \$3.7 million in 1999, representing 3% and 6%, respectively, of total revenues during such periods. The decrease in revenues is due to HMP's default under its manufacturing agreement and to the sale of the remaining assets of IFM to HMP as more fully discussed in Note 3 to the consolidated financial statements.

Grant revenues decreased to \$616,000 in 2000 from \$877,000 in 1999. Grant revenues are primarily attributable to the SynerGraft and BioGlue research and development programs.

Cost of human tissue preservation services aggregated \$27.5 million in 2000 compared to \$24.4 million in 1999, representing 41% of total human tissue preservation service revenues in each period. Cost of products aggregated \$5.8 million in 2000 and 1999, representing 62% and 91%, respectively, of total

product revenues. The decrease in the 2000 cost of products as a percentage of product revenues primarily results from an increase in revenues from BioGlue Surgical Adhesive, which carries higher gross margins than bioprosthetic devices.

General, administrative, and marketing expenses increased 16% to \$28.7 million in 2000, compared to \$24.7 million in 1999, representing 37% of total preservation and product revenues for each period. The increase in expenditures in 2000 resulted from expenses incurred to support the increase in revenues and \$1.4 million of expenses associated with the establishment of the Company's European headquarters.

Research and development expenses increased 18% to \$5.2 million in 2000, compared to \$4.4 million in 1999, representing 7% of total preservation and product revenues for each period. Research and development spending relates principally to the Company's ongoing human clinical trials for its BioGlue Surgical Adhesive and to its focus on its SynerGraft technologies.

The Company recorded a nonrecurring charge of \$2.4 million in 1999 primarily as a result of HMP's default on its manufacturing contract with IFM. See Note 3 to the consolidated financial statements for a more complete discussion of this charge.

Net interest income and expense was \$1.7 million and \$1.2 million in 2000 and 1999, respectively. This increase in interest income was due primarily to the increase in cash generated from operations during the year ended December 31, 2000.

The effective income tax rate was 33% and 32% for the years ended December 31, 2000 and 1999, 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. 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, 2001 net working capital was \$66.7 million, compared to \$69.1 million at December 31, 2000, with a current ratio of 5 to 1. The Company's primary capital requirements arise out of general working capital needs, capital expenditures and lease payments for facilities and equipment, and funding of research and development projects. The Company historically has funded these requirements through bank credit facilities, cash generated by operations, and equity offerings.

Net cash provided by operating activities was \$6.5 million in 2001, as compared to \$10.3 million in 2000. This decrease in cash provided was primarily due to an increase in working capital requirements due to sales growth and expansion of product lines, largely offset by an increase in net income before depreciation, taxes, and non-cash items.

Net cash used in investing activities was \$18.1 million in 2001, as compared to \$6.3 million in 2000. This increase in cash used was primarily attributable to an increase in capital expenditures due to the expansion of the Company's corporate headquarters and manufacturing facilities, an increase in net marketable securities primarily due to the reinvestment of the proceeds of debt securities as they mature, partially offset in 2001 by an increase in proceeds of the note receivable received in the sale of the IFM assets and product line.

The expansion of the Company's corporate headquarters and manufacturing facilities was substantially completed in the first quarter of 2002. At December 31, 2001, the Company had spent approximately \$16.3 million on the expansion and had approximately \$1.5 million remaining to be paid on the expansion contract.

Net cash provided by financing activities was \$1.3 million in 2001, as compared to \$7.4 million in 2000. This decrease was primarily attributable to a decrease in the proceeds from the issuance of debt under the Company's term loan in 2001, an increase in the principle payments of debt and a decrease in proceeds from stock option exercises, partially offset by the lack of treasury stock repurchases in 2001 as compared to the prior year.

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

	Total	2002	2003	2004	Thereafter
Debt	\$11,593	\$5,993	\$1,600	\$1,600	\$2,400
Capital Lease Obligations	4,480	843	843	843	1,951
Operating Leases	28,856	2,283	1,977	1,911	22,685
<b>Total Contractual Obligations</b>	<b>\$44,929</b>	<b>9,119</b>	<b>4,420</b>	<b>4,354</b>	<b>27,036</b>

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 contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios and a minimum tangible net worth requirement. As of December 31, 2001 the Company was in compliance with these covenants.

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.

At December 31, 2001 the notional amount of this swap agreement was \$3.6 million. The Company paid a weighted average rate of 6.9% on the Term Loan during 2001, adjusted for the effect of the interest rate swap. The fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$293,000 at December 31, 2001. The fair value of the swap agreement is recorded as part of long-term liabilities and is recorded net of tax as part of accumulated other comprehensive income within the Statement of Shareholders' Equity.

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., 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, fibrin lysis (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, if successful, will 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 anticipates that current cash, marketable securities and cash generated from operations will be sufficient to meet its operating and development needs for at least the next 12 months. However, the Company's future liquidity and capital requirements beyond that period will depend upon numerous factors, including the timing of the Company's receipt of FDA approvals to begin clinical trials for its products currently in development, the resources required to further develop its marketing and sales capabilities if and when those products gain approval, the resources required for any additional expansion of its corporate headquarters and manufacturing facility, the extent to which the Company's products generate market acceptance and demand, and the outcome of the litigation described at Item 3 of this Form 10-K. There can be no assurance the Company will not require additional financing or will not seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet future requirements. These 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, and results of operations.

#### 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 bioprosthesis devices, funding to continue development of ACT, estimated dates relating to the Company's proposed regulatory submissions, expectations regarding the adequacy of financing 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 most 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 equivalents of \$7.2 million and short-term investments in municipal obligations of \$17.8 million as of December 31, 2001, 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 interest income for 2001.

The Company manages interest rate risk through the use of fixed debt and an interest rate swap agreement. At December 31, 2001 approximately \$8 million of the Company's \$12 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 interest expense for 2001.

#### 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.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

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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, 2002. 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, 2002.

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, 2002.

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 "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, 2002.

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, 2002.

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PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K.

The following are filed as part of this report:



(a) 1. Financial Statements

Report of Independent Public Accountants

Consolidated Balance Sheets as of December 31, 2001 and 2000

Consolidated Income Statements as of December 31, 2001, 2000 and 1999

Consolidated Statements of Cash Flows as of December 31, 2001, 2000 and 1999

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2001, 2000, 1999 and 1998

Notes to Consolidated Financial Statements.

2. Financial Statement Schedule

Report of Independent Public Accountants on Schedule II

Schedule II--Valuation and Qualifying Accounts

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

3. A. Exhibits

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

EXHIBIT NUMBER	DESCRIPTION
2.1	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 Form 10-K for the fiscal year ended December 31, 2000).
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).
4.2	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)

- 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.)
- 10.2 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.)
- 10.3 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).)
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- 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.)
  - 10.10 Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
  - 10.11 Terms of Agreement Between Bruce J. Van Dyne, M.D. and CryoLife, Inc. dated November 1, 1999. (Incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)
  - 10.12 Technology Acquisition Agreement between the Company and Nicholas Kowanko, Ph.D., dated March 14, 1996. (Incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
  - 10.13 Option Agreement, by and between the Company and Duke University, dated July 9, 1990, as amended by that Option Agreement Extension, by and between the parties, dated July 9, 1991. (Incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
  - 10.14 Research and License Agreement by and between Medical University of South Carolina and CryoLife dated November 15, 1985, as amended by Amendment to the Research and License Agreement dated February 25, 1986 by and between the parties and an Addendum to Research and License Agreement by and between the parties, dated March 4, 1986. (Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
  - 10.15 CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated by reference to Appendix 2 to the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
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- 10.16 Lease Agreement between the Company and Aml 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 Aml 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 Aml Land Development- I Limited Partnership, dated August 6, 1999. (Incorporated by reference to Exhibit 10.16(b) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
  - 10.18 CryoLife, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit "A" of the Registrant's Definitive Proxy Statement filed with the Securities and Exchange Commission on April 10, 1996.)

- 10.19 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.)
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- 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.)

- 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.)
- 10.34 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.)

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- 21.1\* Subsidiaries of CryoLife, Inc.
- 23.1\* Consent of Arthur Andersen LLP.
- 99.1\* Letter re: Arthur Andersen.

\* Filed herewith.

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

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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. Employment Agreement, by and between the Company and Gerald B. Seery. (Incorporated by reference to Exhibit 10.9(e) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995.)
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 Exhibit 10.15 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)
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 Exhibit 10.34 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)

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.)

(b) Reports on Form 8-K

1. NONE.

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SIGNATURES

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

CRYOLIFE, INC.

March 29, 2002

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

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

SIGNATURE	TITLE	DATE
/s/ STEVEN G. ANDERSON ----- STEVEN G. ANDERSON	President, Chief Executive Officer  and Chairman of the Board of Directors (Principal Executive Officer)	March 29, 2002
/s/ D. ASHLEY LEE ----- D. ASHLEY LEE	Vice President and Chief Financial  Officer (Principal Financial and Accounting Officer)	March 29, 2002
/s/ RONALD D. MCCALL ----- RONALD D. MCCALL	Director	March 29, 2002
/s/ VIRGINIA C. LACY ----- VIRGINIA C. LACY	Director	March 29, 2002
/s/ RONALD CHARLES ELKINS, M.D. ----- RONALD CHARLES ELKINS, M.D.	Director	March 29, 2002
/s/ JOHN M. COOK ----- JOHN M. COOK	Director	March 29, 2002

## REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To CryoLife, Inc.

We have audited, in accordance with auditing standards generally accepted in the United States, the consolidated financial statements included in CryoLife, Inc.'s 2001 annual report to stockholders and this Form 10-K and have issued our report thereon dated March 27, 2002. Our audits were made for the purpose of forming an opinion on those financial statements taken as a whole. The schedule listed in Item 14 of this Form 10-K is the responsibility of the Company's management, is presented for purposes of complying with the Securities and Exchange Commission's rules, and is not part of the basic financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

/s/ Arthur Andersen LLP

Atlanta, Georgia  
March 27, 2002

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## SCHEDULE II

## CRYOLIFE, INC. AND SUBSIDIARIES

## VALUATION AND QUALIFYING ACCOUNTS

YEARS ENDED DECEMBER 31, 2001, 2000, AND 1999

DESCRIPTION -----	BALANCE BEGINNING OF PERIOD -----	ADDITIONS -----	DEDUCTIONS -----	BALANCE END OF PERIOD -----
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
Year ended December 31, 1999				
Allowance for doubtful accounts.....	\$ 256,000	\$521,000	\$249,000	\$528,000
Deferred preservation costs.....	53,000	235,000	137,000	151,000

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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.

s/ Arthur Andersen LLP  
Atlanta, Georgia  
March 27, 2002

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

ASSETS	2001	2000
December 31,		
-----		
Current assets:		
-----		
Cash and cash equivalents	\$ 7,204	\$ 17,480
Marketable securities, at market	26,483	21,234
Receivables:		
Trade accounts, less allowance for doubtful accounts of \$100 in 2001 and \$85 in 2000	13,305	11,454
Note receivable, less allowance of \$250 in 2001 and \$723 in 2000	1,169	1,833
Income taxes	1,557	574
Other	1,263	711
-----		
Total receivables	17,294	14,572
-----		
Deferred preservation costs, less reserve of \$300 in 2001 and \$229 in 2000	24,199	20,311
Inventories	6,259	3,994
Prepaid expenses	2,341	1,220
Deferred income taxes	688	674
-----		
Total current assets	84,468	79,485
-----		
Property and equipment:		
-----		

Land	1,009	--
Equipment	18,998	15,296
Furniture and fixtures	5,347	4,348
Leasehold improvements	24,990	14,149
Construction in progress	7,767	8,219
	58,111	42,012
Less accumulated depreciation and amortization	18,865	15,601
Net property and equipment	39,246	26,411
Other assets:		
Note receivable, less allowance of \$241 in 2000	--	643
Goodwill, less accumulated amortization of \$501 in 2001 and \$405 in 2000	1,399	1,495
Patents, less accumulated amortization of \$1,102 in 2001 and \$850 in 2000	2,919	2,540
Other, less accumulated amortization of \$135 in 2001 and \$91 in 2000	1,278	1,264
Deferred income taxes	--	171
Total assets	\$ 129,310	\$ 112,009

See accompanying notes to consolidated financial statements.

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

LIABILITIES AND SHAREHOLDERS' EQUITY	2001	2000
December 31,		
Current liabilities:		
Accounts payable	\$ 555	\$ 2,354
Accrued expenses	1,491	767
Accrued compensation	2,560	2,097
Accrued procurement fees	6,592	4,097
Current maturities of capital lease obligation	609	173
Current maturities of long-term debt	1,600	934
Convertible debenture	4,393	--
Total current liabilities	17,800	10,422
Capital lease obligations, less current maturities	3,140	1,361
Convertible debenture	--	4,393
Bank line of credit, less current maturities	5,600	6,151
Deferred income taxes	449	--
Other long-term liabilities	882	287
Total liabilities	27,871	22,614
Commitments and Contingencies		
Shareholders' equity:		
Preferred stock \$.01 par value per share; authorized 5,000 shares including 2,000 shares of series A junior participating preferred stock; no shares issued	--	--
Common stock \$.01 par value per share;		

authorized 75,000 shares; issued 20,172 in 2001 and 20,077 shares in 2000			
Additional paid-in capital		202	201
Retained earnings		66,828	64,936
Deferred compensation		40,547	31,381
Accumulated other comprehensive income, net of tax		(33)	(45)
Treasury stock; 1,286 shares in 2001 and 1,356 shares in 2000, at cost		(145)	(1,088)
		(5,960)	(5,990)
-----			
Total shareholders' equity		101,439	89,395
-----			
Total liabilities and shareholders' equity	\$	129,310	\$ 112,009
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See accompanying notes to consolidated financial statements.

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

Year Ended December 31,	2001	2000	1999
-----			
Revenues:			
Human tissue preservation services	\$ 75,552	\$ 67,096	\$ 59,516
Products	11,130	9,384	6,329
Research grants	989	616	877
	87,671	77,096	66,722
-----			
Costs and Expenses:			
Human tissue preservation services	31,165	27,500	24,416
Products	5,464	5,847	5,754
General, administrative, and marketing	33,844	28,731	24,693
Research and development	4,737	5,207	4,396
Nonrecurring charges	--	--	2,355
Interest expense	96	299	387
Interest income	(1,967)	(1,952)	(1,556)
Other expense (income), net	852	(169)	(224)
	74,191	65,463	60,221
-----			
Income before income taxes	13,480	11,633	6,501
Income tax expense	4,314	3,816	2,050
-----			
Net income	\$ 9,166	\$ 7,817	\$ 4,451
-----			
Earnings per share:			
Basic	\$ 0.49	\$ 0.42	\$ 0.24
-----			
Diluted	\$ 0.47	\$ 0.41	\$ 0.24
-----			
Weighted average shares outstanding:			
Basic	18,808	18,541	18,512
-----			
Diluted	19,660	19,229	18,800
-----			

See accompanying notes to consolidated financial statements.

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

Year Ended December 31,	2001	2000	1999
-----			
Net cash flows from operating activities:			
-----			
Net income	\$ 9,166	\$ 7,817	\$ 4,451
Adjustments to reconcile net income to net cash flows provided by operating activities:			
Deferred income recognized	--	--	(1,176)
Gain on sale of marketable equity securities	(9)	--	(112)
Depreciation of property and equipment	4,203	3,023	2,854
Amortization	404	199	300
Provision for doubtful accounts	304	21	121
Other non-cash adjustments to income	348	--	--
Deferred income taxes	624	1,658	(970)
Nonrecurring charges	--	--	2,355
Tax effect of non-qualified option exercises	421	595	--
Changes in operating assets and liabilities:			
Trade and other receivables	(2,707)	469	(1,707)
Income taxes	(983)	(543)	40
Deferred preservation costs	(3,888)	(2,659)	(3,413)
Inventories	(2,265)	(1,433)	(2,882)
Prepaid expenses and other assets	(1,121)	234	822
Accounts payable	(1,814)	535	(686)
Accrued expenses and other liabilities	3,796	367	1,321
-----			
Net cash flows provided by operating activities	6,479	10,283	1,318
-----			
Net cash flows from investing activities:			
-----			
Capital expenditures	(14,329)	(9,491)	(3,853)
Other assets	(689)	39	(783)
Purchases of marketable securities	(29,336)	(5,729)	(5,123)
Sales and maturities of marketable securities	24,235	8,542	6,149
Proceeds from notes receivable	2,020	360	--
-----			
Net cash flows used in investing activities	(18,099)	(6,279)	(3,610)
-----			
Net cash flows from financing activities:			
-----			
Principal payments of debt	(1,050)	(287)	(514)
Proceeds from debt issuance	1,165	6,835	--
Principal payments on obligations under capital leases	(291)	(180)	(224)
Proceeds from exercise of options and issuance of stock	1,502	1,660	571
Purchase of treasury stock	--	(612)	(4,296)
-----			
Net cash flows provided by (used in) financing activities	1,326	7,416	(4,463)
-----			
(Decrease) Increase in cash	(10,294)	11,420	(6,755)
Effect of exchange rate changes on cash	18	(68)	(2)
-----			
Cash and cash equivalents, beginning of year	17,480	6,128	12,885
-----			
Cash and cash equivalents, end of year	\$ 7,204	\$ 17,480	\$ 6,128
-----			
Supplemental disclosures of cash flow information - cash paid during the year for:			
-----			
Interest	\$ 896	\$ 471	\$ 369
Income taxes	4,996	2,215	3,816
-----			
Non-cash investing and financing activities:			
-----			
Establishing capital lease obligation	\$ 2,506	\$ --	\$ --
-----			
Purchase of property and equipment in accounts payable and accrued expenses	\$ 203	\$ 844	\$ 6
-----			

See accompanying notes to consolidated financial statements.

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

	Common Shares Outstanding Shares	Amount	Additional Paid-In Capital	Retained Earnings	Deferred Compensation	Accumulated Other Comprehensive Income	Treasury Stock Shares	Amount	Total Shareholders' Equity
Balance at December 31, 1998	20,041	\$200	\$64,281	\$19,113	\$--	\$139	(1,268)	\$(3,312)	\$80,421
Net income	--	--	--	4,451	--	--	--	--	4,451
Other comprehensive income, net of taxes	--	--	--	--	--	(924)	--	--	(924)
Comprehensive income									3,527
Exercise of options	--	--	(126)	--	--	--	74	305	179
Employee stock purchase plan	--	--	144	--	--	--	60	248	392
Issuance of stock options to a nonemployee	--	--	60	--	(60)	--	--	--	--
Amortization of deferred compensation	--	--	--	--	3	--	--	--	3
Purchase of treasury stock	--	--	--	--	--	--	(567)	(4,296)	(4,296)
Balance at December 31, 1999	20,041	200	64,359	23,564	(57)	(785)	(1,701)	(7,055)	80,226
Net income	--	--	--	7,817	--	--	--	--	7,817
Other comprehensive income, 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)
Balance at December 31, 2000	20,077	201	64,936	31,381	(45)	(1,088)	(1,356)	(5,990)	89,395
Net income	--	--	--	9,166	--	--	--	--	9,166
Other comprehensive income, net of taxes	--	--	--	--	--	943	--	--	943
Comprehensive income									10,109
Exercise of options	87	1	1,268	--	--	--	46	(78)	1,191
Employee stock purchase plan	8	--	624	--	--	--	24	108	732
Amortization of deferred compensation	--	--	--	--	12	--	--	--	12
Balance at December 31, 2001	20,172	\$202	\$66,828	\$40,547	\$(33)	\$(145)	(1,286)	\$(5,960)	\$101,439

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 the leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular and orthopaedic surgeries throughout the United States and Canada. The Company's human tissue cryopreservation services are marketed in North America, Europe, South America, and Asia. The Company's BioGlue(R) Surgical Adhesive is FDA approved in the United States 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 general surgical repair. The Company's bioprosthetic implantable devices include stentless porcine heart valves marketed in Europe, South America, the Middle East, Canada, and South Africa, as well as tissue-engineered SynerGraft(R) porcine heart valves and SynerGraft 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 fibrin lysis (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.

#### RECLASSIFICATIONS

Certain prior year balances have been reclassified to conform to the 2001 presentation.

#### USE OF ESTIMATES

The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States 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 are used when accounting for depreciation, allowance for doubtful accounts, 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. Revenues for products are recognized at the time the product is shipped, at

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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 collection based on a number of factors, including past transaction history with the customer and the credit-worthiness of the customer.

#### 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, 2001 and 2000, 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 procurement agencies and tissue banks, 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.

#### 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

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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

Goodwill resulting from business acquisitions is amortized on a straight-line basis over 20 years. 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). The Company periodically evaluates the recoverability of noncurrent tangible and intangible assets and measures the amount of impairment, if any. Beginning January 1, 2002 goodwill will no longer be amortized but rather will be subject to periodic impairment testing.

#### LONG-LIVED ASSETS

The Company records impairment losses on long-lived assets in operations when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets.

#### 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.

#### 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.

#### 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 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

Statement of Financial Accounting Standards ("SFAS") No. 130, "Reporting Comprehensive Income" ("SFAS 130"), establishes 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

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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 equity.

#### NEW ACCOUNTING PRONOUNCEMENTS

On July 1, 2001 the Company was required to adopt SFAS No. 141, "Business Combinations" (SFAS 141"). On January 1, 2002 the Company was required to adopt SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), and SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"). SFAS 141 prohibits pooling-of-interests accounting for acquisitions. SFAS 142 specifies that goodwill and certain other intangible assets will no longer be amortized but instead will be subject to periodic impairment testing. SFAS 144 clarifies accounting and reporting for assets held for sale, scheduled for abandonment or other disposal, and recognition of impairment loss related to the carrying value of long-lived assets. The adoption of these statements did not have a material effect on the consolidated financial statements of the Company. However, the adoption of SFAS 142 will increase the Company's pretax income by approximately \$100,000 in 2002 due to the cessation of goodwill amortization.

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 asset 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.

#### 2. CASH EQUIVALENTS AND MARKETABLE SECURITIES

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

December 31, 2001	Cost Basis	Adjustments to Cost Basis	Adjusted Cost Basis	Unrealized Holding Gains/(Losses)	Estimated Market Value
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>

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December 31, 2000	Cost Basis	Adjustments to Cost Basis	Adjusted Cost Basis	Unrealized Holding Gains/ (Losses)	Estimated Market Value
Cash equivalents:					
Money market funds	\$ 3,413	\$ --	\$ 3,413	\$ --	\$ 3,413
Municipal obligations	4,900	--	4,900	--	4,900
	<u>\$ 8,313</u>	<u>--</u>	<u>\$ 8,313</u>	<u>--</u>	<u>\$ 8,313</u>
Marketable securities:					
Municipal obligations	12,887	--	12,887	(2)	12,885
Debt securities	5,989	--	5,989	(580)	5,409
Equity securities	3,900	--	3,900	(960)	2,940
	<u>\$ 22,776</u>	<u>--</u>	<u>\$ 22,776</u>	<u>\$ (1,542)</u>	<u>\$ 21,234</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 gains on sales of available-for-sale securities totaled \$9,000 and zero in 2001 and 2000, respectively. Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of \$50,000 at December 31, 2001 and a net unrealized holding loss less a deferred tax benefit of \$524,000 as of December 31, 2000, are included as a separate component of shareholders' equity.

At December 31, 2001 and 2000, approximately \$3.4 million and \$5.9 million, respectively, of marketable securities had a maturity date between 90 days and 1 year, and approximately \$23.1 million and \$15.3 million of marketable securities mature between 1 and 5 years.

### 3. 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 consolidation 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 pretax effect of the above nonrecurring charges was \$2.2 million and has been included under the caption "Nonrecurring charges" in the accompanying Consolidated Income Statements. At December 31, 1999, after recognition of the impairment loss, IFM assets consisted of \$800,000 of accounts receivable, \$1.7 million of inventory, \$1.6 million of building, and \$360,000 of equipment.

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 \$1.1 million remained to be forgiven if all payments are made according to the terms of the note. At December 31, 2001 the Company reassessed the

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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 Income Statements. The Company will continue to evaluate the collectibility of the note and adjust the reserve accordingly.

#### 4. INVENTORIES

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

	2001	2000
Raw materials	\$ 1,987	\$ 1,796
Work in process	1,183	405
Finished goods	3,089	1,793
	\$ 6,259	\$ 3,994

5. LONG-TERM DEBT

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

	2001	2000
5-year term loan, bearing interest equal to the Adjusted LIBOR plus 1.5%, to be adjusted monthly	\$ 7,200	\$ 6,835
7% convertible debenture, due in March 2002	4,393	4,393
8.25% note payable due in equal annual installments of \$250,000	--	250
Total debt	11,593	11,478
Less current maturities	5,993	934
Total long-term debt	\$ 5,600	\$ 10,544

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% (3.64% at December 31, 2001). The Term Loan contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios and a minimum tangible net worth requirement. The Term Loan is secured by substantially all of the Company's assets. As of December 31, 2001 the Company was in compliance with these covenants.

In March 1997 the Company issued a \$5.0 million convertible debenture in connection with the IFM acquisition. The debenture bears interest at 7% and is due in March 2002. The debenture is convertible into common stock of the Company at any time prior to the due date at \$8.05 per common share. In conjunction with the Company's follow-on equity offering in April of 1998, \$607,000 of the convertible debenture was converted into 75,000 shares of the Company's common stock on March 30, 1998.

On September 12, 1996 the Company acquired the assets of United Cryopreservation Foundation, Inc. ("UCFI"), a processor and distributor of cryopreserved human heart valves and saphenous veins for transplant. The Company issued a \$1.25

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million note in connection with the acquisition. The note bears interest at prime, as adjusted annually on the anniversary date of the acquisition. The Company made the final payment on this note in 2001.

As amended on June 12, 1998, the Company executed a revolving loan agreement (the "Loan Agreement") with a bank which permitted the Company to borrow up to \$2.0 million at either the bank's prime rate of interest or at adjusted LIBOR, as defined, plus an applicable LIBOR margin. The Loan Agreement expired on December 31, 2001.

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

2002	\$ 5,993
2003	1,600
2004	1,600
2005	1,600
2006	800
Thereafter	--
	-----
	\$ 11,593

Total interest costs were \$915,000, \$528,000, and \$387,000 in 2001, 2000, and 1999 which included \$819,000, \$229,000, and \$0, respectively, of interest capitalized in connection with the expansion of the corporate headquarters and manufacturing facilities.

## 6. 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 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.

At December 31, 2001 the notional amount of this swap agreement was \$3.6 million. The Company paid a weighted average rate of 6.9% on the Term Loan during 2001, adjusted for the effect of the interest rate swap. The fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$293,000 at December 31, 2001. The fair value of the swap agreement is recorded as part of long-term liabilities and is recorded net of tax as part of accumulated other comprehensive income within the Statement of Shareholders' Equity.

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## 7. FAIR VALUES OF FINANCIAL INSTRUMENTS

SFAS No. 107, "Disclosures about Fair Value of Financial Instruments", requires the Company to disclose estimated fair values for its financial instruments. The carrying amounts of receivables and accounts payable approximate their fair values due to the short-term maturity of these instruments. The carrying value of the Company's other financial instruments approximated fair value at December 31, 2001 and 2000.

## 8. 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 3. 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, 2001 are as follows (in thousands):

	Capitalized Leases		Operating Leases
2002	\$ 843	\$	2,283
2003	843		1,977
2004	843		1,911
2005	843		1,905
2006	843		1,943
Thereafter	265		18,837
Total minimum lease payments	4,480	\$	28,856

Less amount representing interest	731
-----	
Present value of net minimum	
lease payments	3,749
Less current portion	609
-----	
	\$ 3,140
=====	

Property acquired under capital leases at December 31, 2001 consists of the following (in thousands):

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

Total rental expense for operating leases amounted to \$2,243,000, \$1,478,000, and \$1,457,000, for 2001, 2000, and 1999, respectively. Total rental income under the sublease was \$310,000 in 2001, \$95,000 in 2000, and zero in 1999.

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#### LITIGATION, CLAIMS, AND ASSESSMENTS

The Company is party to various legal proceedings arising in the normal course of business, most of which involve claims for personal injury and intellectual property incurred in connection with its operations. Management believes that the outcome of its various legal proceedings will not have a material adverse effect on the Company's financial position or results of operations.

On May 23, 2001 Colorado State University Research Foundation ("CSURF") filed an action in United States District Court, District of Colorado, alleging that the Company breached a March 26, 1996 Technology License Agreement between CSURF and the Company (the "TLA"). CSURF alleges that the Company uses the licensed technology in the Company's SynerGraft process and that the Company has breached the TLA by not paying royalties to CSURF on tissues processed using the SynerGraft process. The Company denies these allegations and asserts that no royalties are due to CSURF under the TLA because the Company's SynerGraft process does not utilize the licensed technology. CSURF also alleges that the Company is obliged to assign to CSURF certain Company patents and patent applications relating to the Company's SynerGraft process and that the Company engaged in deceptive conduct by not naming CSURF as owner or its representative Christopher Orton as an inventor on those Company patents and patent applications.

The case is currently in discovery. Interrogatory responses and documents have been exchanged. The Company believes that CSURF's allegations are false and that the Company will prevail in the action. Nonetheless, an adverse decision by the court could have a material adverse effect on the Company's business and results of operations.

#### 9. 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, 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, and 594,000 shares of common stock, respectively. As of December 31, 2001 and 2000, there were 128,000 and 424,000, respectively, shares of common stock reserved for future issuance under the Company's stock option plans. A summary of stock option transactions under the plans follows:

Exercise

Weighted Average

	Shares	Price	Exercise Price
Outstanding at December 31, 1998	1,240,000	\$ 2.00-11.50	\$ 7.17
Granted	503,000	7.92-11.42	9.24
Exercised	(74,000)	2.00-6.83	2.44
Canceled	(150,000)	6.83-11.42	11.30
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

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

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 6.83-8.50	526,000	2.8	\$8.11	312,000	\$ 7.99
9.00-11.50	547,000	2.9	11.20	458,000	11.22
11.63-30.14	455,000	4.7	18.75	47,000	14.25
30.73-34.10	234,000	4.7	31.61	98,000	31.99
\$ 6.83-34.10	1,762,000	3.6	\$ 14.94	915,000	\$ 12.49

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").

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:

2001	2000	1999
------	------	------

Expected dividend yield	0%	0%	0%
Expected stock price volatility	.600	.540	.540
Risk-free interest rate	4.73%	6.39%	5.78%
Expected life of options	4.2 Years	4.3 Years	3.6 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

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different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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

	2001	2000	1999
Net income--as reported	\$ 9,166	\$ 7,817	\$ 4,451
Net income--pro forma	\$ 6,934	\$ 6,634	\$ 3,421
Earnings per share--as reported:			
Basic	\$ 0.49	\$ 0.42	\$ 0.24
Diluted	\$ 0.47	\$ 0.41	\$ 0.24
Earnings per share--pro forma:			
Basic	\$ 0.37	\$ 0.36	\$ 0.19
Diluted	\$ 0.35	\$ 0.35	\$ 0.18

Other information concerning stock options follows:

	2001	2000	1999
Weighted average fair value of options granted during the year	\$ 15.20	\$ 6.97	\$ 3.75
Number of shares as to which options are exercisable at end of year	915,000	791,000	923,000

#### 10. SHAREHOLDER RIGHTS PLAN

On November 27, 1995 the Board of Directors adopted a shareholder rights plan to protect long-term share value for the Company's shareholders. Under the plan, the Board declared a distribution of one Right for each outstanding share of the Company's Common Stock to shareholders of record on December 11, 1995. Additionally, the Company has further authorized and directed the issuance of one Right with respect to each Common Share that 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.

## 11. STOCK REPURCHASE

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. The purchase of shares will be made from time-to-time in open market or privately negotiated transactions on such terms as management deems appropriate. The Company did not repurchase any shares of its common stock in 2001. As of December 31, 2001, 2000 and 1999, the Company had purchased an aggregate of 1,159,000, 1,159,000, and 1,081,000 shares, respectively, of its common stock for an aggregate purchase price of \$8,258,000, \$8,258,000, and \$7,646,000, respectively.

## 12. ACCUMULATED OTHER COMPREHENSIVE INCOME

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

	Unrealized Gain/(Loss) on Investments	Change in Fair Value of Interest Rate Swap	Translation Adjustment	Accumulated Other Comprehensive Income/(Loss)
December 31, 1998	\$ 139	\$ --	\$ --	\$ 139
1999 Change	(922)	--	(2)	(924)
December 31, 1999	(783)	--	(2)	(785)
2000 Change	(235)	--	(68)	(303)
December 31, 2000	(1,018)	--	(70)	(1,088)
2001 Change	1,125	(200)	18	943
December 31, 2001	\$ 107	\$ (200)	\$ (52)	\$ (145)

The tax effect on the change in unrealized gain/loss on investments is (\$574,000), \$121,000, and \$474,000 for 2001, 2000, and 1999, respectively. The tax effect on the change in fair value of interest rate swap is \$93,000 for 2001. The translation adjustment is not currently adjusted for income taxes as it relates to a permanent investment in a foreign subsidiary.

## 13. EMPLOYEE BENEFIT PLANS

The Company has a 401(k) savings plan (the "Plan") providing retirement benefits to all employees who have completed at least three months of service. The Company makes matching contributions of 50% of each participant's contribution up to 5% of each participant's salary. Total company contributions approximated \$384,000, \$355,000, and \$309,000, for 2001, 2000, and 1999, 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 2001, 2000, or 1999.

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, 2001 and 2000 there were 657,000, and 688,000, respectively, shares of common stock reserved under the ESPP and there had been 243,000, and 212,000, respectively, shares issued under the plan.

## 14. EARNINGS PER SHARE

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



	2001	2000	1999
Numerator for basic and diluted earnings per share -- income available to common shareholders	\$9,166	\$7,817	\$4,451
Denominator for basic earnings per share - weighted-average shares	18,808	18,541	18,512
Effect of dilutive stock options	852	688	288
Denominator for diluted earnings per share - adjusted weighted-average shares	19,660	19,229	18,800
Basic earnings per share	\$0.49	\$0.42	\$0.24
Diluted earnings per share	\$0.47	\$0.41	\$0.24

#### 15. INCOME TAXES

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

	2001	2000	1999
Current:			
Federal	\$ 4,680	\$ 2,272	\$ 2,912
State	115	(114)	108
Deferred	4,795	2,158	3,020
	(481)	1,658	(970)
	\$ 4,314	\$ 3,816	\$ 2,050

Such amounts differ from the amounts computed by applying the U.S. federal income tax rate of 35% in 2001 and 34% in 2000 and 1999 to pretax income as a result of the following (in thousands):

	2001	2000	1999
Tax expense at statutory rate	\$4,718	\$3,955	\$2,210
Increase (reduction) in income taxes			
Resulting from:			
Entertainment expenses	50	47	47
State income taxes, net of federal Benefit	108	231	163
Nontaxable interest income	(242)	(264)	(232)
Research and development credits	(200)	(125)	(100)
Structure			
Foreign sales corporation	(60)	--	--
Other	(60)	(28)	(38)
	\$4,314	\$3,816	\$2,050

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

	2001	2000
Long-term deferred tax (liabilities) assets:		
Property	\$ (550)	\$ (756)
Intangible assets	153	538
Impairment of IFM long-lived assets	(52)	--
	(449)	(218)

Current deferred tax assets (liabilities):		
Unrealized loss on interest rate swap	93	--
Unrealized loss on marketable securities	449	524
Allowance for bad debts	32	398
Accrued expenses	13	104
Deferred preservation costs and inventory reserves	96	87
Other	5	(50)
	-----	-----
	688	1,063
	-----	-----
Net deferred tax assets	\$ 239	\$ 845
	-----	=====

At December 31, 2001, the Company has recorded a net deferred tax asset of \$239,000. Realization of the net deferred tax asset is dependent on generating sufficient taxable income in future periods. Although realization is not ensured, management believes that it is more likely than not that the deferred tax asset will be realized.

#### 16. EXECUTIVE INSURANCE PLAN

Pursuant to a supplemental life insurance program for certain executive officers of the Company, the Company and the executives share in the premium payments and ownership of insurance policies on the lives of such executives. Upon death of the insured party, policy proceeds equal to the premium contribution are due to the Company with the remaining proceeds due to the designated beneficiaries of the insured party. The Company's aggregate premium contributions under this program were \$75,000, \$53,000, and \$33,000, for 2001, 2000, and 1999, respectively.

#### 17. 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, 2001 freezers with a total cost of approximately \$2.2 million and related accumulated depreciation of approximately \$1.4 million were located at the implanting hospitals' premises. Depreciation is provided over the estimated useful lives of the freezers on a straight-line basis.

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#### 18. TRANSACTIONS WITH RELATED PARTIES

The Company expensed \$87,000, \$78,000, and \$60,000, during 2001, 2000, and 1999, 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, \$102,000, and \$64,000 in 2001, 2000 and 1999, 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 \$473,000, \$44,000 and zero in 2001, 2000, and 1999, respectively, relating to research performed by the university where the same Director and shareholder holds a significant position. The Company paid \$210,000 each in 2001, 2000, and 1999 relating to consulting services performed by a shareholder of the Company.

#### 19. 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.

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

	REVENUE	COST OF PRESERVATION SERVICES AND PRODUCTS	GROSS MARGIN
2001			
Human Tissue Preservation Services	\$ 75,552	\$ 31,165	\$ 44,387
Implantable Medical Devices	11,130	5,464	5,666
All Other (a)	989	--	989
	\$ 87,671	\$ 36,629	\$ 51,042
2000			
Human Tissue Preservation Services	\$ 67,096	\$ 27,500	\$ 39,596
Implantable Medical Devices	7,176	4,068	3,108
All Other (a)	2,824	1,779	1,045
	\$ 77,096	\$ 33,347	\$ 43,749
1999			
Human Tissue Preservation Services	\$ 59,516	\$ 24,416	\$ 35,100
Implantable Medical Devices	2,612	2,941	(329)
All Other (a)	4,594	2,813	1,781
	\$ 66,722	\$ 30,170	\$ 36,552

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

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Net revenues by product for the years ended December 31, 2001, 2000 and 1999 were as follows (in thousands):

REVENUE	2001	2000	1999
Human tissue preservation services:			
Cardiovascular tissue	\$ 28,606	\$ 29,685	\$ 29,043
Vascular tissue	24,488	21,279	19,273
Orthopaedic tissue	22,458	16,132	11,200
Total preservation services	75,552	67,096	59,516
BioGlue surgical adhesive	10,595	6,405	1,657
Bioprosthetic devices	535	771	955
Single-use medical devices	--	2,208	3,717
Grant Revenue	989	616	877
	\$ 87,671	\$ 77,096	\$ 66,722

Net revenues by geographic location for the years ended December 31, 2001, 2000 and 1999 were as follows (in thousands):

REVENUE (b)	2001	2000	1999
United States	\$ 81,657	\$ 72,010	\$ 62,723
International	6,014	5,086	3,999
	\$ 87,671	\$ 77,096	\$ 66,722

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

At December 31, 2001, 2000, and 1999, over 95% of the long-lived assets of the Company were held in the United States, where all Company manufacturing

facilities and the corporate headquarters are located.

## 20. INTERIM FINANCIAL DATA

In the Company's 2001 quarterly 10-Q filings, the Company reported unaudited interim financial data, which included unrealized losses on certain marketable securities. These losses were reported on the balance sheet in other comprehensive income as a separate component of shareholder's equity. The Company had considered the unrealized losses on these marketable securities temporary, and therefore had not recognized the losses through its income statement.

Upon further evaluation the Company has concluded that the decrease in value is "other than temporary" as defined in SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities" and related guidance. This resulted in an increase in other expense of \$747,000 in the quarter ended March 31, 2001, and a cumulative loss of \$1.6 million for the year ended December 31, 2001.

The Company's unaudited quarterly results of operations for the fiscal year ended December 31, 2001 (as previously reported and revised) are as follows (in thousands, except per share amounts):

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	First Quarter		Second Quarter	Third Quarter	Fourth Quarter
	As Previously Reported	Revised	As Reported	As Reported	
Revenues	21,432	21,432	21,697	22,567	21,975
Cost of preservation services and products	9,105	9,105	9,120	9,384	9,020
General, administrative, and marketing	8,159	8,159	8,120	8,290	9,275
Research and development	1,086	1,086	1,286	1,232	1,133
Interest expense	---	---	16	37	43
Interest income	(562)	(562)	(576)	(449)	(380)
Other expense (income), net	---	747	(5)	114	(4)
Income before income taxes	3,644	2,897	3,736	3,959	2,888
Income tax expense	1,166	927	1,196	1,267	924
Net income	2,478	1,970	2,540	2,692	1,964
Earnings per share					
Basic	0.13	0.11	0.14	0.14	0.10
Diluted	0.13	0.10	0.13	0.14	0.10

## 21. SUBSEQUENT EVENT

On March 4, 2002 the \$4.4 million convertible debenture issued by the Company in March 1997 in connection with the IFM acquisition was converted into 546,000 shares of common stock at \$8.05 per common share.

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### SELECTED QUARTERLY FINANCIAL INFORMATION

(In thousands except per share data)

REVENUES	Year	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	2001	\$21,432	\$21,697	\$22,567	\$21,975
	2000	19,623	\$19,454	\$19,524	\$18,495
	1999	16,325	17,395	16,529	16,473

## NET INCOME

2001	\$1,970	\$2,540	\$2,692	\$1,964
2000	1,604	1,979	2,308	\$1,926
1999	1,380	1,727	1,714	(370)

EARNINGS PER SHARE - DILUTED <sup>1</sup>

2001	\$ 0.10	\$ 0.13	\$ 0.14	\$ 0.10
2000	0.09	0.10	0.12	0.10
1999	0.07	0.09	0.09	(0.02)

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

SUBSIDIARIES OF CRYOLIFE, INC.

Subsidiary -----	Jurisdiction -----
Ideas for Medicine, Inc.	Florida
CryoLife Technology, Inc.	Nevada
CryoLife Foreign Sales, Inc.	Barbados
CryoLife Europa, LTD.	United Kingdom
AuraZyme Pharmaceuticals, Inc.	Florida

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CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation by reference of our reports dated March 27, 2002, appearing in this Form 10-K, into the Company's previously filed Registration Statement File Nos. 333-16581, 33-83996, 33-84048, 333-03513, 333-59853, 333-59849, 333-06141, 333-34025, 333-75535, and 333-47310.

/s/ Arthur Andersen LLP

Atlanta, Georgia  
March 27, 2002

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CryoLife, Inc.  
1655 Roberts Blvd.  
Kennesaw, GA 30144

March 29, 2002

SECURITIES AND EXCHANGE COMMISSION  
450 5th Street, N.W.  
Washington D.C. 20549

Dear Sirs:

Re: CryoLife, Inc.  
Form 10-K for the year ended December 31, 2001  
Filed March 29, 2002

This letter is written in accordance with your Temporary Final Rule and Final Rule: Requirements for Arthur Andersen LLP Auditing Clients Release Nos. 33-8070, 34-45590; 35-27503; 39-2395; IA-2018; IC-25464; FR-62; File No. S7-03-02 that became effective on March 18, 2002 (the "Andersen Release").

Our Annual Report on Form 10-K for the year ended December 31, 2001 was filed with the Securities and Exchange Commission on March 29, 2002 and included the accountant's reports of Arthur Andersen LLP ("Andersen") on our consolidated financial statements. In accordance with Temporary Note 3T to Article 3 of Regulation S-X (as announced in the Andersen Release), please be advised that Andersen has represented to us in writing the audit was subject to Andersen's quality control system for the U.S. accounting and auditing practice, that the engagement was conducted in compliance with professional standards and that there was appropriate continuity of Andersen personnel working on audits and availability of national office consultation. Availability of personnel at foreign affiliates is not relevant to this audit.

Very truly yours,

CryoLife, Inc.

By: /s/ D. Ashley Lee

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Chief Financial Officer