FORM 10-K/A
AMENDMENT NO. 1

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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

For the fiscal year ended December 31, 1997
OR
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 1-13165

CRYOLIFE, INC.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

None

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 $111,802,000 at February 18, 1998 (7,985,863 shares). The number of common shares outstanding at February 18, 1998 was 9,700,791 (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, 1998.

PART I

ITEM 1. BUSINESS.

OVERVIEW

CryoLife is the leader in the cryopreservation of viable human tissues for cardiovascular, vascular and orthopaedic transplant applications, and develops and commercializes additional implantable products and single-use medical devices. The Company estimates that it provided approximately 80% of the cryopreserved human tissue implanted in the U.S. in 1997. The Company uses its expertise in biochemistry and cell biology, and its understanding of the needs of the cardiovascular, vascular and orthopaedic surgery medical specialties, to continue expansion of its core cryopreservation business and to develop or acquire complementary implantable products and technologies for these fields. The Company develops bioprosthetic cardiovascular devices including a novel design stentless porcine heart valve currently marketed in the European Community. The Company also develops proprietary implantable surgical bioadhesives, including BioGlue surgical adhesive, which it has begun commercializing for vascular applications within the European Community. In addition, the Company manufactures and distributes, through its Ideas For Medicine, Inc. ("IFM") subsidiary, single-use medical devices for use in vascular surgical procedures. The Company has generated compound annual growth rates in revenues and earnings per share, including contributions from acquisitions, of 24% and 68%, respectively, since 1993.

CryoLife processes and distributes for transplantation cryopreserved human heart valves and conduits, human vascular tissue and human connective tissue for the knee. Revenues from these services, which were $44.2 million, or 87% of total revenues, in 1997, have grown at a compound annual growth rate of 24% since 1993. Management believes that cryopreserved human heart valves and conduits offer certain advantages over mechanical, synthetic and animal-derived alternatives. Depending on the alternative, these advantages include more natural functionality, elimination of a chronic need for anti-coagulation drug therapy, reduced incidence of reoperation and reduced risk of catastrophic failure, thromboembolism (stroke) or calcification. The Company estimates that the potential U.S. market for implantable products targeting indications addressed by the Company's cryopreserved tissues was approximately $950 million in 1997. Since 1993, cryopreserved human tissues have captured an increasing share of this market as the total U.S. replacement heart valve market and CryoLife's revenues from cryopreservation of human heart valves and conduits grew at compound annual growth rates of approximately 7% and 21%, respectively. The Company seeks to expand the availability of human tissue through its established relationships with over 250 tissue banks and organ procurement agencies nationwide.

CryoLife develops and markets outside of the U.S. bioprosthetic cardiovascular devices for transplantation, currently consisting of fixed stentless porcine heart valves. 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. Fixed porcine heart valves address a worldwide target market estimated to have been $175 million in 1997. 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 bacterial infection. The Company's CryoLife-O'Brien aortic heart valve, currently marketed in the European Community and certain other territories outside the U.S., is a stentless porcine heart valve which contains a matched composite leaflet design that approximates human heart valve blood flow characteristics and requires only a single suture line which simplifies surgical implantation. The Company intends to submit a CE Mark application for the CryoLife-Ross pulmonary heart valve, another of the Company's fixed stentless porcine valves, for marketing in the European Community. The Company plans to apply its proprietary SynerGraft technology to its stentless porcine heart valves. SynerGraft involves the depopulation of living cells from the structure of non-viable animal heart tissue and the repopulation of such tissue with human cells. This process is designed to reduce calcification of porcine heart valves, thereby increasing 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 address the broader international and U.S. heart valve markets, estimated to be $348 million and $395 million, respectively, in 1997.

CryoLife is developing implantable biomaterials for use as surgical adhesives and sealants. The Company's patent protected BioGlue surgical adhesive, designed for cardiovascular and peripheral vascular applications, is a polymer based on a derivative of a blood protein and a cross linking agent. The Company's patent protected FibRx surgical sealant, designed for tissue hemostasis and suture line sealing, is a light activated, biodegradable surgical sealant under development which is based on a derivative of the human blood factors fibrinogen and thrombin. Both of these products may be used with or without sutures or staples, and may offer advantages over sutures and staples, including more effective sealing and easier application. The Company estimates that the annual worldwide market for surgical sutures and staples in 1997 was in excess of $2 billion. The Company recently received CE Mark Certification for its BioGlue surgical adhesive which permits the Company to begin marketing this product in the European Community for vascular applications.

CryoLife manufactures and distributes, through its IFM subsidiary, single-use medical devices including endarterectomy surgical instruments, intravascular shunts, infusion ports, accessories utilized in laparoscopic procedures and a wide range of single and dual lumen balloon catheters. The Company believes that many of its existing single-use medical devices have novel proprietary features that offer clinical advantages over competing products. For example, the Company's Pruitt-Inahara Shunt was the first endarterectomy shunt available to surgeons which contains a barrier feature designed to reduce migration of plaque particles to the brain and trauma to the carotid artery during surgery. Another example is the Company's dual lumen embolectomy catheter incorporating a novel water irrigation mechanism which enables physicians to remove whole blood clots more effectively than with single lumen embolectomy catheters. The Company is benefiting from, and intends to utilize, its design and manufacturing expertise to develop single-use medical devices for use in conjunction with its cryopreserved human tissue and biomaterial products. Examples of such devices under development include a family of balloon catheters designed to assist in applying the BioGlue surgical adhesive and a human heart valve holder designed to provide physicians greater control in implantation procedures.

In the U.S., the Company markets its cryopreservation services for human heart valves and conduits and human vascular tissue through its in-house technical service representatives and relies on independent orthopaedic sales representatives to market its cryopreservation services for human connective tissue for the knee. Also in the U.S., the Company markets its single-use medical devices through its in-house technical service representatives. Internationally, cryopreserved human tissues, bioprosthetic cardiovascular devices and single-use medical devices are distributed through independent representatives located in several countries in Europe, South America and Asia. The Company plans to market and distribute its BioGlue surgical adhesive internationally through its existing independent representatives and, if approved for sale in the U.S., through its in-house technical service representatives.

GROWTH STRATEGY

The Company's primary objective is to continue its consistent growth in revenues and profitability. The Company has generated compound annual growth rates in revenues and net income of approximately 21% and 71%, respectively, since 1993, excluding revenues and net income from IFM, which the Company acquired in March 1997. 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:

- Continue Leadership in Cryopreservation of Human Heart Valves and Conduits. The Company intends to increase the market penetration of its cryopreserved 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 more than 250 tissue banks and procurement agencies across the U.S. which direct tissue to the Company for cryopreservation and (iii) expanding its physician training activities.

- Expand Distribution of Cryopreserved Human Vascular Tissue and Connective Tissue for the Knee. Using the same strategy it has successfully employed to expand its distribution of cryopreserved human heart valves and conduits, the Company intends to increase its cryopreservation revenues from human vascular tissue and connective tissue for the knee through continuing educational efforts directed to vascular and orthopaedic surgeons about the clinical advantages of cryopreserved vascular and orthopaedic tissue, expanding its relationships with tissue banks and procurement agencies and expanding its programs for training physicians in the use of tissue cryopreserved by the Company.

- Broaden Application of Cryopreservation Services. The Company will continue to collect, monitor and evaluate implant data to (i) develop expanded uses for the human tissues currently cryopreserved by the Company and (ii) identify new human tissues as candidates for cryopreservation. The Company has recently begun providing cryopreserved human vascular tissue to be used as dialysis access replacement grafts for patients undergoing long-term dialysis, and separately, as venous valve replacements for patients suffering from diseases of the venous system. The Company has ongoing projects for cryopreserving the posterior tibialis and anterior tibialis tendons for use in knee repairs. The Company is also investigating the use of cryopreserved human osteochondral grafts to repair articular defects, and the use of cryopreserved human endothelial cells, peripheral nerves and spinal disks in various surgical applications.

- 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. The Company is expanding its production capacity for its bioprosthetic cardiovascular devices to address the increased demand it is currently experiencing. Separately, the Company's patent protected SynerGraft technology is being developed to expand the target market for the CryoLife-O'Brien aortic heart valve and the CryoLife-Ross pulmonary heart valve by minimizing calcification often associated with porcine tissues and thereby increasing their longevity.

- Develop and Commercialize Biomaterials for Surgical Adhesive and Sealant Applications. In the second quarter of 1998, the Company plans to commercialize its patent protected BioGlue surgical adhesive in the European Community through its existing independent representatives and to file an application to conduct clinical trials for BioGlue surgical adhesive in the U.S. The Company also plans to continue development of its patent protected FibRx surgical sealant. In addition to the adhesive and sealant applications of these biomaterials, the Company intends to pursue, either directly or through strategic alliances, certain drug delivery applications of BioGlue surgical adhesive and FibRx surgical sealant, such as administering antibiotics, attaching chemotherapy drugs to tumors, delivering growth agents or delivering bone chips for orthopaedic bone repair.

- Leverage Existing Capability across Product Lines. The Company plans to expand sales of its single-use medical devices by leveraging its established cryopreservation services marketing and sales staff and by introducing new complementary products. 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 stentless porcine heart valves as a platform for the development and commercialization of the Company's SynerGraft technology. New complementary products under development include a stentless human heart valve holder being designed to provide greater physician control in implantation procedures and modified single and double lumen balloon catheters for use in delivering the Company's implantable bioadhesives.

SERVICES AND PRODUCTS

Cryopreservation of Human Tissue for Transplant/Living Biologic Devices

The Company's proprietary and patent protected cryopreservation process involves the procurement of tissue from deceased human donors, the timely and controlled delivery of such tissue to the Company, the screening, disinfection, dissection and cryopreservation 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 by the Company of its 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 connective tissue for the knee. The following table sets forth, for the types of tissues cryopreserved by the Company, the cumulative number of units shipped, the number of units shipped in 1997 and the total number of target market procedures performed annually in the United States:

	NUMBER OF CRYOLIFE UNITS SHIPPED		NUMBER OF TARGET MARKET PROCEDURES PERFORMED IN THE U.S. IN 1997
	SINCE INCEPTION	DURING 1997	
Human Heart Valves and Conduits	29,500	5,244	95,000
Human Vascular Tissue	9,300	2,621	34,000
Human Connective Tissue for the Knee	4,800	1,859	270,000

CryoLife maintains and collects extensive clinical data on the use and effectiveness of implanted human tissues that it has cryopreserved, and shares this data with implanting physicians. The Company also uses this data to help direct its continuing efforts to improve its cryopreservation 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 its cryopreserved tissues, as well as its programs whereby surgeons train other surgeons in necessary techniques. The Company also assists organ procurement agencies through training and development of protocols and provides necessary materials to improve their internal tissue processing techniques and to increase efficiency and the yield of usable tissue.

Human Heart Valves and Conduits. The Company's revenues have been primarily derived from the cryopreservation of human heart valves and conduits for use in reconstructive heart valve replacement surgery. CryoLife shipped approximately 29,500 cryopreserved human heart valves and conduits from 1984 to 1997. 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 cryopreservion services to human aortic, pulmonary and, more recently, mitral heart valves for implantation by cardiac surgeons. In addition, the Company provides cryopreserved conduit tissue, which is the only

source of tissue available to surgeons who wish to perform certain specialized cardiac repair procedures. Each of these human heart valves and conduits maintains a viable tissue structure which more closely resembles and performs like the patient's own tissue than non-human tissue alternatives.

Based on available market data, the Company estimates that of all heart valve replacement surgeries performed in the U.S. in 1997, 69%, 30% and 1% involved the replacement of diseased or damaged aortic valves, mitral valves and pulmonary valves, respectively. Due to the success of a procedure known as the Ross Switch

Procedure, 53% of the valves which CryoLife shipped in 1997 were pulmonary valves. In the Ross Switch Procedure, the surgeon replaces the patient's damaged aortic valve with the patient's own pulmonary valve. The patient's pulmonary valve is then replaced with a cryopreserved pulmonary valve. The advantage of this procedure is the use of the patient's own valve in the more stressful aortic position. The resulting benefit to CryoLife and the surgical community is a more even demand and distribution of the processed human aortic and pulmonary valves.

The Company estimates that the total heart valve and conduit replacement market in the U.S. in 1997 was approximately $395 million. Management believes that approximately 95,000 heart valve and conduit surgeries were conducted in the U. S. in 1997. Of the total number of heart valve and conduit surgeries, approximately 64,000, or 67%, involved mechanical heart valves, and approximately 31,500, or 33%, involved tissue heart valves or conduits, including porcine and cryopreserved human tissues. Of these tissue heart valve or conduit replacements, management believes that approximately 6,500, or 21%, involved cryopreserved human heart valve or conduit replacements. Over 5,200 human heart valves and conduits cryopreserved by the Company were shipped for implantation in 1997. Since 1993, the total U.S. replacement heart valve market grew at a compound annual growth rate of approximately 7%, while CryoLife's revenues from cryopreservation of human heart valves and conduits grew at a compound annual growth rate of approximately 21%.

Management believes cryopreserved human heart valves and conduits have characteristics that make them the preferred replacement for most 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 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 are difficult to treat with antibiotics after they have become infected, a condition which 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(2)
Materials:	human tissue	glutaraldehyde-fixed pig tissue and synthetic sewing ring	glutaraldehyde-fixed pig tissue	pyrolitic carbon bi-leaflet and synthetic sewing ring	glutaraldehyde-fixed cow tissue and synthetic sewing ring
Blood Flow Dynamics:	normal	moderate elevation	nearly normal	high elevation	high elevation
(Required Pressure) (3)	(0-5)	(10-20)	(5-15)	(10-25)	(10-30)
Mode of Failure:	gradual	gradual	expected to be gradual	catastrophic	gradual
Longevity:	20 years	7-10 years	expected to exceed stented	20 years	10-15 years

			porcine valves		
Increased Risk of Thromboembolic Events (strokes or other clotting):	no	occasional	expected to be rare	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.:	$6,850	$4,228	$5,500	$4,100(4)	$4,500

- --------

(1) Limited long-term clinical data is available since stentless porcine heart valves only recently became commercially available.
(2) Management believes that bovine pericardium heart valves have experienced mixed clinical results and are generally not considered a preferred alternative for most patients.
(3) Pressure measured in mm/Hg.
(4) 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 14 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 would interfere with normal pregnancy.

Human Vascular Tissues. The Company cryopreserves human saphenous and superficial femoral veins 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 and shipped approximately 9,300 human vascular tissues from 1986 to 1997.

A surgeon's first choice for replacing diseased or damaged vascular tissue is generally the patient's own tissue. However, in cases of advanced vascular disease, the patient's own tissue is often unusable and the surgeon may consider using synthetic grafts or transplanted human vascular tissue. Synthetic small diameter vascular grafts are not available for below-the-knee surgeries and, in other procedures, have a tendency to shut down due to occlusion because 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 not to occlude as quickly because of the presence of an endothelial cell lining in the donor vein which remains intact following the cryopreservation process. The Company's cryopreserved human vascular tissues are used for coronary artery bypass surgeries, peripheral vascular reconstruction, dialysis access graft replacement and venous valve transplantation.

In 1986, the Company began a program to cryopreserve saphenous veins for use in coronary artery bypass surgeries. Although the Company's cryopreserved human tissue was used in only a small percentage of the nearly 310,000 coronary artery bypass procedures performed in 1997, the Company believes it is the only commercially available alternative to the patient's own tissue. Approximately 950 cryopreserved human saphenous veins for use in coronary artery bypass surgeries were shipped for this application in 1997, representing approximately 36% of all the human vascular tissue shipped by the Company during such period. The Company estimates that, in 1997, approximately 20,000 coronary artery bypass surgeries were performed in which human vascular tissues cryopreserved by the Company could have been used.

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 clinical data has shown that 80% of patients receiving CryoLife's preserved vascular tissues in this type of surgical procedure still have the use of the affected leg three years after surgery. The alternative for many of these patients was amputation. Approximately 1,570 cryopreserved human saphenous veins were shipped for this application in 1997. The Company estimates that, in 1997, approximately 22,000 peripheral vascular reconstruction surgeries were performed in which its cryopreserved human vascular tissues could have been used.

In 1996, the Company began a program for the cryopreservation 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 than human tissue. The Company shipped less than 100 cryopreserved human superficial femoral veins for this application in 1997. The Company estimates that, in 1997, approximately 30,000 dialysis access graft replacements were performed in which its cryopreserved human vascular tissues could have been used.

In 1997, the Company began a program for the cryopreservation of human superficial femoral veins for venous valve transplant. The cryopreservation of these human tissues is designed for patients suffering from chronic venous insufficiency, a condition in which the blood flow returning to the heart from the legs is compromised due to absent, improperly functioning or destroyed venous valves. Prior to the introduction of CryoLife's

cryopreserved venous valves, treatment for patients suffering from this ailment generally was limited to drug therapy or compression stockings. The Company shipped less than 100 cryopreserved human superficial femoral veins for this application in 1997. The Company estimates that, in 1997, approximately 20,000 patients with chronic venous insufficiency could have benefitted from venous valve transplant procedures using its cryopreserved human vascular tissues.

Human Connective Tissue for the Knee. The Company provides cryopreserved surgical replacements for the meniscus and the anterior and posterior cruciate ligaments, which are connective tissues critical to the proper operation of the human knee. CryoLife has shipped approximately 4,800 human connective tissues for the knee through 1997.

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 1997 in the U.S. approximately 683,000 patients underwent partial or total meniscectomies. The Company believes up to 30% of these patients could become candidates for meniscal replacement within five years.

Tendons cryopreserved by the Company are used for the reconstruction of anterior 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 1997 approximately 175,000 cruciate ligament reconstruction surgeries were performed.

Based on its experience with human heart valves and conduits, management believes that as the body of clinical data builds regarding the use of cryopreserved human connective tissues for the knee, the use of such tissues will increase, although there can be no assurance that this will be the case.

Other Allograft Tissues Under Development. The Company currently has ongoing projects for cryopreserving the posterior and anterior tibialis tendons for use in the repair of anterior cruciate ligaments. The Company has other

projects for using preserved osteochondral grafts to repair articular defects and for the use of cryopreserved human endothelial cells, peripheral nerves and spinal discs, in various surgical applications.

Bioprosthetic Cardiovascular Devices

The Company is developing bioprosthetic cardiovascular 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 bacterial infection.

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, are less expensive than allograft valves and their shorter longevity is more appropriately matched with these patients' life expectancies. Fixed porcine heart valves address a worldwide target market estimated to have been $175 million in 1997.

The Company's SynerGraft technology involves the removal of living cells from the structure of non-viable animal tissue and the repopulation of such tissue with human cells. This process is designed to reduce

calcification of porcine heart valves, thereby increasing their 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 address the broader international and U.S. heart valve markets, estimated to be $348 million and $395 million, respectively, in 1997.

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

	FEATURES	REGULATORY/MARKET STATUS
FIXED STENTLESS PORCINE VALVES		
CryoLife-O'Brien	aortic valve of matched composite leaflet design; single suture line	currently marketed in Europe with regulatory approval under CE Mark
CryoLife-Ross	pulmonary valve with attached conduit	submission of application for CE Mark for European marketing approval anticipated in mid-1998
DEPOPULATED STENTLESS PORCINE VALVES		
CryoLife-O'Brien SG	aortic valve, as above, with antigen reduction properties	submission of application for CE Mark for European marketing approval anticipated in fourth quarter 1998
CryoLife-Ross SG	pulmonary valve, as above, with antigen reduction properties	submission of application for CE Mark for European marketing approval anticipated in fourth quarter 1998
REPOPULATED STENTLESS PORCINE VALVES		
CryoLife-O'Brien SynerGraft	aortic valve, as above, repopulated with human cells	pre-clinical
CryoLife-Ross SynerGraft	pulmonary valve, as above, repopulated with human cells	pre-clinical

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 European Community 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 thereby simplifying surgical implantation. Other stentless porcine valves require a more complicated implant procedure.

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 intends to submit a CE Mark application during 1998 for marketing the Cryolife-Ross pulmonary heart valve, another of the Company's fixed stentless porcine valves, in the European Community.

The Company plans to apply its proprietary SynerGraft technology to its stentless porcine heart valves. The first of the SynerGraft technology applications involves developing depopulated stentless porcine heart valves with antigen reduction properties. This technology removes viable cells from animal tissues thereby reducing the transplant recipient's immune response to the remaining depopulated tissues. The auto-immune response typically deposits calcium which attaches to and hardens implanted porcine heart valve tissue, a process known as calcification, which reduces the useful life of the implant. By removing viable 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 naturally populate the implant. This SynerGraft depopulation technology is being applied to both the CryoLife-O'Brien aortic heart valve and the CryoLife-Ross pulmonary heart valve for products under development anticipated to be known as the CryoLife-O'Brien S.G. and the CryoLife-Ross S.G.

The second of the SynerGraft technology applications involves developing stentless porcine heart valves repopulated with viable human cells prior to implantation. This technology uses porcine tissues that have been depopulated of viable animal cells as in the CryoLife-O'Brien S.G. and the CryoLife-Ross S.G. This SynerGraft repopulation technology is being applied to both the CryoLife-O'Brien aortic heart valve and the CryoLife-Ross pulmonary heart valve for products anticipated to be known as the CryoLife-O'Brien SynerGraft and the CryoLife-Ross SynerGraft.

Implantable Biomaterials for Use as Surgical Adhesives and Sealants

The effective closure of internal wounds following surgical procedures is critical to the restoration of the function of tissue and to the ultimate success of the surgical procedure. Failure to effectively seal surgical wounds can result in leakage of air in lung surgeries, cerebral spinal fluids in neurosurgeries, blood in cardiovascular surgeries and gastrointestinal contents in abdominal surgeries. Air and fluid leaks resulting from surgical procedures can lead to significant post-surgical 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 is developing and commercializing its BioGlue surgical adhesive and is developing its FibRx surgical sealant. The BioGlue surgical adhesive is a polymeric surgical bioadhesive based on a derivative of a blood protein and a

cross-linking agent. BioGlue surgical adhesive is nonbiodegradable and has a tensile strength that is four to five times that of FibRx surgical sealant. Target clinical applications for BioGlue surgical adhesive include cardiovascular and vascular peripheral repair. FibRx surgical sealant is a light activated surgical sealant based on a derivative of the human blood factors fibrinogen and thrombin. The Company believes that FibRx is the only surgical sealant under development offering ease of use to the surgeon through either single-syringe or spray applicators.

The following table summarizes certain important features, targeted applications and regulatory and market status of BioGlue surgical adhesive and FibRx surgical sealant:

	BIOGLUE SURGICAL ADHESIVE	FIBRX SURGICAL SEALANT
COMPOSITION:	animal albumin and glutaraldehyde	thrombin, fibrinogen and a thrombin inhibitor
METHOD OF APPLICATION:	double syringe; mixing device provided	light activated single syringe; or light activated spray applicator
TARGETED CLINICAL APPLICATIONS:	vascular repair; anastomotic sealing; aortic dissection repair; carotid endarterectomy patching; tissue bonding	hemostasis in cardiovascular procedures, skin grafts and breast reconstruction; adhesion for skin grafts and breast reconstruction
PERFORMANCE CHARACTERISTICS:	high tensile strength; non-biodegradable	strength of normal human blood clot; biodegradable; flexible, easily manipulated
REGULATORY/MARKET STATUS		
Europe:	CE Mark received for cardiovascular and vascular repair applications; expect to commence marketing in Europe in second quarter 1998	regulatory pathway not determined; expected to be evaluated in 1998
United States:	submission of application with the FDA for approval to conduct clinical trials anticipated in second quarter 1998	submission of IND application with the FDA for approval to conduct U.S. clinical trials anticipated in third quarter 1998

The Company estimates that the worldwide market for surgical sutures and staples in 1997 was in excess of $2 billion. The Company intends to begin shipping BioGlue surgical adhesive for distribution in the European Community in the second quarter of 1998. FibRx surgical sealant is progressing through pre-clinical trials and is presently undergoing toxicology validation procedures mandated by the FDA prior to the commencement of clinical trials.

Single-Use Medical Devices

CryoLife manufactures and distributes, through its IFM subsidiary, single-use medical devices including endarterectomy surgical instruments, intravascular shunts, infusion ports, accessories utilized in laparoscopic procedures and a wide range of single and dual lumen balloon catheters. The Company believes that many of its existing single-use medical devices have novel proprietary features that offer clinical advantages over competing products. For example, the Company's Pruitt-Inahara Shunt was the first endarterectomy shunt available to surgeons which contains a barrier feature designed to reduce migration of plaque particles to the brain and trauma to the carotid artery during surgery. Another example is the Company's double lumen embolectomy catheter incorporating a novel water irrigation mechanism which enables physicians to remove whole blood clots more effectively than with single lumen embolectomy catheters. The Company is benefiting from, and intends to utilize, its design and manufacturing expertise in developing single-use medical devices for use in conjunction with its human tissue and biomaterial products. Examples of such single-use medical devices under development include a family of balloon catheters designed to assist in applying the BioGlue surgical adhesive and a human heart valve holder designed to provide physicians greater control in implantation procedures.

The Company plans to expand sales of its single-use medical devices by leveraging its established cryopreservation services marketing and sales staff to market existing products and by introducing new products. New complementary products under development include modified single and double lumen balloon catheters to be used to deliver the Company's implantable bioadhesives. The Company is working to develop single-use medical devices for use with its BioGlue surgical adhesive. The Company believes that the introduction of BioGlue surgical adhesive in the European Community for vascular repair will create additional marketing opportunities for its single-use medical devices.

SALES, DISTRIBUTION AND MARKETING

Cryopreservation Services

CryoLife markets its cryopreservation 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 receives a fee for its services, which is paid by the Company. The procurement fee and related shipping costs are ultimately reimbursed to the Company by the hospital with which the implanting physician is associated. The Company has developed relationships with over 250 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 cryopreservation services industry and that the breadth of these existing relationships provides the Company a significant advantage over potential new entrants to this market. As a result of its maintaining and developing these relationships, the Company has consistently increased its annual human heart valve procurement since its inception. The Company employs approximately 14 individuals in the area of tissue procurement, seven of whom are employed as procurement relations managers and are stationed throughout the country. The Company's central procurement office 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/inventory 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 cryopreservation.

Human heart valves and conduits, vascular tissue and connective tissue for the knee are cryopreserved in a proprietary freezing process conducted according to strict Company protocols. After the cryopreservation process, the specimens are transferred to liquid nitrogen freezers for long-term storage at temperatures below -135(degrees)C. The entire cryopreservation process is rigidly controlled by guidelines established by the Company.

Distribution of Tissue to Implanting Physicians. After cryopreservation, 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 encourages hospitals to accept the cryopreserved tissue quickly by providing Company-owned liquid nitrogen freezers to client hospitals without charge. The Company has currently installed more than 300 of these freezers. Participating hospitals 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 cryopreservation services by making the cryopreserved tissue more readily available. Because fees for the Company's cryopreservation 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 1,600 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 cryopreservation services directly to physicians, an important aspect of increasing the distribution of the Company's cryopreservation services is educating physicians on the use of cryopreserved human tissue and on proper implantation techniques. Trained field support personnel provide back-up and support to implanting institutions and surgeons. The Company currently has approximately 98 independent technical service representatives and sub-representatives (who deal primarily with orthopaedic surgeons and who are paid on a commission basis) as well as 37 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 physicians teach other physicians the proper technique for handling and implanting cryopreserved human tissue. The Company conducted seven of these seminars in 1997. Physicians pay their own expenses to attend these seminars in addition to paying the Company a fee for attendance. The Company also produces educational videotapes for physicians. The Company coordinates live surgery demonstrations at various medical schools. The Company also coordinates laboratory sessions that utilize animal tissue to demonstrate the respective 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.

In order to increase the Company's supply of human tissue for cryopreservation, the Company educates and trains procurement agency personnel in procurement, dissection, packaging and shipping techniques. The

Company also produces educational videotapes and coordinates laboratory sessions on procurement techniques for procurement agency personnel. To supplement its educational activities, the Company employs in-house technical specialists that provide technical information and assistance and maintains a staff 24 hours per day, 365 days per year for customer support.

Bioprosthetic Cardiovascular Devices

The Company markets the CryoLife-O'Brien stentless porcine heart valves in the European Community. The Company's European sales, distribution and marketing force consists of eight independent representatives, representing each of the Benelux countries, France, Germany, Greece, Scandinavia, Turkey and the United Kingdom. Each of these representatives is paid on a commission basis. Marketing efforts are directed almost exclusively toward cardiovascular 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. In 1997, the Company conducted one workshop and participated in three European conferences. The Company intends to market its CryoLife-Ross stentless porcine heart valves, if CE Mark approval is obtained, through this same European sales force.

BioGlue Surgical Adhesive

The Company plans to market and distribute its BioGlue surgical adhesive internationally through its existing independent representatives, and if approved for sale in the U.S., through its in-house technical service representatives. The initial shipments of BioGlue surgical adhesive to CryoLife's European distributors, which are currently distributing the CryoLife-O'Brien stentless porcine heart valve and single-use medical devices product lines, are scheduled for the second quarter of 1998. The Company conducts training sessions for European doctors with respect to the application and administration of BioGlue surgical adhesive.

Single-Use Medical Devices

Following its acquisition of IFM in March 1997, the Company terminated the majority of IFM's sales representatives and began transitioning the sales and distribution of single-use medical devices to its in-house technical service representatives. The Company plans to expand sales of its single-use medical devices by continuing new product development and leveraging its established cryopreservation services marketing and sales staff to market the products. The Company conducted two training seminars for these representatives during 1997.

RESEARCH AND DEVELOPMENT

The Company uses its expertise in biochemistry and cell biology, and its understanding of the needs of the cardiovascular, vascular and orthopaedic surgery medical specialties, to continue to expand its core cryopreservation business in the U.S. and to develop or acquire implantable products and technologies for these fields. 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 26 people in its research and development department. There are seven PhDs with specialties as diverse as 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 FibRx surgical sealant, SynerGraft and additional applications of BioGlue surgical adhesive. The Company is currently investigating certain drug delivery applications for BioGlue surgical adhesive and FibRx surgical sealant, such as administering antibiotics, attaching chemotherapy drugs to tumors, delivering growth agents or delivering bone chips for orthopaedic bone repair. 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. The Company's

research and development strategy is to allocate available resources among the Company's four core market areas of cryopreservation services, bioprosthetic cardiovascular devices, implantable biomaterials and single-use medical devices, based on the size of the potential market for any specific product candidate and the estimated development time and cost required to bring the product to market.

Research on these and other projects is conducted in the Company's research and development laboratory or at universities or clinics where the Company sponsors research projects. In 1995, 1996 and 1997, the Company spent approximately $2.6 million, $2.8 million and $3.9 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 9%, 8% and 8% 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

The Company's facilities (other than its single-use medical device manufacturing plant) are located in suburban Atlanta, Georgia, and consist of

three separate locations totaling approximately 130,000 square feet of leased office, laboratory and warehouse space. Approximately 17,500 square feet are dedicated to laboratory work areas. The primary facility, which does not include the bioadhesive laboratory and the bioprosthetic manufacturing operation, has three main laboratory facilities: human tissue processing, 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.

Human Tissue Processing

The human tissue processing laboratory is responsible for the processing and cryopreservation of human tissue for transplant. This includes all processing of heart valves and conduits, vascular tissue and connective tissue for the knee supplied by CryoLife. This laboratory contains approximately 7,700 square feet with a suite of seven clean rooms. Currently there are 37 technicians employed in this area, and the laboratory is staffed for two shifts, 365 days per year. In 1997, the laboratory processed approximately 14,000 human tissues for distribution and transplant. The current staffing 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.

Bioprosthetic Cardiovascular Devices

The bioprosthesis laboratory is responsible for the manufacturing of the CryoLife-O'Brien stentless porcine aortic heart valve. This laboratory is located in Marietta, Georgia and contains approximately 13,000 square feet, with about 3,500 square feet of laboratory space and a suite of four clean rooms for tissue processing. The Company plans renovation to this facility in 1998 which would double the size of the processing area and plans to add the production of the CryoLife-Ross stentless porcine pulmonary heart valve to its product line this summer. Currently, this laboratory employs nine technicians and is scheduled to manufacture approximately 1,500 CryoLife-O'Brien valves in 1998. The planned renovation, with additional staffing, is expected to expand capacity at this facility to over 6,000 valves.

Implantable Biomedical Devices

The Company produces limited quantities of FibRx surgical sealant in the biomedical products laboratory, which is located in Marietta, Georgia and employs 11 technicians. This laboratory contains approximately 11,000 square feet, including 4,000 square feet of laboratory space and a suite of eight clean rooms. The Company is also planning an addition of about 8,000 to 15,000 square feet of laboratory and clean room space to support the manufacture of BioGlue surgical adhesive. BioGlue surgical adhesive is presently manufactured at the Company's headquarters facility, which has an annual capacity of approximately 30,000 units. The facility expansion is expected to allow the manufacture of over 300,000 units of BioGlue surgical adhesive each year, with modest staff additions.

Single-Use Medical Devices

The manufacturing of single-use medical devices is conducted at the Company's IFM subsidiary located in St. Petersburg, Florida. IFM was purchased by CryoLife in 1997 and has recently moved to a renovated 30,000 square foot facility. The Company has 91 employees at this facility. At nearly full capacity in 1997, production was about 180,000 units. In the new facility, a single shift can produce approximately 300,000 units annually with full capacity expected to be nearly 800,000 units annually.

QUALITY ASSURANCE

The Company's operations encompass the provision of cryopreservation services and the manufacturing of bioprosthetics, bioadhesives and single-use medical devices. In all of its facilities, the Company is subject to regulatory standards for good manufacturing practices, including current Quality System Regulations, which are U.S. Food and Drug Administration ("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 European Community 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.

Cryopreservation 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 certain tissues are also sent to independent laboratories for pathology testing. Following removal of the tissue to be cryopreserved, a separate disinfection procedure is begun during which the removed 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 appropriate inspections of the facilities to ensure compliance with state law and regulations. In addition, the Company's human heart valve 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 a FDA regulation which sets forth the requirements with which the Company must comply in determining the suitability of human tissue for implantation.

Bioprosthetic, Bioadhesive and Single-Use Medical Device 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.

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, rights 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 14 U.S. patents and three foreign patents, including patents relating to its technology for human heart valve and conduit, vascular tissue and connective tissue for the knee preservation; tissue revitalization prior to freezing; tissue transport; fibrin adhesive; organ storage solution; and packaging. Certain of the above patents relate to the Company's BioGlue surgical adhesive and FibRx surgical sealant. The Company has eight pending U.S. patent applications and in excess of 20 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 holds six patents and has seven patents pending with respect to its single-use medical devices. 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 5 to 17 years. The Company has licensed from third parties certain technologies used in the development of its FibRx surgical sealant and SynerGraft technology. These licenses 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 FibRx surgical sealant and SynerGraft 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.

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 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 tissue bank for supplies of cryopreserved human heart valves and Baxter International Inc. is the leading supplier of porcine heart valves. In addition, management believes that at least three tissue banks offer cryopreservation 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 two 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 no 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 Connective Tissue for the Knee. The Company's competition in the area of connective tissue for the knee 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. To management's knowledge, there are presently no processed or synthetic alternatives to menisci cryopreserved by the Company.

Implantable Biomedical Devices

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 in Europe, and the Pacific Rim countries by Immuno AG, a subsidiary of Baxter Healthcare Company, Chemo-Sero Therapeutic Research Institute, Hoechst AG and others, and management believes other products are under development by Baxter Healthcare Corporation, Bristol-Myers Squibb Company, V.I. Technologies, Inc. and others. Other competitors in the surgical sealant market include Closure Medical Corporation, B. Braun GmbH and Focal, 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, areas in which it currently has limited experience.

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 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."

Single-Use Medical Devices

The Company competes in this market with many larger companies such as Boston Scientific's SciMed Life Systems, Guidant Corporation's Advanced Cardiovascular Systems, C.R. Bard, Inc. and Baxter Healthcare Corporation. Many of these companies are larger and carry broader product lines than CryoLife which allows them to bundle products to hospitals. Bundling device products has become a cost-effective way of marketing several products in a line and of providing incentives for the customer to use several products in a product line.

At present, CryoLife does not bundle its single-use medical devices but instead offers novel product enhancements.

GOVERNMENT REGULATION

U.S. Federal Regulation

Because human heart valves 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 product (i.e., that it has the same intended use and that it is as safe and effective as a legally marketed 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 device or because it is a Class III device required by the FDCA and implementing regulations to have an approved application for premarket approval ("PMA"), the FDA must approve a PMA application before marketing can begin. PMA applications must demonstrate, among other matters, that the medical device is safe and effective. A PMA application is typically a complex submission, usually including the results of human clinical studies, and preparing an application is a detailed and time-consuming process. Once a PMA application has been submitted, the FDA's review may be lengthy and may include requests for additional data. By statute and regulation, the FDA may take 180 days to review a PMA application although such time may be extended. Furthermore, there can be no assurance that a PMA application will be reviewed within 180 days or that a PMA application will be approved by the FDA.

The FDCA also provides for an investigational device exemption ("IDE") which authorizes distribution for clinical evaluation of devices that lack a PMA or 510(k). 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.

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 validaiton 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. 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 are 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, none of the Company's other tissue services or 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. Human tissue is regulated by the FDA in a manner 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, 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.

Single-Use Medical Devices. The products offered by the Company through IFM are regulated as Class I and Class II medical devices by the FDA. These products require clearance under a 510(k) procedure. All products currently marketed by IFM have received a 510(k) clearance from the FDA. In addition, the IFM facilities are subject to periodic review by the FDA, as are the Company's records on returned products and reported problems.

BioGlue Surgical Adhesive. It is anticipated that BioGlue surgical adhesive will be regulated as a Class III medical device, as a biologic or in some other capacity by the FDA. The Company is currently preparing to submit an application with the FDA for approval to conduct clinical trials for BioGlue surgical adhesive. There can be no assurance that approval of this application will be obtained.

Possible Other FDA Regulation. Other products and processes under development by the Company are likely to be subject to regulation by the FDA (e.g.,

SynerGraft and FibRx surgical sealant). 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 NOTA, which makes it unlawful for any person to knowingly acquire, receive or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. NOTA excludes from the definition of "valuable consideration" reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control and storage of a human organ. The purpose of this statutory provision is to allow for compensation for legitimate services. The Company believes that to the extent its activities are subject to NOTA, it meets this statutory provision relating to the reasonableness of its charges. There can be no assurance, however, that restrictive interpretations of NOTA will not be adopted in the future that would call into question one or more aspects of the Company's methods of charging for its preservation services.

State Licensing Requirements

Some states have enacted statutes and regulations governing the processing, transportation and storage of human organs and tissue. The activities engaged in by the Company require it to be licensed as a clinical laboratory and tissue bank under Georgia, New York, California and Florida law. The Company has such licenses, and the Company believes it is in compliance with applicable state laws and regulations relating to clinical laboratories and tissue banks which store, process and distribute human tissue designed to be used for medical purposes in human beings. There can be no assurance, however, that more restrictive state laws or regulations will not be adopted in the future that could adversely affect the Company's operations. Certain employees of the Company have obtained other required licenses.

Foreign Approval Requirements

Sales of medical devices and biological products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. Approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to commercialization 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 European Community recognizes a single approval, called a CE Mark, which allows for distribution of an approved product throughout the European Community (15 countries) without additional applications to each country. 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 European Community 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 CyroLife-O'Brien porcine heart valves, BioGlue surgical adhesive and IFM single-use medical devices by LRQA. The Company's porcine heart valves may be exported to specified developed nations, including countries in the European Community, Australia, Canada, Israel, Japan, 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 will be required to market porcine heart valves and other bioprosthetics in the European Community.

ENVIRONMENTAL MATTERS

The Company's tissue processing activities generate some biomedical wastes consisting primarily of human pathological and biological wastes, including human 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

The Company presently has approximately 330 employees. These employees include nine 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 CRYOPRESERVATION OF HUMAN TISSUE

A significant portion of the Company's current revenues is derived from the cryopreservation of human tissue, particularly heart valves and conduits. 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 heart tissue could restrict the Company's growth. The Company relies primarily upon the efforts of third party procurement agencies (all 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 human heart valves, 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. While availability is not currently a limiting factor for most vascular tissue and connective tissue for the knee, growth in these areas could ultimately be limited by tissue availability, in addition to other factors. Failure of the Company to maintain its supply of tissue for cryopreservation 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. Management believes that at least three tissue banks offer cryopreservation 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 Baxter International Inc. The Company also faces competition from a number of competitors in the area of single-use medical devices and 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. 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 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 are currently only offered for sale outside of the U.S., and beginning in the second quarter of 1998, the Company expects to begin shipping its BioGlue surgical adhesive for distribution in the European Community. The Company's porcine heart valves and BioGlue surgical adhesive 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.

EXTENSIVE GOVERNMENT REGULATION

Government regulation in the U.S., the European Community 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 cryopreservation 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 a rule promulgated by the FDA pursuant to the Public Health Services Act. This rule establishes requirements for donor testing and screening of human tissue and recordkeeping relating to these activities. 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.

Although the regulatory status of the Company's BioGlue surgical adhesive and FibRx surgical sealant is not certain, the Company believes that FibRx surgical sealant will be regulated as a biologic and anticipates that BioGlue surgical adhesive will be regulated as a Class III medical device, as a biologic or in some other capacity by the FDA. These products have not been approved for distribution within the U.S. To date, the FDA has never approved for sale in the U.S. a surgical adhesive or sealant which, like FibRx surgical sealant, is composed of human blood components. Management believes that concerns over viral transmission may have hindered FDA approval of such products. There can be no assurance that CryoLife's quality control protocols will sufficiently address FDA concerns or that CryoLife will be able to develop viral inactivation processes acceptable to the FDA or license such processes at an acceptable cost. 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 surgical adhesives, surgical sealants or porcine heart valve products in the U.S. Distribution of these products within the European Community 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 scientists, 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. To date, the Company has never had to submit clinical trials for any of its products. In the event that it should be required to perform clinical trials, there can be no guarantee that it will be able to do so effectively and efficiently. 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 and, in the case of biologics, licensed establishments and must be produced in accordance with Quality System Regulations. Manufacturing facilities and processes are subject to periodic FDA inspection. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of devices and biologics is also subject to regulation and may require FDA approval. From time to time, the FDA may modify such regulations, imposing additional or different requirements. Failure to comply with any applicable FDA requirements, which may be ambiguous, could result in civil and criminal enforcement actions, 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, the National Organ Transplant Act ("NOTA") prohibits the acquisition or transfer of human organs for "valuable consideration" for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, processing, preservation, quality control and storage of human organs. There can be no assurance that restrictive interpretations of NOTA will not be adopted in the future that will challenge one or more aspects of the Company's methods of charging for its cryopreservation 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.

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 cryopreservation 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 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 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 is currently involved in one such proceeding. 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 $14 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."

USE AND DISPOSAL OF HAZARDOUS MATERIAL

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 growth of human cells and the processing of human tissue. Although the Company believes that its safety procedures for handling, processing and disposing of hazardous materials and human 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.

SHARES ELIGIBLE FOR FUTURE SALE

Substantially all of the Company's outstanding Common Stock is available for sale in the public marketplace. As of February 27, 1998, there were also outstanding stock options to purchase an aggregate of 747,000 shares of Common Stock at various exercise prices per share. The majority of the shares to be received upon exercise of these options will be available for immediate resale in the public markets. No prediction can be made as to the effect, if any, that sales of shares of Common Stock or the availability of such shares for sale will have on the market prices prevailing from time to time. The possibility exists that substantial amounts of Common Stock may be sold in the public market, which may adversely affect prevailing market prices for the Common Stock and could impair the Company's ability to raise capital through the sale of its equity securities.

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 approval of statements regarding the Company's competitive position, the timing and of the application to the FDA for the stentless CryoLife-O'Brien porcine heart valves, BioGlue surgical adhesive, and FibRx surgical sealant, other estimated dates relating to the Company's proposed regulatory submissions, estimates regarding 1998 research and development expenditures, the Company's expectations regarding the adequacy of current financing arrangements, 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 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 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 their earlier removal by the Board of Directors or their 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	59	President, Chief Executive Officer and Chairman	February, 1984
Kirby S. Black, PhD	43	Vice President, Research and Development	July, 1995
Edwin B. Cordell, Jr., CPA	39	Vice President and Chief Financial Officer	December, 1994
Albert E. Heacox, PhD	47	Vice President, Laboratory Operations	June, 1995
Gerald B. Seery	41	Vice President, Marketing	August, 1995
James C. Vander Wyk, PhD	53	Vice President, Regulatory Affairs and Quality Assurance	February, 1996
Ronald D. McCall, Esq.	61	Director, Secretary and Treasurer	January, 1984

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 1982 of Intermedics, Inc., a manufacturer and distributor of pacemakers and other medical devices. Mr. Anderson received his BA from the University of Minnesota.

KIRBY S. BLACK, PHD, has served as Vice President of Research and Development since July 1995. 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 three patents and has authored 118 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 BS degree from the University of California, Los Angeles, and his PhD degree from the University of California at Irvine.

EDWIN B. CORDELL, JR., CPA, has served as Vice President and Chief Financial Officer of the Company since November 1994. From August 1987 to November 1994, Mr. Cordell served as Controller and Chief Financial Officer of Video Display Corporation, a cathode ray tube remanufacturing and distribution company. Mr. Cordell received his BS in Accounting from the University of Tennessee.

ALBERT E. HEACOX, PHD, has served as Vice President, Laboratory Operations since June 1988 and has been with the Company since June of 1985. 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 cryopreservation of cells and animal germ plasm storage. Dr. Heacox received a BA and an MS in Biology from Adelphi University, and 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.

GERALD B. SEERY has served as Vice President of Marketing since August 1995 and has been with the Company since July 1993. Mr. Seery is responsible for developing and implementing the Company's sales and marketing plans and supervising all tissue procurement activities. Prior to joining the Company, Mr. Seery held senior marketing management positions with Meadox Medicals from 1982 until 1985, Electro Catheter Corporation from 1985 until 1989 and Daig Corporation from 1992 until 1993, accumulating fifteen years of specialized marketing experience in cardiovascular medical devices. Mr. Seery received his BA in International Economics at The Catholic University of America in Washington, D.C. in 1978 and completed his MBA at Columbia University in New York in 1980.

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.

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 Form 10-K or incorporated herein by reference. 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, 1996 and 1997 are derived from the Company's Consolidated Financial Statements which have

been audited by Ernst & Young LLP, independent auditors, and which are included elsewhere in this Form 10-K and are qualified by reference to such Consolidated Financial Statements and Notes thereto. The selected data presented below for, and as of

the end of, each of the years in the three-year period ended December 31, 1995, are derived from the Consolidated Financial Statements of the Company, which Consolidated Financial Statements have been audited by KPMG Peat Marwick LLP, independent auditors. The Consolidated Income Statement for the year ended December 31, 1995, and the report thereon, are included elsewhere in this Form 10-K. The historical results are not necessarily indicative of future results of operations.

	YEAR ENDED DECEMBER 31,				
	1993	1994	1995	1996	1997
	(IN THOUSANDS, EXCEPT PER SHARE DATA)				
INCOME STATEMENT DATA:					
Revenues:					
Cryopreservation	$18,938	$22,818	$27,994	$36,293	$44,242
Bioprosthetic cardiovascular devices	933	414	263	385	576
Single-use medical devices	--	--	--	--	5,591
Other income	1,470	578	969	550	460
Total Revenues	21,341	23,810	29,226	37,228	50,869
Expenses:					
Cost of cryopreservation and products	8,759	8,965	10,485	12,593	17,764
Research and development	1,384	1,975	2,634	2,807	3,946
General, administrative and marketing	10,282	11,085	12,807	15,673	20,548
Interest expense	23	21	4	72	978
Total Expenses	20,448	22,046	25,930	31,145	43,236
Income before income taxes	893	1,764	3,296	6,083	7,633
Income tax expense	339	498	1,094	2,156	2,908
Net income	$ 554	$ 1,266	$ 2,202	$ 3,927	$ 4,725
Earnings per share of common stock:					
Basic	$ .06	$ .14	$ .23	$ .41	$ .49
Diluted	$ .06	$ .14	$ .23	$ .40	$ .48
Weighted average number of shares of common stock outstanding:					
Basic	9,018	9,312	9,379	9,505	9,642
Diluted	9,114	9,373	9,568	9,906	9,942

	DECEMBER 31,				
	1993	1994	1995	1996	1997
BALANCE SHEET DATA:					
Cash, cash equivalents and marketable securities	$ 5,079	$ 6,366	$ 6,182	$ 1,370	$ 111
Total assets	20,075	21,417	24,132	34,973	53,749
Long-term debt, including current maturities	--	--	--	3,326	18,362
Retained earnings	506	1,773	3,975	7,902	12,627
Total shareholders' equity	16,615	17,933	20,465	24,929	30,227

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 the cryopreservation of viable human tissue for cardiovascular, vascular and orthopaedic applications. A majority of the Company's current revenues are derived from the cryopreservation of human heart valves and conduits, reflecting CryoLife's initial exclusive focus on this area. The Company began cryopreserving aortic heart valves in 1984, pulmonary heart valves in 1986 and mitral heart valves in 1995. CryoLife has also expanded into the cryopreservation of other human tissue, including vascular tissue and connective tissue for the knee.

The Company pays a fee to an organ procurement agency or tissue bank at the time such organization consigns human tissue to the Company. The Company generates revenues from cryopreservation services by charging hospitals a fee, which covers the Company's services, the associated procurement fee and applicable shipping

expenses. The Company records revenue upon shipping tissue. Costs associated with the procurement, processing and storage of tissue are accounted for as deferred preservation costs on the Company's balance sheet and are expensed when the tissue is shipped. The Company continually monitors cryopreserved tissue in its possession to determine its viability. Tissue determined not to be suitable for implantation is disposed of properly, and the associated deferred preservation costs are expensed. As part of an effort to reduce its working capital needs, while simultaneously facilitating the use of cryopreserved tissue, the Company provides liquid nitrogen freezers to a number of hospitals. The Company retains ownership of the liquid nitrogen freezers and, consequently, incurs associated depreciation charges. The hospitals are responsible for operating expenses related to the use of the liquid nitrogen freezers.

The Company has expanded, and intends to continue to expand, its portfolio of products and services. Much of this expansion has been accomplished through acquisitions of intellectual property businesses. In 1992, the Company purchased for $730,000 the exclusive distribution rights for a line of stentless porcine heart valves which the Company currently markets in the European Community. In 1996, the Company purchased for $275,000 a patent for an advanced design stentless pulmonary porcine heart valve. Also in 1996, the Company acquired the assets of UCFI, a tissue processor, for $750,000 in cash and a $1.3 million note. In 1997, the Company acquired IFM and its line of single-use medical devices for $4.5 million in cash, a $5.0 million convertible debenture and a commitment to pay additional cash consideration (not to exceed $1.8 million) if certain target net revenues of IFM are exceeded.

The composition of the Company's revenues is expected to change in future years, reflecting, among other things, the anticipated growth in shipments of human vascular tissue and human connective tissue for the knee, the acquisition of IFM and the introduction into the European Community of BioGlue surgical adhesive as well as other expected new products.

The following table outlines product shipment and revenue data for the Company's major product lines from 1995 to 1997:

UNITS SHIPPED AND REVENUES BY MAJOR PRODUCT LINE	YEAR ENDED DECEMBER 31, 1995	1996	1997
	(DOLLARS IN THOUSANDS)		
Human Heart Valves and Conduits:			
Units shipped	3,499	4,528	5,244
Revenues	$19,767	$24,763	$29,046
Human Vascular Tissue:			
Units shipped	1,765	2,147	2,621
Revenues	$ 6,771	$ 8,172	$10,469
Human Connective Tissue for the Knee:			

Units shipped	573	1,562	1,859
Revenues	$ 1,456	$ 3,358	$ 4,727
Bioprosthetic Cardiovascular Devices:			
Units shipped	198	256	532
Revenues	$ 263	$ 385	$ 576

RESULTS OF OPERATIONS

Year Ended December 31, 1997 Compared to Year Ended December 31, 1996

Revenues increased 37% to $50.9 million in 1997 from $37.2 million in 1996. The increase in revenues was primarily due to the growing acceptance in the medical community of cryopreserved tissues, the Company's ability to procure greater amounts of tissue, price increases for certain cryopreservation services and revenues attributable to the Company's line of single-use medical devices following the IFM acquisition in March 1997. Revenues attributable to IFM were $5.6 million in 1997.

Revenues from human heart valve and conduit cryopreservation services increased 17% to $29.0 million in 1997 from $24.8 million in 1996, representing 57% and 67%, respectively, of total revenues during such years. This increase in revenues was primarily due to a 16% increase in the number of heart allograft shipments.

Revenues from human vascular tissue cryopreservation services increased 28% to $10.5 million in 1997 from $8.2 million in 1996, representing 21% and 22%, respectively, of total revenues during such years. This increase in revenues was primarily due to a 22% increase in the number of vascular allograft shipments resulting from the introduction of cryopreserved tissues for new procedures and an increased demand for the Company's existing cryopreservation services.

Revenues from human connective tissue for the knee cryopreservation services increased 38% to $4.7 million in 1997 from $3.4 million in 1996, representing 9% of total revenues during each year. This increase in revenues was primarily due to a 19% increase in the number of allograft shipments and a greater proportion of the 1997 shipments consisting of cryopreserved menisci, which have a significantly higher per unit revenue than the Company's cryopreserved tendons.

Revenues from the sale of bioprosthetic cardiovascular devices in 1997 were $576,000 compared to $385,000 in 1996, representing 1% of revenues during each year. Other revenues decreased to $460,000 in 1997 from $550,000 in 1996. Other revenues in 1997 consisted primarily of research grant award revenues related to the Company's SynerGraft technology.

Cost of cryopreservation services and products increased to $17.8 million in 1997 from $12.6 million in 1996. Cost of cryopreservation services and products as a percentage of revenues increased to 35% in 1997 from 34% in 1996. This increase was primarily due to the increased overhead costs associated with the new corporate headquarters and the addition of the IFM product line, partially offset by efficiencies gained with the increase in the number of allografts processed.

General, administrative and marketing expenses increased 31% to $20.5 million in 1997 from $15.7 million in 1996, representing 40% and 42%, respectively, of total revenues during such years. The increased expenses of approximately $4.8 million were primarily attributable to increased costs associated with the Company's new corporate headquarters, increased fees paid to technical representatives and other related marketing expenses relating to the growth in revenues and increases in general overhead expenses to support the growth in revenues.

The Company has continued its commitment to research and development activity, spending approximately $3.9 million in 1997 and $2.8 million in 1996, representing 8% of total revenues during each year. The Company's research and development expenditures during 1997 were primarily for the development of bioadhesives for surgical applications and its SynerGraft technology.

Year Ended December 31, 1996 Compared to Year Ended December 31, 1995

Revenues increased 27% to $37.2 million in 1996 from $29.2 million in 1995. The increase in revenues was primarily due to growing acceptance in the medical community of cryopreserved tissues, the Company's ability to procure greater amounts of tissue and price increases for certain services.

Revenues from human heart valve and conduit cryopreservation services increased 25% to $24.8 million in 1996 from $19.8 million in 1995, representing 67% and 68%, respectively, of total revenues during such years. This increase in revenues was primarily due to a 29% increase in the number of heart allograft shipments.

Revenues from human vascular tissue cryopreservation services increased 21% to $8.2 million in 1996 from $6.8 million in 1995, representing 22% and 23%, respectively, of total revenues during such years. This increase in revenues was primarily due to a 22% increase in the number of vascular allograft shipments.

Revenues from human connective tissue for the knee cryopreservation services increased 127% to $3.4 million in 1996 from $1.5 million in 1995, representing 9% and 5%, respectively, of total revenues during each year. This increase in revenues was primarily due to a 173% increase in the number of allograft shipments partially offset by a decrease in the unit revenue of cryopreserved tendons.

Revenues from the sale of bioprosthetic cardiovascular devices in 1996 were $385,000 compared to $263,000 in 1995, representing 1% of revenues during each year. This increase in revenues was primarily due to a 29% increase in the number of units shipped.

Other revenues decreased to $550,000 in 1996 from $969,000 in 1995. Other revenues in 1996 consisted primarily of research grant award revenues and a fee from a terminated agreement with Bayer Corporation. Research grant award revenues in 1996 were primarily related to the development of bioadhesives for surgical application and the Company's SynerGraft technology. The decrease compared to 1995 was primarily attributable to the sale of the Company's patented Viral Inactivation Process ("VIP") technology to Osteotech, Inc. for approximately $450,000 in 1995. The Company had developed its VIP technology to eliminate potential viruses from human bone processed by the Company. The Company sold its bone processing business in 1993.

Costs of cryopreservation services and products increased to $12.6 million in 1996 from $10.5 million in 1995. Cost of cryopreservation services and products as a percentage of cryopreservation revenues decreased to 34% in 1996 from 36% in 1995. This decrease was primarily due to an increase in the volume of processed tissue and more efficient processing methods.

General, administrative and marketing expenses increased 23% to $15.7 million in 1996 from $12.8 million in 1995, representing 42% and 44%, respectively, of total revenues during such years. The increased expenses of approximately $2.9 million were primarily attributable to additional regulatory and quality assurance costs related to the Company's CE Mark and ISO 9001 certifications, increased fees paid to technical representatives and other related marketing expenses resulting from the growth in revenues and increases in general overhead expenses to support the growth in revenues.

The Company continued its commitment to research and development activity, spending approximately $2.8 million and $2.6 million in 1996 and 1995, representing 8% and 9%, respectively, of total revenues during such years. The Company's research and development expenditures during 1996 were primarily for the development of bioadhesives for surgical applications and the SynerGraft technology.

Seasonality

The demand for the Company's human heart valve and conduit cryopreservation services is seasonal, with peak demand generally occurring in the second and third quarters. Management believes that this demand trend for human heart valve and conduit cryopreservation services is primarily due to the high number of surgeries scheduled during the summer months. Management believes that the trends experienced by the Company to date for its human connective tissue for the knee cryopreservation services indicate that this business may

also be seasonal because it is an elective procedure that may be performed less frequently during the fourth quarter holiday months. However, the demand for the Company's vascular tissue cryopreservation services, bioprosthetic cardiovascular devices and single-use medical devices does not appear to experience this seasonal trend.

Quarterly Results

The Company achieved record revenues and earnings in both the year and three months ended December 31, 1997, as compared to comparable prior periods, with the fourth quarter of 1997 being the Company's tenth consecutive quarter of record revenues and earnings as compared to the same quarter for prior years. In the opinion of management, the information set forth in the table below has been prepared on a basis consistent with the Company's audited Consolidated Financial Statements appearing elsewhere in the Form 10-K, and all necessary adjustments (consisting only of normal recurring adjustments) have been included to present fairly the unaudited quarterly results in accordance with generally accepted accounting principles ("GAAP"). The results for any quarter are not necessarily indicative of results to be expected in any future period.

The following table presents selected unaudited quarterly income statement data for each of the eight quarters in the period ended December 31, 1997:

	QUARTER ENDED							
	1996				1997			
	MARCH 31	JUNE 30	SEPT. 30	DEC. 31	MARCH 31	JUNE 30	SEPT. 30	DEC. 31
	(IN THOUSANDS EXCEPT PER SHARE DATA)							
REVENUES:								
Cryopreservation services	$8,103	$9,544	$10,067	$8,579	$9,725	$10,910	$12,689	$10,918
Bioprosthetic cardiovascular devices	157	75	71	82	104	135	177	160
Single-use medical devices	--	--	--	--	554	1,596	1,703	1,738
Interest and other income	174	79	273	24	30	82	72	276
Total Revenues	8,434	9,698	10,411	8,685	10,413	12,723	14,641	13,092
EXPENSES:								
Cost of cryopreservation services and products	2,879	3,289	3,563	2,862	3,426	4,550	5,112	4,676
Research and development	690	701	616	800	849	857	1,243	997
General, administrative and marketing	3,626	4,181	4,239	3,627	4,479	5,165	5,620	5,284
Interest expense	--	--	39	33	132	296	317	233
Total Expenses	7,195	8,171	8,457	7,322	8,886	10,868	12,292	11,190
INCOME BEFORE INCOME TAXES	1,239	1,527	1,954	1,363	1,527	1,855	2,349	1,902
Income tax expense	457	539	693	467	575	695	891	747
NET INCOME	$ 782	$ 988	$ 1,261	$ 896	$ 952	$ 1,160	$ 1,458	$ 1,155
EARNINGS PER SHARE OF COMMON STOCK:								
Basic	$ .08	$ .11	$ .13	$ .09	$ .10	$ .12	$ .15	$ .12
Diluted	$ .08	$ .10	$ .13	$ .09	$ .10	$ .12	$ .15	$ .12
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK OUTSTANDING:								
Basic	9,433	9,491	9,529	9,575	9,581	9,615	9,670	9,694
Diluted	9,756	9,933	9,925	9,943	9,877	9,889	9,978	10,023

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 1997, net working capital was $18.8 million, compared to $10.8 million at December 31, 1996, with a current ratio of 4-to-1 at December 31, 1997. The Company's primary capital requirements arise out of general working capital needs, including capital expenditures 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 used in operating activities was $2.2 million for the year ended December 31, 1997, as compared to net cash provided by operating activities of $3.2 million for the year ended December 31, 1996. This decrease resulted from an increase in deferred cryopreservation costs to support the growing acceptance of the Company's existing cryopreserved tissues as well as new cryopreserved tissue offerings in 1997.

Net cash used in investing activities was $9.6 million for the year ended December 31, 1997, as compared to $4.2 million for the year ended December 31, 1996. This increase primarily resulted from the Company's acquisition of IFM.

Net cash provided by financing activities was $10.6 million for the year ended December 31, 1997, as compared to $1.8 million for the year ended December 31, 1996. This increase was primarily attributable to borrowings under the Company's credit facility in connection with the acquisition of IFM and the construction of the new Company and IFM facilities and increased deferred cryopreservation costs.

The Company intends to file a registration statement with the Securities and Exchange Commission in connection with a public offering of up to 2,500,000 shares of Common Stock (excluding over-allotments) (the "Offering"). The Company anticipates that, even if the Offering is not consummated, borrowings under its existing credit agreements and cash generated from operations will be sufficient to meet its operating and development needs for 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 to expand manufacturing capacity and the extent to which the Company's products generate market acceptance and demand. There can be no assurance that 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.

INFLATION

Although the Company cannot determine the precise effects of inflation, management does not believe it has had a significant effect on revenues or results of operations and does not expect it to have a significant effect in the near future.

YEAR 2000

The Company is aware of the issues that many computer systems will face as the millennium (year 2000) approaches. The Company, however, believes that its own internal software and hardware is year 2000 compliant. The Company believes that any year 2000 problems encountered by procurement agencies, hospitals and other customers and vendors are not likely to have a material adverse effect on the Company's operations. The Company anticipates no other year 2000 problems which are reasonably likely to have a material adverse effect on the Company's operations. There can be no assurance, however, that such problems will not arise.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 1997, the Financial Accounting Standards Board ("FASB") issued Statement No. 130, Reporting Comprehensive Income ("Statement 130"). Statement

130 establishes new standards for the reporting and display of comprehensive income and its components in a full set of general purpose financial statements. These new standards require that all items recognized as components of comprehensive income be reported in a financial statement that is displayed with the same prominence as other financial statements. Statement 130 is effective for fiscal years beginning after December 15, 1997. The adoption of Statement 130 will not have a significant impact on the Company's Consolidated Financial Statements.

In June 1997, the FASB issued Statement 131, Disclosures About Segments of an Enterprise and Related Information ("Statement 131"). Statement 131 changes the way public companies report segment information in annual financial statements and also requires those companies to report selected segment information in interim financial reports. Statement 131 is effective for years beginning after December 15, 1997. The adoption of Statement 131 will not have a significant impact on the Company's consolidated financial position and results of operations, but will require additional disclosure in the notes to the Company's Consolidated Financial Statements.

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 23, 1998

/s/ Edwin B. Cordell, Jr.
By_____
Edwin B. Cordell, Jr.,
Vice President and
Chief Financial Officer