#### FORM 10-K 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, 1996

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 0-21104

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida ate or other jurisdic

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

(State or other jurisdiction of incorporation or organization)

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:

Name of each exchange on

Title of each class

which registered

None

Not applicable

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

Common Stock, \$.01 par value (Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

[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 \$77,208,000 at March  $18,\ 1997$  (7,720,772 shares). The number of common shares outstanding at March  $18,\ 1997$  was 9,585,808 (exclusive of treasury shares).

PART I

ITEM 1. BUSINESS.

OVERVIEW

CryoLife, Inc. (the "Company") is a leader in the development and commercialization of technology for cryopreservation of viable human cardiovascular, vascular and orthopaedic tissues for transplant. The Company was organized in 1984 to address market opportunities in the area of biological implantable devices and materials, and it is today the dominant provider of

cryopreservation services for viable human heart valves. Based on clinical studies, management believes transplanted human tissues may offer, depending on the particular tissue and application, certain advantages over mechanical, synthetic, or animal-derived alternatives, including more natural functionality, elimination of the need for anticoagulant therapy, reduced incidence of reoperation, and reduced risk of catastrophic failure, thromboembolism (stroke), or calcification.

The Company uses proprietary or patented processes to disinfect, preserve, store, and transport human heart valves, veins, and connective tissues for use in cardiac, vascular, and orthopaedic surgeries. Tissue preserved using the Company's proprietary cryogenic processes can be stored for extended periods of time and retains cell viability when properly thawed for implantation into human recipients. Tissue is procured from deceased human donors by organ procurement agencies and tissue banks (most of which are not-for-profit), which consign the tissue to the Company for processing and preservation. After preservation, tissue is stored by the Company or delivered directly to hospitals at the implanting physician's request. The Company charges a fee for performing its services but does not buy or sell human tissue.

#### STRATEGY

The Company is becoming active in the development and acquisition of new technologies that do not require donated human tissue and are therefore not dependent upon the availability of human tissue. The Company's acquisition in 1992 of distribution rights for certain porcine heart valves was the first addition of a product that did not require donated human tissue. In March 1997, the Company acquired Ideas for Medicine ("IFM"), a medical device company specializing in the manufacture and design of endarterectomy surgical instruments, intravascular shunts, infusion ports, accessories utilized in laparoscopic procedures and a wide range of single and dual lumen balloon catherters. Products and applications currently under development, some of which are based on acquired or licensed technologies, are a surgical bio-adhesive based on a derivative of the human blood factor fibrinogen, a surgical bio-adhesive based on blood protein and a cross linking agent, and a process for transplanting human cells onto the structure of non-viable animal tissue.

## RECENT DEVELOPMENTS

On September 12, 1996 the Company acquired the assets of United Cryopreservation Foundation, Inc. (UCFI), a processor and distributor of cryopreserved human heart valves and saphenous vein for transplant. The acquisition provided the tissue bank clients of UCFI with access to the Company's advanced cryopreservation technology for human tissue.

On October 30, 1996 the Company purchased the patent for an advanced-design stentless pulmonary porcine heart valve developed by English heart surgeon, Donald N. Ross, D.Sc., F.R.C.S. (Doctor of Science, Fellow Royal College of Surgeons). The Ross pulmonary porcine valve was designed for heart valve replacement surgery for correcting cardiac valve anomalies in children.

As noted above, the Company acquired IFM in March 1997. The Company will apply its comprehensive quality assurance program to the manufacturing process of IFM and will endeavor to follow good manufacturing processes based on FDA standards. The Company intends to use its existing distribution channels to market IFM's vascular access products while maintaining IFM's existing distribution channels for IFM's non-vascular products. The Company contracts with third parties to sterilize products connected with the IFM acquisition and believes that it is in compliance with the United States Environmental Protection Agency and its regulations. IFM currently employs approximately 100 individuals, none of which are represented by unions. Management believes that its relations with its employees are good.

#### MARKETS

Cardiac Surgery. Based on clinical studies, management believes cryopreserved human heart valves have characteristics that make them one of the preferred replacement alternatives for children. They are also indicated for patients with bacterial endocarditis and women in their child-bearing years. Cryopreserved human heart valves do not require postoperative anticoagulant therapy, which could interfere with a normal pregnancy, or have a catastrophic failure, as do some mechanical valves. In addition, based on clinical studies, management believes human heart valves are more durable than porcine valves. Cryopreserved human heart valves also have good flow characteristics, which

provide an advantage when treating children.

Vascular Surgery. The vascular surgery market addressed by the Company involves coronary bypass and peripheral revascularization surgeries, both of which require small diameter (4 to 6 mm) conduits. Failure to bypass or revascularize an obstruction in such cases may result in death or the loss of a limb.

The Company cryopreserves saphenous veins for use in coronary bypass and revascularization surgeries. In such surgeries, physicians prefer to use the patient's own vein tissue and consider using cryopreserved veins or synthetic veins only when the patient does not have suitable vein tissue available. Synthetic veins in such small diameters are currently not a suitable alternative. The patient may not have suitable vein tissue available because of a previous coronary bypass or other vascular surgery, or such tissue may be unsuitable due to injury or disease. Based on a market report commissioned by the Company, management believes that the patient's own vein tissue is available in all but a very small percentage of these surgeries and that cryopreserved veins may provide an alternative treatment when the patient's own veins are not available.

In analyzing alternative treatments, physicians generally focus on the patency (openness to the flow of blood) of available vein tissue, given the position of implantation, flow characteristics, and other factors. If a physician believes that a vein graft will retain patency for a relatively short period, the physician may conclude that the risks of surgery outweigh any potential benefits. Thus, physicians may recommend amputation over revascularization using cryopreserved veins. At this time, there are no long-term clinical data that establish a reliable minimum patency rate for cryopreserved veins, and patency is not easily measured in asymptomatic patients. In order to achieve wider acceptance of its cryopreserved veins, the Company believes that clinical data establishing the efficacy and patency of cryopreserved  $\,$  veins must be generated and that  $\,$  physicians  $\,$  must be educated to consider the use of cryopreserved veins to save limbs even in the absence of definitive patency data. There can be no assurance that clinical data will establish acceptable patency rates for cryopreserved veins sufficient to make the use of such vein tissue an accepted alternative to amputation. In addition, Medicare patients account for most below-the-knee vascular procedures, and fixed fee payments for these patients do not specifically incorporate cryopreserved

Also, in 1996, the Company began a program for the recovery and cryopreservation of human superficial femoral veins. This program is important for patients suffering from chronic venous insufficiency, a condition where the blood supply through the superficial veins in the legs is severely reduced. Prior to the introduction of CryoLife's cryopreserved veins, patients suffering with this ailment were restricted to drug or compression therapy.

Orthopaedic Surgery (Sports Medicine). The orthopaedic surgery market addressed by the Company involves surgical replacements of the meniscus and the anterior and posterior cruciate ligaments. The Company is currently focusing its cryopreservation efforts in this area to menisci, anterior cruciate ligaments, and patellar tendons, which are available for use as replacement tissue in surgeries involving the knee.

Meniscal insufficiency increases the risk of premature knee degeneration and arthritis. Management believes the Company is the only provider of cryopreserved menisci tissue and that there are no synthetic menisci on the market. When a patient has a damaged meniscus, the present surgical alternatives are to repair, partially remove, or completely remove the patient's meniscus, with partial removal being the most common procedure. Management believes its cryopreserved menisci offer physicians an alternative treatment option in such surgeries.

#### SERVICES AND PRODUCTS

Preservation Services. The transplant of human tissue that has not been preserved must be accomplished in extremely short time frames (not to exceed eight hours for transplants of the human heart). The application by the Company of its preservation and other processes to donated tissue expands the amount of human tissue available to physicians for transplantation. It also expands the treatment options available to physicians and their patients by offering alternatives to implantable mechanical devices and animal tissues. The tissues presently cryopreserved by the Company include human heart valves, veins, and

connective tissues of the knee, and, outside the United States, processed porcine heart valves.

Human Heart Valves. The Company's primary business is the cryopreservation of human heart valves for use in cardiac reconstructive surgery and heart valve replacement. Based on its discussions with physicians and data contained in published reports of clinical studies, management believes that the Company's success in the allograft heart valve market is due in part to physicians' recognition of the durability and good blood flow characteristics of the Company's cryopreserved tissues. The Company first made its cryogenically preserved human heart valves available to physicians in 1984. Company revenues attributable to human heart valve preservation in 1994, 1995, and 1996 were \$16.7 million, \$19.7 million, and \$24.8 million, respectively, accounting for 70%, 67%, and 67% respectively, of the Company's total revenues during those years.

Veins. The Company cryopreserves human saphenous and superficial femoral veins for use in vascular surgeries that require small diameter conduits, such as coronary bypass surgery and below-the-knee vascular reconstructions. The Company first made its cryogenically preserved saphenous veins available to physicians in 1986, utilizing technology licensed from a third party. Company revenues attributable to vein preservation in 1994, 1995, and 1996 were \$5.5 million, \$6.8 million, and \$8.2 million, respectively, accounting for 23%, 23%, and 22% respectively, of the Company's total revenues during those years.

Connective Tissue. The Company entered the growing field of sports medicine in 1990 with the introduction of cryopreserved orthopaedic tissues, including the meniscus, anterior and posterior cruciate ligaments, and patellar tendon, which are connective tissues critical to the proper operation of the human knee. Human menisci cryopreserved by the Company provide orthopaedic surgeons with a new alternative treatment in cases where a patient's meniscus must be completely removed. Ligaments and tendons cryopreserved by the Company are used for the reconstruction of the ligaments and tendons within and about the knee in cases where such ligaments and tendons must be completely removed.

Company revenues attributable to connective tissue preservation in 1994, 1995, and 1996 were \$593,000, \$1.5 million, and \$3.4 million, respectively, accounting for 2%, 5%, and 9%, respectively, of the Company's total revenues during each of those years. Based on its experience with human heart valves, management believes that, as the body of clinical data builds regarding the efficacy of using cryopreserved orthopaedic tissues, the use of such tissues will increase, although there can be no assurance that this will be the case.

Porcine Heart Valves. In July, 1992, in order to improve its competitive position in the cardiac reconstructive surgery market, the Company acquired exclusive, worldwide distributor rights to certain low pressure, gluteraldehyde fixed porcine aortic and mitral heart valves processed by Bravo Cardiovascular, Inc. ("Bravo"). Marketing efforts for the porcine heart valves were hindered during 1994 and 1995 by legal actions between the Company and Bravo. In February 1995, the Company and Bravo reached an agreement to settle their differences whereby the Company obtained ownership of the trademarks, trade secrets, and technology of the stentless porcine heart valves and Bravo retained the same for the stented porcine heart valves. Sales of the stentless porcine valves in 1994, 1995, and 1996 were \$268,000 \$263,000, and \$385,000, respectively. Stented porcine valve sales totaled \$146,000 in 1994. Accordingly, total Company revenues attributable to porcine heart valve sales in 1994, 1995, and 1996 were \$414,000, \$263,000, and \$385,000 respectively, accounting for 2%, 1%, and 1%, respectively, of the Company's total revenues during those years.

The Company will concentrate marketing efforts for the stentless porcine heart valve in Europe where it has been approved for sale in certain countries. During December 1995, the Company obtained CE Mark Certification for the stentless porcine heart valves and ISO 9001 Certification, a European quality standards system, for its tissue processing laboratory. Management believes that CE Mark Certification and ISO 9001 Certification will help the Company gain entry and approval for its porcine heart valves in the European community. The Company will also investigate the process for IDE and PMA approval of stentless porcine heart valves in the United States in 1998.

#### OPERATIONS

The Company's 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.

Procurement of Tissue. Tissue is procured from deceased human donors by organ procurement agencies. 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 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.

Each procurement agency procuring tissue for the Company is given a protocol that describes the techniques required by the Company for dissection and packaging of the tissue. The tissue is transported to the Company's laboratory in Kennesaw, Georgia, in containers provided by the Company 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.

Although the Company is developing or has acquired rights to some products that are not supply constrained, such as the stentless Bravo porcine valves, SynerGraft(R) and the product line acquired in the IFM acquisition, the Company's business depends on the availability of sufficient quantities of tissue from human donors. Over the past several years, the procurement of human tissue by the Company has been increasing; however, there is no assurance that the trend will continue. The Company must rely primarily on the efforts of third party procurement agencies (most of which are not-for-profit) and others to educate the public and foster an increased willingness to donate tissue. The inability to obtain sufficient supplies of human tissue could have a material adverse effect on the Company's business.

Preservation of Tissue. Upon receiving the 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, blood type, and cause of death. A trained technician then removes from the delivered tissue the portion or portions of the 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.

Preserved human heart valves, veins, and connective tissues are then frozen in a controlled freezing process conducted according to strict Company protocols. After the freezing process, the specimens are transferred to liquid nitrogen freezers for long-term storage at temperatures below -190 C. The entire cryopreservation process is rigidly controlled by guidelines established by the Company.

Shipment of Tissue to Implanting Physicians. After preservation, tissue is stored by the Company or is delivered directly to hospitals at the implanting physician's request. Cryopreserved tissue is packaged for shipping 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. The Company will store tissue for up to 90 days at no charge. Thereafter, there is a nominal monthly charge. After the Company ships the tissue to the hospital, the Company invoices the institution for its services, the procurement fee, and shipping costs.

The Company encourages hospitals to accept the cryopreserved tissue back quickly by providing Company-owned liquid nitrogen freezers to client hospitals without charge. 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 improves the Company's cash flow.

# QUALITY ASSURANCE

The Company employs a comprehensive quality assurance program in all of its tissue processing activities. The Company endeavors to follow good manufacturing

processes ("GMPs"), based on FDA standards, to assure the consistency of the Company's processing and cryopreservation operations. 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. A trained technician then removes samples from the delivered tissue upon which serial cultures are performed to identify any disease or fungal growth. 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 preserved, a separate disinfection procedure is begun during which the removed tissue is treated with proprietary antibiotic solutions.

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 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.

#### RESEARCH AND DEVELOPMENT

The Company's preservation service efforts have been directed toward tissue transplant opportunities in the medical specialties of cardiac, vascular and orthopaedic surgery. The company seeks to identify medical market areas that can benefit from its expertise in biochemistry and cell biology in order to develop innovative techniques and biological products for the cardiac, vascular and orthopaedic reconstructive surgery fields.

Additionally, the Company seeks to expand the Company's implantable product lines and laboratory service business to include biological products that are not dependent upon the availability of human tissue. The Company is currently in the process of developing or investigating the development of several technologies and products, several of which are licensed by the Company pursuant to exclusive license agreements from third parties, to expand the Company's service and product offerings, including the following:

o FibRx(R) - The Company is developing a surgical bio-adhesive based on a derivative of the human blood factor fibrinogen. This technology creates a stable and unique delivery method for fibrin adhesive to be used in a variety of surgical applications, which, if successful, may control bleeding and assist in positioning tissue at wound sites during and after surgery. FibRx is progressing through animal trials and is presently undergoing toxicology validation procedures mandated by the FDA prior to the approval for human clinical trials.

o BioGlue(R) - Surgical bio-adhesive. This technology creates a surgical bio-adhesive based on a derivative of blood protein and a cross linking agent. Management believes that this adhesive may be stronger than FibRx. BioGlue is currently preparing through animal and toxicity evaluation. In addition, the Company's emphasis with respect to its BioGlue product continues to undergo modification regarding delivery mechanism and evaluation of its key components and intended application. During March 1996, the Company acquired the technology underlying the BioGlue.

o SynerGraft(R) - The Company is developing a process for transplanting human cells onto the structure of a non-viable animal tissue. This technology, which has demonstrated feasibility in animal trials, may avoid donor supply constraints associated with human tissue. The technology underlying the SynerGraft project was licensed by the Company pursuant to an exclusive, worldwide license agreement.

Under the agreement, the licensor retains title to such technology and any patents and patent applications relating thereto.

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. Historically, the Company has allocated a significant portion of its revenues to research and development. In 1994, 1995 and 1996 the Company expended approximately \$2.0 million, \$2.6 million and \$2.8 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 8%, 9% and 7.5%, respectively, of the Company's revenues for those years. The Company's research and development program is overseen by its medical and scientific advisory boards. The Company's animal 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.

#### DISTRIBUTION

Cryopreserved tissues do not lend themselves to the traditional medical products distribution systems and are subject to governmental regulations that forbid the purchase or sale of human organs. Also, cryopreserved tissue must be transported under stringent handling conditions and maintained within specific temperature tolerances at all times. The Company utilizes proprietary shipping containers for transporting tissue to implanting surgeons.

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, as well as 23 technical service representatives who are Company employees, who provide field support. Some of these representatives are independent contractors who visit physicians to explain the use of the Company's cryopreserved tissues and to answer questions that doctors may have regarding the Company's products and services. These representatives receive fees based on service fees received by the Company that are attributable to physicians in their territory.

#### GOVERNMENT REGULATION

FDA Regulation--General. Because human heart valves are, and other Company products may be, 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 United States Food and Drug Administration ("FDA") regulates the distribution, manufacture, labeling, and promotion of medical devices in the United States. 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 commercially distributed in the United States 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 exemptions from the premarket approval process for investigational devices ("IDEs"), which authorize 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 may not be advertised, or otherwise promoted, and the charges that may be made 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 GMPs, which require that companies manufacture their products and maintain their documents in a prescribed manner with respect to manufacturing, testing, and 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 devices, 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 United States have FDA approval before they are exported.

The FDA inspects medical device manufacturers and distributors, and has broad authority to order recalls of medical devices, to seize noncomplying medical devices, to enjoin and/or to impose civil penalties on manufacturers and distributors marketing non-complying medical devices, and to criminally prosecute violators.

FDA Regulation--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 "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 a Class II Medical Device and has removed them from clinical trial status. It also allows the Company to distribute such valves to cardiovascular surgeons throughout the United States.

FDA Regulation--Other Tissue. Other than human and porcine heart valves, none of the Company's other products or services is currently subject to regulation as a medical device 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. On December 14, 1993 the FDA promulgated an interim rule to require certain infectious disease testing, donor screening, and record keeping with respect to human tissue held by tissue banks and establishments engaged in the recovery, processing, storage or distribution of banked human tissue. There are certain exemptions to this interim rule, including an exemption for human tissue that is regulated as a human drug, biological product or medical device. This rule applies to the veins and connective tissue that are currently processed by the Company. 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, 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, Congress is expected to consider legislation that would regulate human tissue for transplant. Such legislation could have a material adverse effect on the Company.

FDA Regulation--Porcine Valves. Porcine heart valves are Class III medical devices, and FDA approval is required prior to commercial distribution of such

valves in the United States. The porcine heart valves currently held by the Company have not been approved by the FDA for commercial distribution in the United States and may be distributed from the United States to foreign countries only if FDA export approval is obtained.

 ${\tt FDA}$  Regulation--IFM. The products offered by IFM are regulated as Class I and Class II medical devices by the FDA.

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, FibRx, BioGlue). Some may be medical devices; others may be drugs or biological products. Regulation of drugs and biological products is substantially similar to medical device regulation as described above. Obtaining FDA approval or clearance to market these products is likely to be a time consuming and expensive process, and there can be no assurance that any of these products will ever receive FDA approval, if required, to be marketed.

NOTA Regulation. The Company's activities in processing and transporting human hearts and certain other organs are also subject to federal regulation under the National Organ Transplant Act ("NOTA"), which makes it unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. NOTA excludes from the definition of "valuable consideration" reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ. The purpose of this statutory provision is to allow for compensation for legitimate services. The Company believes that to the extent its activities are subject to NOTA, it meets this statutory provision relating to the reasonableness of its charges. There can be no assurances, 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 under Georgia law. The Company has such a license, and the Company believes it is in compliance with applicable Georgia regulations relating to clinical laboratories which procure, store, or process human tissue designed to be used for medical purposes in human beings. There can be no assurances, 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 certain licenses as required.

#### COMPETITION

The Company faces competition from non-profit tissue banks that cryopreserve human tissue, as well as companies that market mechanical valves and synthetic and animal tissue for implantation. Many established companies, some with resources greater than those of the Company, are engaged in manufacturing alternatives to preserved human tissue. Based on its interviews with physicians and its experience to date, management believes that, as compared to other entities that cryopreserve human tissue, the Company competes on the basis of technology, customer service and quality assurance. As compared to mechanical valves or synthetic or animal tissue, management believes that the Company's cryopreserved human heart valves compete on the factors set forth above, as well as by providing a tissue that is one of the preferred replacement alternatives 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 bacterial endocarditis. Although tissue cryopreserved by the Company is initially higher priced than are porcine and mechanical alternatives, the mechanical alternatives typically require that the patient take daily doses of anticoagulants for the lifetime of the implant. As a result of the costs associated with anticoagulants, mechanical valves are generally, over the life of the implant, more expensive than the Company's cryopreserved tissue. Notwithstanding the foregoing, management believes that, to date, price has not been a significant competitive factor.

For each procedure that may utilize other human tissue the Company preserves, there generally 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 for reimplantation. 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 preserved by the Company.

Heart Valves. Alternatives to the Company's cryopreserved human heart valves include mechanical valves and processed porcine and bovine (cow) valves. St. Jude Medical, Inc. is dominant in the mechanical heart valve market, and a division of Baxter International Inc. is dominant in the porcine heart valve market. In addition, management believes that at least four tissue banks offer cryopreservation services for human heart valves in competition with the Company.

Veins. Synthetic alternatives to the Company's cryopreserved veins are available primarily in medium and large diameters. Synthetic conduits in small diameters are not a suitable alternative because they tend to occlude when implanted. At present, management believes that one other tissue bank processes human veins in competition with the Company. Other companies may enter this market and compete with the Company in the future.

Connective Tissue. The Company's competition in the area of connective tissue varies according to the tissue involved. Freeze dried and fresh frozen human connective tissues and the Company's preserved ligaments and tendons constitute the principal treatment alternatives to complete removal when the repair or partial removal of damaged tissue is not possible. These alternative allografts are distributed by distributors of Osteotech, Inc. and various tissue banks, among others. Synthetic alternatives also exist for anterior cruciate ligaments and patellar tendons. There are presently no processed or synthetic alternatives to the Company's preserved menisci.

Porcine Heart Valves. The Company presently distributes its stentless porcine heart valves only outside the United States. These porcine heart valves compete with mechanical valves, human heart valves, and processed bovine valves. The Company is aware of at least three other companies that offer stentless porcine heart valves.

#### EDUCATION AND TECHNICAL SUPPORT

An important aspect of increasing the distribution of the Company's cryopreservation services is educating physicians on the use of cryopreserved tissue and on proper implantation techniques. The Company sponsors physician training seminars where physicians teach other physicians the proper technique for handling and implanting cryopreserved tissue. The Company also produces educational videotapes for use by the physicians. The Company coordinates live surgery demonstrations at various medical schools with patients selected by the medical school. The medical facilities chosen for live surgery demonstrations are selected in part based on their ability to broadcast the surgery to an amphitheater of medical personnel by closed circuit television. The Company also coordinates laboratory sessions that utilize animal tissue to duplicate 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 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. As with the education of physicians, the Company 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 24-hour telephone support service.

# 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 United States 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

#### PATENTS AND OTHER PROPRIETARY RIGHTS

The Company believes that its patents, trade secrets, and technology licensing rights provide it with important competitive advantages. The Company owns United States patents relating to its technology for human heart valve, vein, and connective tissue preservation; tissue revitalization prior to freezing; tissue transport; fibrin adhesive; organ storage solution; and packaging. The Company has United States patents pending that relate to alternative human heart valve processing methods, fibrin adhesive preparation, stabilization of proteins for freeze drying, and vein and connective tissue preservation. The Company also has exclusive licensing rights for technology relating to light-sensitive enzyme inhibitors. The remaining duration of the Company's patents ranges from 4 to 15 years, exclusive of any renewals thereof.

In 1985, the Company entered into an agreement with Medical University of South Carolina and one of its employees, pursuant to which it agreed to co-sponsor research regarding certain technologies relating to the cryopreservation of vein tissue and acquired an option to license such technologies. The University subsequently waived any rights it may have had in respect of such technologies, and the Company and such employee (who subsequently left the employ of the university) are now co-owners of certain patents relating to such technologies. The Company pays such co-owner royalties on "net revenues" derived from the cryopreservation of vein tissue.

ALT, the Company's logo, CryoGraft, CryoKids, CryoLife, CryoLife International, CryoPak, CryoSafe, CryoValve, CryoValve-ALT, CryoVein, BioGlue, FibRx and SynerGraft are registered trademarks of the Company, and CryoLife-O'Brien is a trademark of the Company.

#### EMPLOYEES

The Company presently has approximately 315 employees, including those employed at IFM. These employees include 13 persons with Ph.D. degrees or higher. 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

#### GOVERNMENT REGULATION

The processing and distribution of the Company's human heart valves are currently regulated as Class II medical devices by the U.S. Food and Drug Administration ("FDA"), and are subject to significant regulatory requirements, including current good manufacturing regulations (GMP) and record-keeping 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 impact the marketing of these products or could affect market demand for these products.

Other allograft tissues processed and distributed by the Company are currently regulated as "banked human tissue" under an interim rule promulgated by the FDA pursuant to the Public Health Services Act. This interim rule establishes requirements for donor testing and screening for human tissue and record-keeping 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 premarket approval or product licensing requirements.

The Company's porcine heart valve products are classified as Class III medical devices and have not been approved for distribution within the United States. Distribution of these porcine heart valves within the European common market is dependent upon the Company maintaining its CE Mark and ISO 9001 status. There can be no assurance that the Company will be able to obtain the FDA approval which will be required to distribute its porcine heart valve products in the United States or that it will be able to maintain its CE Mark or ISO 9001 status.

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 and other regulatory authorities normally involves clinical trials in humans and the preparation of an extensive premarket approval 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 meet applicable regulatory criteria to receive the required approvals for manufacturing and marketing. Delays in obtaining United States 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 clearances 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.

Products marketed by the Company pursuant to FDA or foreign oversight or approval are subject to pervasive and continuing regulation. In the United States, devices and biologics must be manufactured in registered, and in the case of biologics, licensed establishments and must be produced in accordance with GMP 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.

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, however, that restrictive interpretations of NOTA will not be adopted in the future that will call into question one or more aspects of the Company's methods of charging for its preservation services. The Company's laboratory operations are subject to the U.S. Department of Labor, Occupational Safety and Health Administration and Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations governing the processing, transportation and storage of human organs and tissue, and 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 adversely affect the Company's operations.

# 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 four 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. and Medtronic Inc. (mechanical valves) and a division of Baxter International Inc. (porcine valves). Many of the Company's competitors have greater financial, technical 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 continue 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. An important factor in such competition may be the timing of market introduction of competitive products. Accordingly, the relative speed with which the Company can develop products, gain regulatory approval and reimbursement acceptance and supply commercial quantities of the product to the market are expected to be important competitive factors. In addition, the Company believes that the primary competitive factors for its products include safety, efficacy, ease of use, reliability, suitability for their specified uses in service and price. The Company also believes that physician relationships are important competitive

#### LIMITED AVAILABILITY OF TISSUE

Although the Company is pursuing the development of products and services that would not be constrained by tissue availability, such as its porcine heart valves, biological glues, and the product line acquired from IFM, much of the Company's current business depends upon the availability of sufficient quantities of tissue from human donors. In particular, continuing limits on the supply of donated heart tissue could restrict the Company to modest, if any, growth in the number of human heart valves preserved by the Company. A significant reduction in supplies of human tissue could have a material adverse effect on the Company's business. 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 an increased 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 tissue gains acceptance, demand for transplantable tissue will exceed the amount of tissue available from human donors. While tissue availability is not currently a limiting factor for most vein tissue and orthopedic tissues, rapid growth in these areas could ultimately be limited by tissue availability, in addition to other factors.

#### UNCERTAINTIES REGARDING PRODUCTS IN DEVELOPMENT

The Company's porcine heart valve products are currently only offered for sale outside of the United States. The porcine heart valves are subject to the risk that the Company may be unable to obtain governmental approval necessary to permit commercial distribution of these valves in the United States.

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 cost 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 human implants in order to gain community acceptance. With respect to the Company's major products under development, FibRx(R) is progressing through animal trials and is presently undergoing toxicology validation procedures mandated by the FDA prior to the approval for human clinical trials, BioGlue(R) is progressing through animal and toxicity evaluations, and SynerGraft(R) has begun initial animal testing. In addition, the Company's emphasis with respect to its BioGlue product in development continues to undergo modification regarding delivery mechanisms and evaluation of its key components and their intended applications. As a result of the foregoing, management cannot effectively predict the duration or extent of, or whether any newly introduced products will successfully complete, these initial stages, and as a result, there is no guaranty that any of these products will ultimately be approved for use on human tissue.

#### DEVELOPMENT PARTNERS

The Company's strategy for developing, testing and commercializing certain of its products in development includes entering into collaborations with academic institutions, corporate partners, licensors, licensees and others. These collaborations potentially will provide access to technologies, technical expertise and financial and other resources that might otherwise be unavailable to the Company. The Company has entered into collaborations with various institutions related to the development and testing of its tissue technologies. Although the Company believes that its partners in these collaborations are motivated to succeed in performing their contractual responsibilities, their actual and timely success cannot be assured.

Furthermore, the Company anticipates that its future research and development projects, including those with respect to its Synergraft and Bioglue products under development, may require the assistance of third party collaborators with respect to the provision of capital and know-how. There can be no assurance, however, that the Company will be able to negotiate additional collaborative agreements in the future on acceptable terms, if at all, or that such collaborative arrangements will be successful. Failure to obtain and successfully execute such arrangements in the future could increase the Company's capital requirements to undertake research, development and marketing

of its proposed products. In addition the Company may encounter significant delays in introducing its proposed products into certain markets or find that the development, manufacture or sale of its proposed products in certain markets is adversely affected by the absence of such collaborative agreements or the failure of collaborative partners to perform their obligations in a timely fashion.

#### 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 would 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, licenses to which may not be available to the Company. 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. Additionally, the Company protects its proprietary technology 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.

#### UNCERTAINTIES REGARDING FUTURE HEALTH CARE REIMBURSEMENTS

Even though the Company does not receive payments directly from third party healthcare payers, their reimbursement methods may impact demand for the Company's cryopreserved tissue. The Company is unable to predict what changes will be made in the reimbursement methods utilized by third party healthcare payers or their effect on the Company. Changes in the reimbursement methods utilized by third party healthcare payers, 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 payers are increasingly attempting to contain healthcare cost 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 payers for uses of the Company's new products and services, market acceptance of these products could be adversely affected.

#### 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 materially adversely affect the Company's business, financial condition and results of operations.

#### ACQUISITIONS

The Company's growth strategy includes the consummation of strategic acquisitions of other companies and products. The integration of such acquisitions can require substantial efforts on the part of management and can distract attention from the Company's core business. There can be no assurance

that the Company will be able to successfully integrate the operations of any such business, including IFM, nor can there be any assurance that the Company will be able to successfully market IFM's medical devices, which represent a new product line for the Company.

#### PRODUCT LIABILITY AND INSURANCE

The Company faces the inherent business risk of financial exposure to product liability claims in the event that the use of tissue processed, preserved or distributed by the Company results in personal injury or the transmission of infectious disease. Although the Company has incurred minimal losses due to product liability claims to date, there can be no assurance that it will not incur such losses in the future. The Company currently maintains product liability insurance in the aggregate amount of \$14 million per occurrence 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 demand for the Company's services.

#### 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. Any failure to comply with such regulations could result in the imposition of penalties, fines and sanctions which could have a material adverse effect on the Company's business.

#### 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 or cardiovascular 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 By-laws 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 stockholder rights plan adopted in 1995, the Company has distributed a dividend of one right for each outstanding share of Common Stock. 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. There are also outstanding stock options to

purchase an aggregate of approximately 708,000 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 effect 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. It is not likely that any cash dividends will be paid in the foreseeable future.

#### ITEM 2. PROPERTIES.

The Company's facilities are located in suburban Atlanta, Georgia, and consist of three facilities totaling approximately 130,000 square feet of leased office and laboratory space. Approximately 17,500 square feet are dedicated to laboratory space. The primary laboratory facilities (excluding the Bio-Adhesive laboratory) currently contain three main operating areas: Cryopreserved Tissue Processing, Research and Development, and Microbiology. Each laboratory consists of a general work area and adjoining "clean rooms" for work with human tissue or in sterile processing. The clean rooms are designed to provide a near sterile environment. The Cryopreserved Tissue Laboratory contains approximately 7,700 square feet with a suite of seven clean rooms. The Research and Development Laboratory is approximately 5,500 square feet with a suite of five clean rooms. The Microbiology Laboratory is approximately 3,200 square feet with a suite of three clean rooms. The Bio-Adhesive facility contains approximately 11,000 square feet, including approximately 4,000 square feet of laboratory space with a suite of eight clean rooms. The Company's Porcine heart valves are manufactured in the Company's bioprosthesis laboratory, which contains approximately 13,000 square feet, with a suite of three clean rooms.

#### ITEM 3. LEGAL PROCEEDINGS.

Inapplicable.

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

 ${\tt Inapplicable.}$ 

# ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT.

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

Name	Age	Office With Registrant	Date First Elected to Present Office
Steven G. Anderson	58	Chairman of the Board of Directors, President and Chief Executive Officer	February, 1984
Robert T. McNally, Ph.D.	49	Senior Vice President, Clinical Research	June, 1984
Albert E. Heacox, Ph.D.	46	Vice President, Laboratory Operations	June, 1985
Gerald B. Seery	40	Vice President, Marketing	August, 1995
Ronald D. McCall, Esq.	60	Director, Secretary and Treasurer	January, 1984
Edwin B. Cordell, Jr., CPA	38	Vice President and Chief Financial Officer	December, 1994
James C. Vander Wyk, Ph.D.	52	Vice President, Regulatory Affairs and Quality Assurance	February, 1996
Kirby S. Black, Ph.D.	42	Vice President, Research and Development	July, 1995

Steven G. Anderson, a founder of the Company, has served as the Company's President, Chairman of the Board, and Chief Executive Officer since its inception. Mr. Anderson has 30 years of experience in the implantable medical

device industry. Prior to joining the Company, Mr. Anderson was Senior Executive Vice President of Intermedics, Inc., a manufacturer and distributor of pacemakers and other medical devices. Mr. Anderson has a B.A. from the University of Minnesota.

Robert T. McNally, Ph.D., a founder of the Company, served as Vice President, Clinical Research from June, 1984, until September, 1991, when he was promoted to his current position, Senior Vice President, Clinical Research. Dr. McNally has been responsible for clinical research and development, which includes all testing of the Company's processes and services, supervision of new product development, and oversight of all regulatory affairs. Prior to joining the Company, Dr. McNally was employed as Regional Manager-Europe by Intermedics International, Inc., which markets pacemakers and other medical devices. Dr. McNally has a Ph.D. in bioengineering from the University of Pennsylvania, and M.S.E. in biomedical electronic engineering from the University of Pennsylvania, and a B.E.E. in electrical engineering from Villanova University.

Albert E. Heacox, Ph.D. has served as Vice President, Laboratory Operations since June, 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, he 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 his Ph.D. in Biology from Washington State University in 1980. He completed his post-doctorate training in cell biology at the University of Cologne, West Germany in 1981.

Gerald B. Seery joined the Company in 1993 as Director, Vascular Marketing. In August, 1995 he was promoted to the position of Vice President of Marketing. Mr. Seery is responsible for developing and implementing the Company's marketing plans and supervising all tissue procurement activities. Prior to joining the Company, Mr. Seery held senior marketing management positions with Meadox Medical, Electro Catheter Corporation and Daig Corporation, accumulating some sixteen years specialized marketing experience in cardiovascular medical devices. Mr. Seery received a Bachelor of Arts degree in international economics at The Catholic University of America in Washington D.C. in 1978 and completed his Masters of Business Administration at Columbia University in New York in 1980.

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. He has a juris doctor degree from the University of Florida.

Edwin B. Cordell, Jr., CPA was appointed as Vice President and Chief Financial Officer of the Company in November, 1994. From August, 1987 to November, 1994, he served as Controller and Chief Financial Officer of Video Display Corporation, a cathode ray tube remanufacturing and distribution company. Mr. Cordell graduated from the University of Tennessee with a B.S. in Accounting.

James C. Vander Wyk, Ph.D. was appointed as Vice President, Regulatory Affairs and Quality Assurance of the Company in February 1996. Prior to that, he held senior management positions at Schneider (USA), Inc., Pharmacia Deltec, Inc. and Delmed, Inc. gaining some sixteen years experience in Regulatory Affairs and Quality Assurance. Dr. Vander Wyk received his B.S. in Pharmacy from the Massachusetts College of Pharmacy and his Ph.D. in Microbiology from the University of Massachusetts. He performed his NIH Postdoctoral Fellowship at the University of Illinois.

Kirby S. Black was appointed as Vice President of Research and Development in July 1995. Dr. Black is responsible for new product research and development. Prior to joining the Company, Dr. Black was Director, Medical Information and Project Leader at Advanced Tissue Sciences, La Jolla, 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 holds a B.S. degree from the University of California, Los Angeles, and a Ph.D. degree from the University of California at Irvine.

#### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The following information contained in the 1996 Annual Report to Stockholders is incorporated herein by reference: information concerning stock prices on page 22. CryoLife, Inc. common stock is traded on The Nasdaq Stock Market under the Symbol CRYL. As of March 14, 1997 the Company had 384 shareholders of record and approximately 6,000 benficial owners, including shares held in brokerage accounts. CryoLife, Inc. has not paid any cash dividends on its common stock and has no present plans to pay cash dividends in the near future.

#### ITEM 6. SELECTED FINANCIAL DATA.

Selected Financial Data on page 23 of the 1996 Annual Report to Stockholders are incorporated herein by reference.

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

Management's Discussion and Analysis of Financial Condition and Results of Operations included on pages 4 through 9 of the 1996 Annual Report to Stockholders is incorporated herein by reference.

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The following consolidated financial statements and supplementary data of the Company included in the 1996 Annual Report to Stockholders, are incorporated herein by reference.

#### Financial Statements:

Consolidated Statements of Income for each of the three years in the period ended December 31, 1996, page 12.

Consolidated Statements of Shareholders' Equity for each of the three years in the period ended December 31, 1996, page 14.

Consolidated Balance Sheets as of December 31, 1996 and 1995, pages 10 through 11.

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 1996, page 13.

Notes to Consolidated Financial Statements, pages 15 through 21

Independent Auditors' Report, page 22.

#### Supplementary Data:

Selected Financial Information and Selected Quarterly Financial Information, page 23.

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

Effective April 17, 1996, the Audit Committee of the Board of Directors of Registrant engaged the accounting firm of Ernst & Young LLP as independent auditors for the Registrant to replace the firm of KPMG Peat Marwick LLP, which was terminated by Registrant's Audit Committee effective that date.

There were no disagreements between Registrant and KPMG Peat Marwick LLP in connection with the audits of the two most recent fiscal years ended December 31, 1995, or any subsequent interim period, on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements if not resolved to their satisfaction would have caused KPMG Peat Marwick LLP to make reference in connection with their reports

#### PART III

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The response to Item 10, applicable to the Directors of the Company, is incorporated herein by reference to the information set forth under the caption "Election of Directors" in the Proxy Statement for the Annual Meeting of Stockholders to be held May 15, 1997. Information concerning executive officers is included in Part I, Item 4.A of this Form 10-K.

The response to item 10, applicable to Section 16(a) of the Securities Exchange Act of 1934, as amended, is incorporated herein by reference to the information set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement for the Annual meeting of Stockholders to be held May 15, 1997.

#### ITEM 11. EXECUTIVE COMPENSATION.

The response to Item 11 is incorporated herein by reference to the information set forth under the captions "Report of the Compensation Advisory Committee on Executive Compensation," "Performance Graph" and "Executive Compensation" in the Proxy Statement for the Annual Meeting of Stockholders to be held May 15, 1997.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The response to Item 12 is incorporated herein by reference to the information set forth under the captions "Ownership of Principal Shareholders and Certain Executive Officers" and "Election of Directors" in the Proxy Statement for the Annual Meeting of Stockholders to be held May 15, 1997.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The response to Item 13 is incorporated herein by reference to the information set forth under the caption "Executive Compensation" in the Proxy Statement for the Annual Meeting of Stockholders to be held May 15, 1997.

#### PART IV

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

The following are filed as part of this report:

# (a) 1. Financial Statements

The following consolidated financial statements are incorporated herein by reference to the 1996 Annual Report to Stockholders, portions of which are filed as an exhibit to this Form 10-K.

Consolidated Statements of Income for each of the three years in the period ended December 31, 1996, page 12.

Consolidated Statements of Shareholders' Equity for each of the three years in the period ended December 31, 1996, page 14.

Consolidated Balance Sheets as of December 31, 1996 and 1995, pages 10 through 11.

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 1996, page 13.

Notes to Consolidated  $\,$  Financial Statements,  $\,$  pages 15 through 21.

Independent Auditors' Report, page 22.

#### 2. Financial Statement Schedule

Independent Auditors' Report on Schedule

Schedule II - Valuation and Qualifying Accounts

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

#### 3. A. Exhibits

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

The Tollowing	exhibits are fired herewith of incorporated herein by reference:
Exhibit Number	Description
2.1	Sale Agreement dated August 16, 1996 between the Company and Donald Nixon Ross. (Incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly report on form 10-Q for the quarter ended September 30, 1996.)
2.2	Asset Purchase Agreement among the Company and United Cryopreservation Foundation, Inc., United Transplant Foundation, Inc. and QV, Inc. dated September 11, 1996. (Incorporated by reference to Exhibit 2.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
3.1	Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
3.2	Amendment to Articles of Incorporation of the Company dated November 29, 1995. (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
3.3	Amendment to the Company's Articles of Incorporation to increase the number of authorized shares of common stock from 20 million to 50 million shares and to delete the requirement that all preferred shares have one vote per share. (Incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.)
3.4	ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.1	Lease, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company, as Tenant, dated February 13, 1986, as amended by that Amendment to Lease, by and between the parties, dated April 7, 1986, as amended by that Amendment to Lease, by and between the parties, dated May 15, 1987, as amended by that Second Amendment to Lease, by and between the parties, dated June 22, 1988, as amended by that Third Amendment to Lease, by and between the parties, dated April 4, 1989, as amended by that Fourth Amendment to Lease, by and between the parties, dated April 4, 1989 as amended by that Fifth Amendment to Lease, by and between the parties, dated October 15, 1990. (Incorporated by reference to Exhibit 10.1 to the

Registrant's Registration Statement on Form S-1 (No. 33-56388).)

- 10.1(a) Seventh Amendment to Lease dated February 13, 1986, by and between New Market Partners III, Laing Properties, Inc., General Partner, as Landlord, and the Company as tenant, dated May 15, 1996.
- Lease by and between Newmarket Partners I, Laing Properties, Inc. and Laing Management Company, General Partner, as Landlord, and the Company as Tenant, dated July 23, 1993. (Incorporated by reference to Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
- 10.3 1993 Employee Stock Incentive Plan adopted on July 6, 1993. (Incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
- 10.4 1989 Incentive Stock Option Plan for the Company, adopted on March 23, 1989. (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10.5 Incentive Stock Option Plan, dated as of April 5, 1984. (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10.6 Form of Stock Option Agreement and Grant under the Incentive Stock Option and Employee Stock Incentive Plans. (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10.7 CryoLife, Inc. Profit Sharing 401(k) Plan, as adopted on December 17, 1991. (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- Form of Supplemental Retirement Plan, by and between the Company and its Officers -- Parties to Supplemental Retirement Plans: Steven G. Anderson, Robert T. McNally, Gerald B. Seery, James C. Vander Wyk, Albert E. Heacox, Kirby S. Black, and Edwin B. Cordell, Jr. (Incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10.9(a) Employment Agreement, by and between the Company and Steven G. Anderson. (Incorporated by reference to Exhibit 10.9(a) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- 10.9(b) Employment Agreement, by and between the Company and Robert T. McNally. (Incorporated by reference to Exhibit 10.7(b) to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10.9(c) Employment Agreement, by and between the Company and Albert E. Heacox. (Incorporated by reference to Exhibit 10.7(c) to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10.9(d) Employment Agreement, by and between the Company and Edwin B. Cordell, Jr. (Incorporated by reference to Exhibit 10.9(f) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- 10.9(e) Employment Agreement, by and between the Company and Gerald B. Seery. (Incorporated by reference to Exhibit 10.9(e) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- 10.9(f) Employment Agreement, by and between the Company and James C. Vander Wyk, Ph.D. (Incorporated by reference to Exhibit 10.9(f) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- 10.9(g) Employment Agreement, by and between the Company and Kirby S. Black, Ph.D.
- 10.10 Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated by reference to Exhibit

10.9 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)

- 10.11 Registration Rights Agreement, by and among the Company, Galen Partners, L.P., and Galen Partners International, L.P., both Delaware limited partnerships, dated August 22, 1991. (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- Technology Acquisition Agreement between the Company and Nicholas Kowanko, Ph.D., dated March 14, 1996. (Incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- Option Agreement, by and between the Company and Duke University, dated July 9, 1990, as amended by that Option Agreement Extension, by and between the parties, dated July 9, 1991. (Incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- Research and License Agreement by and between Medical University of South Carolina and CryoLife dated November 15, 1985, as amended by Amendment to the Research and License Agreement dated February 25, 1986 by and between the parties and an Addendum to Research and License Agreement by and between the parties, dated March 4, 1986. (Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10.15 Technical Services Agreement by and between the Company and Validation Systems, Inc., dated as of January 1, 1994. (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
- 10.16 CryoLife, Inc. Non-Employee Directors Stock Option Plan adopted on March 27, 1995. (Incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- 10.17 Settlement Agreement between the Company and Bravo Cardiovascular, Inc., dated February 14, 1995. (Incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- 10.18 Sale Agreement between the Company and Bravo Cardiovascular, Inc. dated February 14, 1995. (Incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- 10.19 Private Label Agreement between the Company and Bravo Cardiovascular, Inc. dated February 14, 1995. (Incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- Consignment Agreement between the Company and Bravo Cardiovascular, Inc. dated February 14, 1995. (Incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- Sale and Assignment Agreement between the Company and Osteotech, Inc. dated July 17, 1995. (Incorporated by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- 10.22 Lease Agreement between the Company and Amli Land Development I
  Limited Partnership, dated April 18, 1995. (Incorporated by
  reference to Exhibit 10.26 to the Registrant's Annual Report on
  Form 10-K for the fiscal year ended December 31, 1995.)
- Preoccupancy and Construction Agreement between the Company and Amli Land Development I Limited Partnership dated April 18, 1995. (Incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)

- Funding Agreement between the Company and Amli Land Development I Limited Partnership dated April 18, 1995. (Incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- 10.25 Employee Stock Purchase Plan dated May 22, 1995. (Incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- Noncompetition Agreement between the Company and United Cryopreservation Foundation, Inc. dated September 11,1996. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.27 Noncompetition Agreement between the Company and QV, Inc. dated September 11, 1996. (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.28 Revolving\Term Loan Facility between the Company and NationsBank N.A., dated August 30, 1996. (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
- 10.29 Research and Option Agreement between the Company and Biocompatibles Limited dated July 29, 1996. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.)
- 10.30 Technology License Agreement between the Company and Colorado State University Research Foundation dated March 28, 1996. (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 1996.)
- Noncompetition Agreement between the Company and United Transplant Foundation, Inc. dated September 11, 1996. (Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1996.)
- 11.1 Statement re: Computation of Per Share Earnings.
- 13.1 1996 Annual Report to Stockholders. The portions of the Annual Report which are not specifically incorporated herein by reference are provided for informational purposes only.
- 21.1 Subsidiaries of CryoLife, Inc.
- 23.1 Consent of Independent Auditors.
- 23.2 Consent of Independent Auditors.
- 27.1 Financial Data Schedule
- 3. B. Executive Compensation Plans and Arrangements.
- 1. 1993 Employee Stock Incentive Plan adopted on July 6, 1993. (Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- 2. 1989 Incentive Stock Option Plan for the Company, adopted on March 23, 1989 (Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 3. Incentive Stock Option Plan, dated as of April 5, 1984 (Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 4. Form of Stock Option Agreement and Grant under the Incentive Stock Option and Employee Stock Incentive Plans (Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)

- 5. CryoLife, Inc. Profit Sharing 401(k) Plan, as adopted on December 17, 1991 (Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- Form of Supplemental Retirement Plan, by and between the Company and its Officers -- Parties to Supplemental Retirement Plans: Steven G. Anderson, Robert T. McNally, Gerald B. Seery, James C. Vander Wyk, Albert E. Heacox, Kirby S. Black and Edwin B. Cordell, Jr. (Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 7. Employment Agreement, by and between the Company and Steven G. Anderson. (Exhibit 10.7(a) to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 8. Employment Agreement, by and between the Company and Robert T. McNally. (Exhibit 10.7(b) to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 9. Employment Agreement, by and between the Company and Albert E. Heacox. (Exhibit 10.7(c) to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
- 10. Employment Agreement, by and between the Company and Gerald B. Seery. (Incorporated by reference to Exhibit 10.9(e) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995.)
- 11. Employment Agreement, by and between the Company and James C. Vander Wyk, Ph.D. (Incorporated by reference to Exhibit 10.9(f) to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995.)
- 12. Employment Agreement, by and between the Company and Edwin B. Cordell, Jr. (Incorporated by reference to Exhibit 10.9(f) to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- 13. CryoLife, Inc. Non-Employee Directors Stock Option Plan adopted on March 27, 1995. (Incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1994.)
- 14. Employee Stock Purchase Plan. (Incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1995.)
- 15. Employment Aggrement by and between the Company and Kirby S. Black (Exhibit 10.9(g) to this Form 10-K.)

#### (b) Reports on Form 8-K

The Registrant did not file a report on Form 8-K during the fourth quarter of the recently completed fiscal year.

#### SIGNATURES

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

CRYOLIFE, INC.

March 29, 1997

By: Steven G. Anderson

Steven G. Anderson,

President Chief Execution

President, Chief Executive Officer and Chairman of

#### the Board of Directors

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

Signature	Title	Date
Steven G. Anderson	President,	March 29, 1997
Steven G. Anderson	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	
Edwin B. Cordell, Jr.	Vice President and	March 29, 1997
Edwin B. Cordell, Jr.	Chief Financial Officer (Principal Financial and Accounting Officer)	
Ronald D. McCall	Director	March 29, 1997
Ronald D. McCall		
	Director	March 28, 1997
Benjamin H. Gray		
Rodney G. Lacy	Director	March 28, 1997
Rodney G. Lacy		
Ronald Charles Elkins, M.D.	Director	March 31, 1997
Ronald Charles Elkins, M.D.		

## Independent Auditors' Report

The Board of Directors and Shareholders CryoLife, Inc.

We have audited the accompanying consolidated balance sheet of CryoLife, Inc., and subsidiaries as of December 31, 1995, and the related consolidated statements of income, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 1995. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial

statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CryoLife, Inc., and subsidiaries as of December 31, 1995 and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 1995 in conformity with generally accepted accounting principles.

KPMG PEAT MAKWICK LLP

KPMG PEAT MARWICK LLP

Atlanta, Georgia February 14, 1996

Independent Auditors' Report

The Board of Directors and Shareholders CryoLife, Inc.

Under date of February 14, 1996, we reported on the consolidated balance sheet of CryoLife, Inc. and subsidiaries as of December 31, 1995, and the related consolidated statements of income, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 1995, as contained in the annual report on Form 10-K for the year 1996. In connection with our audits of the aforementioned consolidated financial statements, we also audited the related consolidated financial statement schedule as listed in the accompanying index, This financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on this financial statement schedule based on our audits.

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

KPMG PEAT MARWICK LLP

KPMG PEAT MARWICK LLP

Atlanta, Georgia March 28, 1997

CRYOLIFE, INC.

Index to Financial Statement Schedule

Page No.

# SCHEDULE II CRYOLIFE, INC. AND SUBSIDIARIES

# VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 1996, 1995, and 1994

	Balance beginning of period			Balance end of period
Description	-	Additions	Deductions	•
Year ended December 31, 1996				
Allowance for doubtful accounts	\$ 30,000	\$88,400	\$24,113	\$ 94,287
Allowance for doubtful	Ψ 30 <b>,</b> 000	900,400	Y24,113	9 34,207
note receivable	225,000		225,000	
Deferred preservation				
costs	247,484	140,000	109,085	278 <b>,</b> 399
Year ended December 31, 1995 Allowance for doubtful				
accounts	\$24,938	\$41,433	\$36,371	\$30,000
Allowance for doubtful				
note receivable		225,000		225,000
Deferred preservation	242,883	740,000	735,399	247,484
Inventory	150,000		150,000	
Year ended December 31, 1994 Allowance for doubtful				
accounts	\$ 10,000	\$ 150,000	\$ 135,062	\$ 24,938
Deferred preservation				
costs		523,891	281,008	242,883
Inventory		150,000		150,000

#### EXHIBIT 10.1(a)

#### SEVENTH AMENDMENT TO LEASE

THIS AGREEMENT, made and entered into this 15th day of May, 1996, by and between Newmarket Partners III, Limited, a Georgia Limited Partnership, whose general partners are Laing Properties, Inc. and Laing Management Company (hereinafter called "Landlord") and CryoLife, Inc., a Florida corporation (hereinafter called "Tenant").

#### WITNESSETH THAT:

WHEREAS, Landlord and Tenant entered into a certain Lease Agreement dated February 13, 1986, as amended April 7, 1986, May 15, 1987, June 22, 1988, April 4, 1989, October 15, 1990, and March 14, 1995 (collectively hereinafter "Lease") for Suites 122 through 150 (hereinafter "Premises") at 2211 Newmarket Parkway, Building 8, Marietta, Georgia 30067.

WHEREAS, Tenant desires to reduce the size of the Premises and extend the Term of the Lease, and;

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

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

#### 42. BROKER DISCLOSURE

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

- a) In this transaction, Laing Marketing Company represents Landlord and not Tenant.
- b) In this transaction, Richard Bowers and Company represents Tenant and not Landlord.
- c) In this transaction, both Laing Marketing Company and Richard Bowers and Company shall receive their compensation from Landlord exclusively.

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

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

To have and to hold the same for the term to commence on December 1, 1996 and ending on the 30th day of November, 1999, at midnight unless sooner terminated as hereinafter provided.

44. Paragraph 3, Rental, of the Lease shall be amended to read:

The Tenant agrees to pay to the Landlord promptly on the first day of each month in advance, during the term of this Lease, a monthly rental as follows:

December 1, 1996 through November 30, 1997 @ \$13,342.88 per month December 1, 1997 through November 30, 1998 @ \$13,876.59 per month December 1, 1998 through November 30, 1999 @ \$14,431.65 per month

Payments received after the tenth day of the month may be assessed an additional five percent (5%) charge as agreed liquidated damages due

Landlord. Acceptance by Landlord of a rental payment in an amount less than that which is currently due shall in no way affect Landlord's rights under this Lease and in no way be an accord and satisfaction.

#### 45. Paragraph 1, Premises, of the Lease shall be amended to read:

The Landlord, for and in consideration of the rents, covenants, agreements, and stipulations hereinafter mentioned, reserved and contained, to be paid, kept and performed by the Tenant, has leased and rented, and by these presents does lease and rent, unto the Tenant, and the Tenant hereby agrees to lease and take upon the terms and conditions which hereinafter appear, the following described space (herein called the "Premises").

Project: Newmarket Business Park Building: Eight (8)

Address: 2211 Newmarket Parkway Suite: 134, 136, 138, 140, 142, 144

City: Marietta Rentable Square Feet: 18,837

County: Cobb State: Georgia

Premises are more particularly shown on Exhibit "A-1", attached hereto and made a part hereof.

#### 46. COMMON AREA MAINTENANCE EXPENSE

Paragraph 12, Common Area Maintenance, of the Lease shall be amended to read:

Landlord shall maintain and keep clean all common areas of the site shown on Exhibit "B-1" which is attached hereto and made a part hereof including grounds, landscaping drives, parking and loading areas. Tenant shall reimburse Landlord for Tenant's share of the cost of maintaining the common areas of the Building. Tenant shall pay Landlord for its share of Common Area Maintenance expense at a rate of \$0.65 per rentable square foot, per year, payable in equal monthly payments along with monthly rental. The Common Area Maintenance expense shall be escalated the same time and manner as the rentals hereunder are increased.

#### 47. TENANT IMPROVEMENTS

Tenant agrees to lease the Premises in an "as-is" condition. Tenant shall be solely responsible for the cost of any improvements; such improvements shall be subject to Landlord's prior approval. Landlord, at Landlord's cost, shall provide for demising the Premises, isolating and installing the electrical service, heating and cooling system and gas service.

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

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

Signed, sealed and delivered in the presence of:

LANDLORD: Newmarket Partners III, Limited, a Georgia Limited Partnership, whose general partners are Laing Properties, Inc. and Laing Management

# Company

	BY: LAING PROPERTIES, INC. MANAGING GENERAL PARTNER
	BY:
	TITLE:
	ATTEST:
	TITLE:
the	TENANT: CryoLife, Inc., a Florida corporation
	BY:
	TITLE:
	ATTEST:
	TITLE:
	the

EXHIBIT "A-1"

[GRAPHIC]

EXHIBIT "B-1"

[GRAPHIC]

# EXHIBIT 11.1 STATEMENT RE: COMPUTATION OF EARNINGS PER SHARE

	Y∈ 1996 	ear Ended December 31 1995 	1994
Primary:			
Average shares outstanding	9,504,666	9,379,472	9,311,918
Net effect of dilutive stock options based on the treasury stock method using the greater of quarter-end market price or average market			
price	401,370	189,026	60,978 
Totals	9,906,036		9,372,896
Net Income	\$3,927,481	\$2,201,729	\$1,266,367
Per share amount	\$.40 ====	\$.23 ====	\$.14 ====
Fully diluted: Average shares outstanding	9,504,666	9,379,472	9,311,918
Net effect of dilutive stock options based on the treasury stock method using the greater of quarter-end market price or average market			
price	401,434	269,370	60 <b>,</b> 978
Totals	9,906,100	9,648,842	9,372,896 ======
Net Income	\$3,927,481	\$2,201,729	\$1,266,367
Per share amount	\$.40 ====	\$.23 ===	\$.14 ====

#### CRYOLIFE, INC.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### RESULTS OF OPERATIONS

The Company's revenues have been derived primarily from human heart valve, vein and orthopaedic tissue preservation services.

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. These revenue increases were primarily due to greater allograft shipments resulting from an increase in demand.

Revenues from human heart valve preservation increased 26% to \$24.8 million in 1996 from \$19.7 million in 1995, representing 67% of total revenues during each year. These revenue increases were primarily due to a 29% increase in the number of allograft shipments resulting from an increase in demand. Heart valve revenues attributable to the acquisition of United Cryopreservation Foundation, Inc. (UCFI) were \$263,000 in 1996.

Revenues from human vein preservation 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. These revenue increases were primarily due to a 22% increase in the number of allograft shipments resulting from an increase in demand. Vein revenues attributable to the acquisition of UCFI were \$63,000 in 1996.

Revenues from orthopaedic connective tissue preservation 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. These revenue increases were primarily due to a 173% increase in the number of allograft shipments resulting from an increase in demand.

Revenues from the sale of porcine heart valves in 1996 were \$385,000 compared to \$263,000 in 1995, representing 1% of revenues during each year. These revenues increased due to a 29% increase in the number of units shipped. The Company has concentrated marketing efforts for stentless porcine heart valve sales in Europe. During December 1995, the Company obtained CE Mark certification for the stentless porcine valves. Management believes that CE Mark certification will help the Company gain entry and approval for its porcine heart valves in the European Community. The Company currently intends to initiate the process for Investigational Device Exemption (IDE) and Premarket Approval (PMA) approval of stentless porcine heart valves in the United States in 1998.

Other revenues decreased to \$362,000 in 1996 from \$712,000 in 1995. Other revenues in 1996 consist primarily of research grant award revenues and income from the termination of the option agreement with Bayer Corporation. Research grant award revenues in 1996 were primarily related to the bioadhesive and SynerGraft projects. Income from the termination of the Bayer agreement totaled \$88,000, net of related expenses. The decrease compared to 1995 is primarily attributable to the sale of the Company's patented Viral Inactivation Process technology in 1995.

Preservation costs increased to \$12.6 million in 1996 from \$10.5 million in 1995. Cost of preservation services as a percentage of cryopreservation revenues decreased to 34% in 1996 from 37% in 1995. This favorable decrease is 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 are primarily attributable to additional regulatory and quality 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 has continued its commitment to research and development activity, spending approximately \$2.8 million and \$2.6 million in 1996 and 1995, representing 7.5% and 9.0%, respectively, of total revenues during such years. The Company invested significantly during 1996 in the development of bioadhesives for surgical applications and in its SynerGraft technology.

YEAR ENDED DECEMBER 31,1995

COMPARED TO YEAR ENDED DECEMBER 31, 1994

Revenues increased 23% to \$29.2 million in 1995 from \$23.8 million in 1994. These revenue increases were primarily due to greater allograft shipments resulting from an increase in demand, coupled with a general cryopreservation fee increase in early 1995.

Revenues from human heart valve preservation increased 18% to \$19.7 million in 1995 from \$16.7 million in 1994, representing 67% and 70%, respectively, of total revenues during such years. These revenues increased due in part to a 14% increase in the number of preserved units shipped resulting from an increase in demand, and the general cryopreservation fee increase in early 1995.

Revenues from human vein preservation increased 24% to \$6.8 million in 1995 from \$5.5 million in 1994, representing 23% of total revenues during each year. These revenues increased due to an 11% increase in the number of preserved units shipped resulting from an increase in demand, coupled with the general cryopreservation fee increase in early 1995.

Revenues from orthopaedic connective tissue preservation increased 153% to \$1.5 million in 1995 from \$593,000 in 1994, representing 5% and 2%, respectively, of total revenues during each year. These revenues increased due to a 160% increase in the number of preserved units shipped resulting from an increase in demand.

Porcine heart valve revenue in 1995 was \$263,000 compared to \$414,000 in 1994. Marketing efforts for the porcine heart valves were hindered by ongoing legal actions between the Company (the exclusive worldwide distributor) and the manufacturer (Bravo). In early 1995, the Company and Bravo reached an agreement to settle their differences whereby the Company obtained ownership of the trademarks, rights and patents of the stentless porcine heart valves and Bravo retained the same for the stented porcine heart valves. Consequently, revenues decreased due to the transfer of the stented porcine valve technology to Bravo.

Cost of preservation services as a percentage of cryopreservation revenues decreased to 37% in 1995 from 39% in 1994. This favorable decrease was primarily due to an increase in the volume of processed tissue, more efficient processing methods and the general cryopreservation fee increase.

Other revenues increased to \$712,000 in 1995 from \$412,000 in 1994. The increase was primarily attributable to the sale of the Company's patented Viral Inactivation Process technology. Also contributing to this increase was an increase in research grants revenue from \$320,000 in 1994 to \$353,000 in 1995. The Company has continued to receive research grants for both bioadhesives and tissue engineering research.

General, administrative and marketing expenses increased 15% to \$12.8 million in 1995 from \$11.1 million in 1994, representing 44% and 47%, respectively, of total revenues during such years.

The increased expenses of approximately \$1.7 million were primarily attributable to additional regulatory consulting related to the Company's bioadhesives, provisions for a sales and use tax audit, additional direct technical representatives, increased fees paid to technical representatives and other related marketing expenses.

The Company continued its commitment to research and development activity, spending approximately \$2.6 million in 1995 and \$2.0 million in 1994 representing 9.0% and 8.4% of revenues, respectively, in such years. The Company invested heavily during 1995 in the development of bioadhesives for surgical applications.

#### CONTINUING OPERATIONS

REVENUES AND PERFORMANCE DATA FROM CONTINUING OPERATIONS BY MAJOR PRODUCT LINES FOR THE YEARS ENDING 1996, 1995 AND 1994.

Year Ended December 31, (Dollars in Thousands)	1996	1995	1994
Heart Valves and Conduits:			
Units shipped Revenues	•	3,499 \$19,723	•
VEINS:			
Units shipped Revenues	•	1,765 \$6,771	•
ORTHOPAEDIC TISSUES:			
Units shipped Revenue	1,562 \$3,358	573 \$1 <b>,</b> 456	220 593

Human heart valve preservation services currently account for the majority of the Company's revenues, followed by vein and orthopaedic services. The business of the Company is expected to change in future years, reflecting, among other things, the anticipated growth in vein and orthopaedic tissue services.

Orthopaedic tissue units shipped consist of both tendons and menisci. The number of tendons shipped increased to 1,272 in 1996, from 338 in 1995 and 35 in 1994. The increase in shipments resulted from an increase in demand for such tissue. Menisci shipments were 290 in 1996, 235 in 1995 and 185 in 1994.

The Company continually reviews tissue on hand to determine its viability. Tissue determined not to be suitable for implantation is disposed of properly and the associated deferred preservation costs are expensed.

In July, 1992, the Company acquired the exclusive distribution rights to certain aortic and mitral porcine heart valves principally for sale in overseas markets. Revenues from the sale of porcine valves totaled \$385,000, \$263,000 and \$414,000 for 1996, 1995 and 1994, respectively.

#### SEASONALITY

The demand for the Company's human heart valve tissue preservation services is seasonal, with peak demand generally occurring in the second and third quarters. Management believes this demand trend for human heart valves is primarily due to the high number of pediatric surgeries scheduled during the summer months. However, the demand for the Company's vein preservation services does not appear to experience this seasonal trend. Management believes the trends experienced by the Company to date for its orthopaedic tissue preservation services indicate this business may also be seasonal because it is an elective procedure that may be performed less frequently during the fourth quarter holiday months.

#### LIQUIDITY AND CAPITAL RESOURCES

The Company's primary capital requirements arise out of working capital needs, capital expenditures for additional lab and production facilities, research and development spending, and acquisitions. Historically, the Company has met these requirements primarily with proceeds from sales of common stock, loans under its credit facilities and earnings.

The decrease in marketable securities results from the sale of such securities to finance the leasehold improvements and furnishings for the new corporate headquarters. The increase in accounts receivable is due to the growth in revenues. The increase in deferred preservation costs relates to an increase in donors necessary to support the previously mentioned revenue growth. The

increase in property and equipment relates primarily to the Company's new corporate headquarters. The Company does not expect to incur significant additional costs relating to the new headquarters. The increase in other assets relates primarily to the acquisition of the BioGlue(R) technology and to intangible assets recorded in connection with the acquisition of UCFI. The increase in accounts payable results primarily from liabilities associated with the construction and equipping of the new corporate headquarters. The increase in accrued procurement fees results from the increase in tissue procurement in the fourth quarter of 1996. Long-term debt results from the acquisition of the BioGlue technology and from the acquisition of UCFI. The increase in the bank line of credit is primarily due to leasehold improvements, furniture and equipment purchases for the new facility.

Net cash provided by operating activities was \$4.0 million in 1996, as compared to net cash provided by operating activities of \$2.4 million in 1995. The increase in net cash provided by operating activities during 1996 was primarily a result of an increase in earnings and payables, partially offset by increased receivables.

Net cash flows from financing activities were \$1,816,000 in 1996 and \$265,000 in 1995. This activity primarily consists of net proceeds from borrowings under the Company's line of credit and the exercise of stock options.

The Company's capital expenditures totaled \$9,220,000, the majority of which relates to the construction and equipping of the Company's new corporate headquarters. Also, the Company has made a commitment for up to \$1,000,000 in construction costs for a new manufacturing facility for Ideas for Medicine.

The Company's research and development expenditures totaled \$2.8 million in 1996 and \$2.6 million in 1995. Management estimates that research and development expenditures for 1997 will be approximately \$3.9 million but are dependent upon achieving certain milestones in clinical testing. A large portion of this spending relates to the continued development of bioadhesives and application for clinical trial approval of the bioadhesives to the FDA.

During 1996 the Company secured a revolving credit facility of \$10.0 million at the bank's prime rate of interest. In addition, the Company may supplement its financial resources from time to time, as market conditions permit, through additional financing through collaborative marketing and distribution agreements.

The Company believes that the cash generated from operations and loans available under its revolving credit facility will be sufficient to meet the Company's funding needs for the foreseeable future, including the approximately \$4.5 million cash portion of the purchase price relating to the acquisition of Ideas for Medicine which was completed on March 5, 1997.

# 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.

#### OUTLOOK

Management expects 1997 to be another strong year. The existing markets for the Company's products continue to grow. The Company's backlog remains strong, and new products introduced during 1996, together with expanded international marketing efforts, should spur demand. Management does not anticipate that the move to the new corporate headquarters will adversely affect product gross margins. Management expects that the acquisition of Ideas of Medicine will not have a significant impact on 1997 earnings.

## FOWWARD-LOOKING STATEMENTS

Statements in this Management's Discussion and Analysis of Financial Condition and Results of Operations, and elsewhere in this 1996 Annual Report that state the Company's or management's intentions, hopes, beliefs, expectations or predictions of the future are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Such forward-looking statements include, among others, statements regarding the Company's competitive position, the acquisition and subsequent integration of Ideas for Medicine, the application to the U.S. FDA for the stentless O'Brien

porcine heart valves, estimates regarding 1997 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. It should be noted that the Company's actual results could differ materially from those contained in such forward-looking statements mentioned above, due to adverse changes in any number of factors that affect this Company's business, including without limitation, changes in government regulation of the Company's business, the availability of tissue for implant, the status of the Company's products under development, the protection of the Company's proprietary technology, the reimbursement of health care costs by third-party payors, and the Company's ability to sufficiently integrate acquired businesses.

# CRYOLIFE, INC.

ecembe.	r 31,	1996	1995	
	assets:			
	Cash and cash equivalents	\$ 1,369,699	\$ 516,416	
	Marketable securities	43,145	6,015,158	
	Receivables:			
	Trade accounts, less allowance for doubtful accounts of			
	\$94,287 in 1996 and \$30,000			
	in 1995	6,571,751	5,092,658	
	Income taxes	150,123		
	Other	1,474,793	194,260	
	Total receivables	8,196,667	5,286,918	
	Deferred preservation costs, less			
	allowance of \$278,399 in 1996			
	and \$247,484 in 1995	7,178,043	5,996,201	
	Inventories	260,796	424,200	
	Prepaid expenses	846,294	369,594	
	Deferred income taxes	286 <b>,</b> 679	275,375	
	Total current assets	18,181,323	18,883,862	
ropert	y and equipment:			
	Equipment	8,366,234	5,692,383	
	Equipment Furniture and fixtures	8,366,234 1,493,239	5,692,383 382,605	
	Furniture and fixtures Leasehold improvements	1,493,239 7,494,487	382,605 2,018,722	
	Furniture and fixtures Leasehold improvements	1,493,239 7,494,487	382,605	
	Furniture and fixtures Leasehold improvements  Less accumulated depreciation	1,493,239 7,494,487 17,353,960	382,605 2,018,722 8,093,710	
	Furniture and fixtures Leasehold improvements	1,493,239 7,494,487	382,605 2,018,722	
	Furniture and fixtures Leasehold improvements  Less accumulated depreciation	1,493,239 7,494,487 17,353,960	382,605 2,018,722 8,093,710	
ther as	Furniture and fixtures Leasehold improvements  Less accumulated depreciation and amortization  Net property and equipment	1,493,239 7,494,487 17,353,960 5,787,596	382,605 2,018,722 8,093,710 4,814,542	
ther as	Furniture and fixtures Leasehold improvements  Less accumulated depreciation and amortization  Net property and equipment	1,493,239 7,494,487 17,353,960 5,787,596	382,605 2,018,722 8,093,710 4,814,542	
ther as	Furniture and fixtures Leasehold improvements  Less accumulated depreciation and amortization  Net property and equipment  Ssets:	1,493,239 7,494,487 17,353,960 5,787,596	382,605 2,018,722 8,093,710 4,814,542	
ther as	Furniture and fixtures Leasehold improvements  Less accumulated depreciation and amortization  Net property and equipment  Patents and other intangibles, less accumulated amortization of \$669,140 in 1996 and \$286,570	1,493,239 7,494,487  17,353,960 5,787,596  11,566,364	382,605 2,018,722 8,093,710 4,814,542 3,279,168	
ther as	Furniture and fixtures Leasehold improvements  Less accumulated depreciation and amortization  Net property and equipment  Seets:  Patents and other intangibles, less accumulated amortization of \$669,140 in 1996 and \$286,570 in 1995	1,493,239 7,494,487  17,353,960 5,787,596  11,566,364  4,701,281	382,605 2,018,722 8,093,710 4,814,542 3,279,168	
ther as	Furniture and fixtures Leasehold improvements  Less accumulated depreciation and amortization  Net property and equipment  Patents and other intangibles, less accumulated amortization of \$669,140 in 1996 and \$286,570	1,493,239 7,494,487  17,353,960 5,787,596  11,566,364	382,605 2,018,722 8,093,710 4,814,542 3,279,168	

See accompanying notes to consolidated financial statements.

December	ES AND SHAREHOLDERS' EQUITY 31, 	1996	1995	
	iabilities:			
	Accounts payable	\$ 3,695,862	\$ 1,372,862	
	Accrued expenses	719,427	388,579	
	Accrued compensation	878,263	610,194	
	Accrued fees to technical service			
	representatives	213,828	391,300	
	Accrued procurement fees	1,210,194	694,486	
	Current maturities of debt	527,054		
	Income taxes payable		209,574	
	Total current liabilities	7,244,628	3,666,995	
	Bank line of credit Long-term debt	1,250,000 1,548,900	<del></del> 	
	Total liabilities	10,043,528	3,666,995	
	Commitments and Contingencies			
Sharehold	ers' equity:			
	Preferred stock of \$.01 par value per share. Authorized 5,000,000			
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares; no shares issued. Common stock of \$.01 par value per share. Authorized 50,000,000			
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares; no shares issued.  Common stock of \$.01 par value per share. Authorized 50,000,000 shares; issued 10,110,326 shares in 1996 and	101,103	 99,743	
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares; no shares issued. Common stock of \$.01 par value per share. Authorized 50,000,000 shares; issued 10,110,326 shares in 1996 and 9,974,332 shares in 1995	101,103	 99,743	
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares; no shares issued. Common stock of \$.01 par value per share. Authorized 50,000,000 shares; issued 10,110,326 shares in 1996 and 9,974,332 shares in 1995 Additional paid-in capital	101,103 17,127,706	 99,743 16,568,313	
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares; no shares issued. Common stock of \$.01 par value per share. Authorized 50,000,000 shares; issued 10,110,326 shares in 1996 and 9,974,332 shares in 1995 Additional paid-in capital Retained earnings	101,103	 99,743	
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares; no shares issued. Common stock of \$.01 par value per share. Authorized 50,000,000 shares; issued 10,110,326 shares in 1996 and 9,974,332 shares in 1995 Additional paid-in capital Retained earnings Unrealized gain (loss) on marketable securities	101,103 17,127,706	 99,743 16,568,313	
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares, no shares issued.  Common stock of \$.01 par value per share. Authorized 50,000,000 shares; issued 10,110,326 shares in 1996 and 9,974,332 shares in 1995 Additional paid-in capital Retained earnings Unrealized gain (loss) on marketable securities Treasury stock of 543,000 shares, at cost	101,103 17,127,706 7,902,019	99,743 16,568,313 3,974,538	
	Preferred stock of \$.01 par value per share. Authorized 5,000,000 shares; no shares issued. Common stock of \$.01 par value per share. Authorized 50,000,000 shares; issued 10,110,326 shares in 1996 and 9,974,332 shares in 1995 Additional paid-in capital Retained earnings Unrealized gain (loss) on marketable securities Treasury stock of 543,000	101,103 17,127,706 7,902,019 (1,146)	99,743 16,568,313 3,974,538 28,092	

Total liabilities and shareholders' equity \$34,972,719 \$24,132,189

See accompanying notes to consolidated financial statements.

# C R Y O L I F E, I N C. CONSOLIDATED STATEMENTS OF INCOME

December 31,		1996	1995	1994
Revenues:				
	Cryopreservation	\$36,677,973	\$28,257,333	\$23,231,841
	Research grants, licenses,			
	lease and other revenues	361,613	712,352	412,386
	Interest income	188,768	255,817	165,794
		37,228,354	29,225,502	23,810,021
Costs and	l expenses:			
	Preservation General, administrative and	12,593,126	10,485,225	8,965,087
	marketing	15,672,550	12,806,706	11,084,492
	Research and development	2,807,262	2,633,311	1,975,238
	Interest expense	71,800	4,398	21,468
		31,144,738	25,929,640	22,046,285
Income be	fore income taxes	6,083,616	3,295,862	1.763.736
	x expense	2,156,135	1,094,133	497,369
Net incom	ne	\$3,927,481	\$2,201,729	\$1,266,367
Earnings	per share of common stock	\$ 0.40	\$ 0.23	\$ 0.14

See accompanying notes to consolidated financial statements.

# C R Y O L I F E, I N C. CONSOLIDATED STATEMENTS OF CASH FLOWS

ecember 31,		1996	1995	1994
et cash flow from operating activities:				
Net income	 \$	3,927,481	\$ 2,201,729	\$ 1,266,367
Adjustments to reconcile net income to net cash provided by				
operating activities:				
Depreciation and				
amortization		1,355,624	979,682	1,027,286
Provision for doubtful				
accounts		166,600	266,433	150,000
Gain on sale of equipment Deferred income taxes		(11,304)	(107,415)	(34,148) (167,960)
Changes in operating assets and liabil	ities:	(11/001)	(10.7110)	(107,300)
Trade and other receivables		2,561,176)	(1,779,993)	(206,167)
Income taxes		(359,697)	105,859	50,892
Deferred preservation costs	(	1,053,287)	378,974	199,754
Inventories Prepaid expenses		163,404 (476,700)	432,000 (145,471)	438,000 (32,987)
Accounts payable		2,085,097	37,629	(316,712)
Accrued expenses		739,899	39,383	289,949
Net cash flows provided by operating				
activities		3,975,941	2,408,810	2,664,274
et cash flows used in investing activities:				
Capital expenditures	,	9,220,250)	(1 572 020)	(1 410 000)
Cash paid for acquisition, net of	(	9,220,230)	(1,572,928)	(1,418,880)
cash acquired		(721,721)		
Other assets		(939,216)	(1,001,633)	(87,108)
Net sales (purchases) of				
marketable securities		5,942,775	(2,175,833)	(106,654)
Proceeds from sale of property and equipment				77,072
and equipment				
Net cash flows used in investing activities	(	4,938,412)	(4,750,394)	(1,535,570)
t cash flows from financing activities:				
Principal payments of debt		(750,000)		
Proceeds from debt issuance		2,000,000		
Proceeds from exercise of options		560,753	264,920	58,185
Net payments on notes receivable		F 001	201	21 000
from shareholder		5,001	281	31,000
Net cash provided by financing				
activities		1,815,754	265,201	89,185
		052.000		
ncrease (decrease) in cash ssh and cash equivalents at beginning of		853,283	(2,076,383)	1,217,889
period		516,416	2,592,799	1,374,910
sh and cash equivalents at end of period		,	-,,	-,0.1,010
-	\$	1,369,699	\$ 516,416	\$ 2,592,799
				<del></del>
upplemental disclosures of cash flow information cash paid during the year for:				
information cash paid during the year for:		22 017	e 4 200	
information cash paid during the year for: Interest		33,917 2,528,598	\$ 4,398 \$ 1.089.466	\$ 21,468 \$ 640.727
information cash paid during the year for:  Interest Income taxes		33,917 2,528,598	\$ 4,398 \$ 1,089,466	
information cash paid during the year for: Interest				
information cash paid during the year for:  Interest Income taxes Noncash investing and financing	\$			
information cash paid during the year for:  Interest Income taxes Noncash investing and financing activities: Note issued for patent	\$ \$	2,528,598 825,953	\$ 1,089,466 	\$ 640,727 
Interest Income taxes Noncash investing and financing activities: Note issued for patent Fair value of assets acquired	\$ \$	2,528,598 825,953 533,605		
Interest Income taxes Noncash investing and financing activities: Note issued for patent  Fair value of assets acquired Cost in excess of assets	\$ \$	2,528,598 825,953	\$ 1,089,466 	\$ 640,727 
Interest Income taxes Noncash investing and financing activities: Note issued for patent  Fair value of assets acquired Cost in excess of assets acquired	\$ \$	2,528,598 825,953 533,605 1,873,274	\$ 1,089,466 	\$ 640,727 
Interest Income taxes Noncash investing and financing activities: Note issued for patent  Fair value of assets acquired Cost in excess of assets	\$ \$	2,528,598 825,953 533,605	\$ 1,089,466 	\$ 640,727 
Interest Income taxes Noncash investing and financing activities: Note issued for patent  Fair value of assets acquired Cost in excess of assets acquired Liabilities assumed	\$ \$	2,528,598 825,953 533,605 1,873,274	\$ 1,089,466 	\$ 640,727 
Interest Income taxes Noncash investing and financing activities: Note issued for patent  Fair value of assets acquired Cost in excess of assets acquired Liabilities assumed Note issued for assets acquired	\$ \$	2,528,598 825,953 533,605 1,873,274 (435,158)	\$ 1,089,466 	\$ 640,727 
Interest Income taxes Noncash investing and financing activities: Note issued for patent  Fair value of assets acquired Cost in excess of assets acquired Liabilities assumed Note issued for assets	\$ \$ \$	2,528,598 825,953 533,605 1,873,274 (435,158)	\$ 1,089,466 	\$ 640,727 

# C R Y O L I F E, I N C. CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

ecember 31,	1996		1995		1994
ommon Stock	 				
Balance beginning of year (9,974,332, 9,326,372, and 9,300,512 shares outstanding at January 1, 1996, 1995 and 1994, respectively)  Issuances of common stock:	\$ 99,743	ş	98,693	Ş	98,434
Employee stock purchase plan (1,939 shares)	19				
Purchase of other assets (10,395 shares) Exercise of options (123,660, 104,960, and 25,860 shares in 1996, 1995, and 1994, respectively)	104				
	1,237		1,050		259
Balance, end of year	101,103		99,743		98,693
dditional Paid-in Capital					
Balance, beginning of year Issuances of common stock: Employee stock purchase			16,304,443	\$	16,246,517
plan Purchase of other assets	20,996 129,834				
Exercise of options	408,563		263,870		57,926
Balance, end of year	 17,127,706		16,568,313		16,304,443
Balance, beginning of year Net income	\$ 3,974,538 3,927,481 7,902,019		1,772,809 2,201,729 3,974,538		
Balance, end of year	 7,902,019		3,974,336		1,772,009
Balance, beginning of year Unrealized gain (loss)	\$ 28,092 (29,238)		(37,628) 65,720	\$	(37,628)
Balance, end of year	 (1,146)		28,092		(37,628)
reasury Stock					
Balance, beginning and end of year	(179,625)		(179,625)		(179,625)
otes Receivable From Shareholders					
Balance, beginning of year Payments on shareholder notes	\$ (25,867) 5,001	\$	(26,148) 281	 \$	(57,148) 31,000
Balance, beginning of year	\$ (25,867) 5,001	\$	(26,148) 281	\$	(57,148) 31,000 (26,148)
Balance, beginning of year Payments on shareholder notes	\$  (25,867) 5,001	\$	(26,148) 281	\$	

See accompanying notes to consolidated financial statements.

# CRYOLIFE, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## NATURE OF BUSINESS

Founded in 1984, CryoLife, Inc. was the first company in the United States to specialize in the commercialization of ultra-low temperature preservation of human tissues for transplant. The Company markets its products in North and South America, Europe and Asia. The Company's preservation efforts have been directed toward tissue transplant opportunities in the areas of cardiac, vascular and orthopaedic surgery. The Company seeks to identify medical market areas that can benefit from its expertise in biochemistry and cell biology to develop innovative techniques and biological products for cardiac, vascular and orthopaedic reconstructive surgery. Additionally, the Company seeks to develop and investigate the development of new technologies and products to expand the Company's implantable product lines and laboratory service business to include biological products that are not dependent upon the availability of human tissue.

## PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany balances have been eliminated.

#### RECLASSIFICATIONS

Certain prior year balances have been reclassified to conform with the 1996 presentation.

#### USE OF ESTIMATES

The financial statements have been prepared in conformity with generally accepted accounting principles and, as such, include amounts based on informed estimates and judgments of management with consideration given to materiality. Actual results could differ from those estimates.

# CASH EQUIVALENTS

Cash equivalents consist primarily of highly liquid investments with insignificant interest rate risk and maturity dates of 90 days or less at the time of acquisition.

## MARKETABLE SECURITIES

Marketable securities consist primarily of municipal bond investments. The Company adopted the provisions of Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities", on January 1, 1994. Under that Statement, the Company classifies its marketable securities as available-for-sale with unrealized gains and losses excluded from earnings and reported as a separate component of shareholders' equity. The aggregate amortized cost of such securities at December 31, 1996 and 1995 was \$43,145 and \$5,987,066, respectively. The investments mature at various dates through 2027.

## DEFERRED PRESERVATION COSTS AND REVENUE RECOGNITION

Tissue is procured from deceased human donors by organ procurement agencies and tissue banks which consign the tissue to the Company for processing and preservation. Preservation costs related to tissue held by the Company are deferred until shipment to the implanting hospital. Deferred preservation costs consist primarily of laboratory expenses, organ procurement fees, and freight-in charges and are stated at average cost, determined annually, on a first-in, first-out basis. When the tissue is shipped to the implanting hospital, revenue is recognized and the related deferred preservation costs are charged to operations.

# INVENTORIES

Inventories are comprised of purchased porcine heart valves and are valued at the lower of cost (first-in, first-out) or market.

## PROPERTY AND EQUIPMENT

Property and equipment are stated at cost. Depreciation is provided over the estimated useful lives of the assets, generally 5 to 10 years, on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the lease term or the estimated useful lives of the assets, whichever

is shorter.

#### INTANGIBLE ASSETS

Goodwill resulting from business acquisitions is amortized on a straight-line basis over 20 years. Patent costs are amortized over the expected useful life of the patent (primarily 17 years) using the straight-line method. Other intangibles, which consist primarily of manufacturing rights and agreements, are being amortized over the expected useful lives of the related assets (primarily five years).

The Company periodically evaluates the recoverability of intangible assets and measures the amount of impairment, if any, by assessing current and future levels of income and cash flows as well as other factors, such as business trends and prospects and market and economic conditions.

## INCOME TAXES

Deferred income tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

#### LICENSE FEE AND RESEARCH GRANT REVENUES

License fee revenues are recognized in the period the cash is received and all licensor obligations have been fulfilled. Revenues for research grants are recognized in the period the associated costs are incurred.

## EARNINGS PER SHARE

The Company's earnings per share are computed by dividing net income by the weighted average number of common and common equivalent shares. Dilutive common stock options have been included in the earnings per share calculation using the treasury stock method.

On May 16, 1996 the Board of Directors declared a two-for-one stock split, effected in the form of a stock dividend, payable on June 28, 1996 to shareholders of record on June 7, 1996. All share and per share information in the accompanying consolidated financial statements have been adjusted to reflect such split.

# 2. REVOLVING TERM LOAN AGREEMENT

On August 30, 1996 the Company executed a Revolving Term Loan Agreement with a bank which permits the Company to borrow up to \$10,000,000 at either the bank's prime rate of interest (8.25% at December 31, 1996) or adjusted Libor, as defined, plus an applicable Libor margin. This credit agreement contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios and a minimum tangible net worth requirement. The credit agreement is secured by substantially all of the Company's assets, excluding intellectual property. Commitment fees are paid based on the unused portions of the facility. At December 31, 1996 \$1,250,000 was outstanding under this agreement. (See Note 13).

## 3. LONG-TERM DEBT

Long-term debt at December 31, 1996 consists of the following:

8.25% note payable due in equal annual installments of \$250,000

\$1,250,000

Note payable due in 2000 with an effective interest rate of 8%, net of unamortized discount of \$84,046 825,954

Total long-term debt	\$1,548,900

In September 1996 the Company issued \$1,250,000 of notes in connection with the acquisition of certain assets of United Cryopreservation Foundation, Inc. Also, in April 1996 the Company issued \$910,000 of non-interest bearing notes in connection with the acquisition of its BioGlue(R) technology.

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

1997	\$527 <b>,</b> 054
1998	496,088
1999	515 <b>,</b> 775
2000	287,037
2001	250,000
 	\$2,075,954

## 4. FAIR VALUES OF FINANCIAL INSTRUMENTS

Statement of Financial Accounting Standards No. 107, "Disclosures about Fair Value of Financial Instruments" (Statement 107), requires the Company to disclose estimated fair values for its financial instruments. The carrying amounts of cash and cash equivalents, marketable securities, trade receivables and accounts payable approximate their fair values due to the short-term maturity of these instruments and because they are marked to market. The estimated fair value of long-term debt approximates the carrying amount of such debt at December 31, 1996.

## 5. LEASES

The Company leases equipment and office space under various operating leases with terms of up to 15 years. Certain leases contain escalation clauses and renewal options for additional periods. Future minimum lease payments under noncancelable operating leases as of December 31, 1996 are as follows:

Year ending December 31,	
1997	\$1,140,962
1998	1,158,418
1999	1,076,357
2000	934,748
2001	951 <b>,</b> 887
Thereafter	9,885,044
Total minimum lease payments	\$ 15,147,416

Total rental expense for operating leases amounted to \$713,571, \$740,588, and \$692,159, for 1996, 1995, and 1994, respectively.

# 6. STOCK OPTION PLANS

The Company has certain stock option plans that provide for grants of options to employees to purchase shares of common stock at an exercise price generally equal to the fair value at the date of grant, which generally become exercisable over a five-year vesting period and expire within ten years of grant date. A summary of stock option transactions under the plans follows:

Price

Outstanding at December	er 31, 1993			
	279,880	\$2.25 -	\$4.13	
Granted	201,000	3.13 -	3.85	
Exercised	(25,860)	2.25		
Canceled	(40,900)	2.25 -	4.13	
Outstanding at Decembe	21 1004			
	414,120	2.25 -	4.13	
Granted	321,000	3.63 -	7.74	\$4.90
Exercised	(104,960)	2.25 -	4.13	2.53
Canceled	(40,000)	2.25 -	4.13	3.10
Outstanding at Decembe	er 31, 1995			
	590,160	2.25 -	7.74	4.21
Granted	247,000	8.50 -	18.43	15.70
Exercised	(123,660)	2.26 -	7.26	3.31
Canceled	(5,200)	2.25 -	3.75	3.68
Outstanding at Decembe	er 31, 1996			
	708,300	2.25 -	18.43	7.36

The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related Interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under FASB Statement No. 123, "Accounting for Stock-Based Compensation" (Statement 123) requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of the grant, no compensation expense is recognized.

Pro forma information regarding net income and earnings per share is required by Statement 123, which also requires that the information be determined as if the Company has accounted for its employee stock options granted subsequent to December 31, 1994 under the fair value method of that Statement. The fair value for these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	1996	1995
Expected Dividend Yield	0%	0%
Expected Stock Price Volatility	0.552	0.515
Risk-Free Interest Rate	6.48%	5.91%

\_\_\_\_\_\_

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

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting periods. The Company's pro forma information follows:

	1996	1995
Net income - as reported	3,927,481	2,201,729
Net income - pro forma		2,123,134
Earnings per share - as reported		0.23
Earnings per share - pro forma	0.37	
Other information concerning stock options follows:		
Weighted average fair value of options granted during the year		\$2.36
Number of shares as to which options as exercisable at end of year		73,600
Weighted average remaining contractual of outstanding options		

Because Statement 123 is applicable only to options granted subsequent to December 31, 1994, its pro forma effect will not be fully reflected until 2000.

## 7. EMPLOYEE BENEFIT PLANS

The Company has a 401(k) savings plan providing retirement benefits to all employees who have completed six months of service. The Company makes matching contributions of 50% of each participant's contribution up to 5% of each participant's salary. The total contributions charged to operations were \$123,193, \$131,399 and \$100,114 in 1996, 1995 and 1994, respectively. Additionally, the Company may make discretionary contributions to the Plan that are allocated to each participant's account. No such discretionary contributions were made for 1996, 1995 or 1994.

On May 16, 1996 the Company's shareholders approved the CryoLife, Inc. Employee Stock Purchase Plan (ESPP). The ESPP allows eligible employees the right to purchase common stock on a quarterly basis at the lower of 85% of the market price at the beginning or end of each three-month offering period. As of December 31, 1996 there were 598,061 shares of common stock reserved for the ESPP and there had been 1,939 shares issued under the plan.

## 8. INCOME TAXES

Income tax expense consists of the following:

		1996	1995	1994
Current:				
	Federal	\$ 1,826,144	\$ 1,012,356	\$ 537,795
	State	341,295	189,192	127,534
	Total current	 2,167,439	 1,201,548	665,329
	Deferred	(11,304)	(107,415)	(167,960)
	Total income tax	 	 	 
	expense	\$ 2,156,135	\$ 1,094,133	\$ 497,369

Such amounts differ from the amounts computed by applying the U.S. Federal income tax rate of 34% to pretax income as a result of the following:

		1996	1995	1994
	Tax expense at statutory rate	\$ 2,068,429	\$ 1,120,593	\$ \$599 <b>,</b> 670
INCREASE (REDUCT RESULTING FROM:	CION) IN INCOME TAXES			
	Change in validation allowance for deferred tax assets	 (129,171)	(51,529)	 (184,664)
	Entertainment expenses	 29,855	 32,845	 17,684
	Officer's life insurance	 3,532	 3,873	 7,613
	State income taxes, net of federal benefit	 240,911	 126,464	 99,480
	Non-taxable interest income	 (50,142)	 (73, 955)	 (48,217)
	Other	 (7,279)	 (64,158)	 (5,803)
		 \$2,156,135	\$ 1,094,133	\$ 497,369

The tax effects of temporary differences which give rise to deferred tax assets and deferred tax liabilities are presented below:

December 31,			1996	1995
DEFERRED TAX	ASSETS:			
De	preciation	\$ 111	L,298	\$ 186 <b>,</b> 262

and inventory reserves	86,616	94,044
Note receivable reserve		85,500
Other	118,765	68,740
	316 <b>,</b> 679	434,546
Less valuation allowance	30,000	159,171
Net deferred tax assets	\$ 286 <b>,</b> 679	\$ 275,375

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not the Company will realize the benefits of these deductible differences, net of the existing valuation allowances.

#### 9. FDA REGULATION

Human heart valves historically have not been subject to regulation by the United States Food and Drug Administration (FDA). However, in June 1991 the FDA published a notice stating that human heart valves for transplantation are medical devices subject to Premarket Approval (PMA) or an Investigational Device Exemption (IDE). In October 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 1991. This action by the FDA has removed allograft heart valves from clinical trial status thus allowing the Company to distribute such valves to cardiovascular surgeons throughout the United States.

# 10. EXECUTIVE INSURANCE PLAN

In December 1992 the Company's Board of Directors approved a supplemental life insurance program for certain executive officers of the Company. The Company and the executives share in the premium payments and ownership of insurance policies on the lives of the executives. The Company's aggregate premium contributions were \$37,515, \$30,864 and \$36,269 for 1996, 1995 and 1994, respectively.

# 11. EQUIPMENT ON LOAN TO IMPLANTING HOSPITALS

The Company consigns liquid nitrogen freezers with the implanting hospitals for tissue storage. The freezers are the property of the Company. At December 31, 1996, freezers with a total cost of approximately \$1,021,000 and related accumulated depreciation of approximately \$678,000 were located at the implanting hospitals' premises. Depreciation is provided over the estimated useful lives of the freezers on a straight-line basis.

# 12. TRANSACTIONS WITH RELATED PARTIES

The Company expensed \$39,208, \$66,609, and \$64,767 during 1996, 1995 and 1994, respectively, relating to services performed by a law firm whose sole proprietor is a member of the Company's Board of Directors and a shareholder of the Company.

# 13. SUBSEQUENT EVENT

On March 5, 1997 the Company acquired the stock of Ideas for Medicine, Inc. (IFM) of Clearwater, Florida, a medical device company specializing in the manufacture and distribution of single use cardiovascular products, for consideration of approximately \$4.5 million in cash and approximately \$5 million in convertible debentures plus related expenses. The cash portion of the

purchase price was financed by borrowings under the Company's Revolving Term Loan Agreement discussed in Note 2. The acquisition will be accounted for as a purchase.

## INDEPENDENT AUDITORS' REPORT

[LOGO] ERNST & YOUNG LLP

The Board of Directors and Shareholders of CryoLife, Inc.:

We have audited the accompanying consolidated balance sheet of CryoLife, Inc. as of December 31, 1996 and the related consolidated statements of income, shareholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. The consolidated financial statements of CryoLife, Inc. for the years ended December 31, 1995 and 1994 were audited by other auditors whose report dated February 14, 1996, except as to Note 13, which is as of March 18, 1996, expressed an unqualified opinion on those statements.

We conducted our audit in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the 1996 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of CryoLife, Inc. at December 31, 1996, and the consolidated results of its operations and its cash flows for the year then ended in conformity with generally accepted accounting principles.

# ERNST & YOUNG LLP

Atlanta, Georgia February 7, 1997, except for Note 13 as to which the date is March 5, 1997

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# MARKET PRICE OF COMMON STOCK

The following table sets forth the range of high and low sales prices for the Company's common stock, on the NASDAQ National Market System, for each of the quarters of fiscal 1996 and 1995. Such prices have been restated to reflect the two-for-one stock split effected June 28, 1996.

 	High	Low	
 1996			
First quarter Second quarter Third quarter Fourth quarter	12 5/8 20 3/4 20 1/2 15 3/4	7 10 4/5 11 1/4 12 3/16	
1995			
First quarter Second quarter Third quarter Fourth quarter	4 1/4 5 5/8 9 1/8 9 1/16	3 1/8 3 3/8 5 3/8 6 1/8	

# SELECTED FINANCIAL & QUARTERLY INFORMATION

# SELECTED FINANCIAL INFORMATION

In thousands except share data) December 31,	 1996	 1995	 1994	 1993	 1992
PERATIONS					
Revenues Net income	\$ 37,228 3,927	\$ 29,226 2,202	\$ 23,810 1,266	21,340 554	\$ 19 <b>,</b> 633
Research and development as a percent of revenues	7.5%	9.0%	8.3%	6.5%	7.19
ARNINGS PER SHARE					
Net income*	\$ 0.40	\$ 0.23	\$ 0.14	\$ 0.06	\$ 0.09
CAR-END FINANCIAL POSITION					
Total assets Working capital	\$ 34,973 10,937	24,132 15,217	21,417		12,441
Long-term liabilities Shareholders' equity	2,799 24,929	0 20,465	0 17,933		1,141 7,333
Current ratio Shareholders' equity per common share*	3:1	5:1	5:1	5:1	2:1
	\$ 2.61	\$ 2.17	\$ 1.92	\$ 1.83	\$ 1.00
ELECTED QUARTERLY FINANCIAL INFORMATION					
In thousands except share data)		First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	 1996	\$ 8,434	\$ 9,698	\$ 10,411	\$ 8,685
	 1995 1994	 6,605 5,281	 7,230 5,876	8,347 6,647	 7,044 6,006
Net Income	1996	\$ 782	\$ 988	\$ 1,261	\$ 896
	 1995 1994	 390 195	 559 289	685 349	 568 433
Earnings per share*	1996	\$ 0.08	\$ 0.10	\$ 0.13	\$ 0.09
	 1995 1994	 0.04	 0.06 0.03	0.07 0.04	 0.06

<sup>\*</sup> Reflects adjustment for the two-for-one stock split effected June 28, 1996.

CRYOLIFE, INC.

# Board of Directors

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

Ronald C. Elkins, M.D.
Chief, Department of Thoracic and
Cardiovascular Surgery
University of Oklahoma Health
Science Center
Oklahoma City, Oklahoma

Benjamin H. Gray Partner Massey Burch Capital Corp. (An investment firm) Nashville, Tennessee

Rodney G. Lacy President AI Industries (A manufacturing concern) West Chicago, Illinois

Ronald D. McCall, Esq. Attorney at Law Tampa, Florida

# Corporate Officers

Steven G. Anderson Chairman, President and Chief Executive Officer

Kirby S. Black, Ph.D.
Vice President, Research &
Development

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

Albert E. Heacox, Ph.D. Vice President, Laboratory Operations

Ronald D. McCall, Esq.
Secretary/Treasurer

Robert T. McNally, Ph.D. Senior Vice President, Clinical Research

Gerald B. Seery Vice President, Marketing

James C. Vander Wyk, Ph.D. Vice President, Regulatory Affairs and Quality Assurance

[LOGO]

# EXHIBIT 21.1

# Exhibit 21.1 Subsidiaries of CryoLife, Inc.

Name State of Incorporation

CryoLife International Incorporated Florida

CryoLife Acquisition Corporation Florida

# EXHIBIT 23.1

# Accountants' Consent

The Board of Directors CryoLife, Inc.

We consent to incorporation by reference in the registration statements (Nos. 33-83996, 33-84048, 333-03513 and 333-06141) on Form S-8 and registration statement (No. 333-16581) on Form S-3 of CryoLife, Inc. of our reports dated February 14, 1996, relating to the consolidated balance sheet of CryoLife, Inc. and subsidiaries as of December 31, 1995, and the related consolidated statements of income, shareholders' equity, and cash flows and related schedule for each of the years, in the two-year period ended December 31, 1995, which reports appear in the December 31, 1996 annual report on Form 10-K of CryoLife, Inc.

KPMG PEAT MARWICK LLP KPMG PEAT MARWICK LLP

Atlanta, Georgia March 28, 1997

## EXHIBIT 23.2

# CONSENT OF ERNST & YOUNG LLP INDEPENDENT AUDITORS

We consent to the incorporation by reference in this Annual Report (Form 10-K) of CryoLife, Inc. of our report dated February 17, 1997, except for Note 13 as to which the date is March 3, 1997, included in the 1996 Annual Report to shareholders of CryoLife, Inc.

Our audit also included the financial statement schedule of CryoLife, Inc. listed in Item 14(a). This schedule is the responsibility of the Company's management. Our responsibility is to express an opinion based on our audit. In our opinion, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also consent to the incorporation by reference in Registration Statement No. 333-16581 on Form S-3 and Registration Statement Nos. 33-83996, 33-84048, 33-03513 and 333-06141 on Form S-8, of our report dated February 7,1997, except for Note 13 as to which the date is March 5, 1997, with respect to the consolidated financial statements incorporated herein by reference, and our report included in the preceding paragraph with respect of the Financial Statement Schedule included in this Annual Report (Form 10-K) of CryoLife, Inc.

Atlanta, Georgia March 26, 1997

# <ARTICLE>5

# <LEGEND>

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE FINANCIAL STATEMENTS OF CRYOLIFE, INC. FOR THE YEAR ENDED DECEMBER 31, 1996 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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