FORM 10-K/A
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 [FEE REQUIRED]

For the fiscal year ended December 31, 1995
OR
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [NO FEE REQUIRED]

For the transition period from _____ to _____

Commission file number 0-21104

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

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

2211 New Market Parkway, Suite 142, Marietta, GA 30067
(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code (770) 952-1660

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

Title of each class	Name of each exchange on which registered
None	Not applicable

Securities registered pursuant to Section 12(g) 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 $71,093,213 at March 15, 1996 (3,791,638 shares). The number of common shares outstanding at March 15, 1996 was 4,716,166 (exclusive of treasury shares).

Item 1. of this Report is hereby amended to correct certain information contained therein.

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 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. 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.

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 veins.

Orthopaedic Surgery (Sports Medicine). The orthopaedic surgery market addressed by the Company involves surgical replacements of the meniscus, the anterior and posterior cruciate ligaments, and the patellar tendon. 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 1993, 1994, and 1995 were $13.7 million, $16.7 million, and $19.7 million, respectively, accounting for 64%, 71%, and 67% respectively, of the Company's total revenues during those years.

Veins. The Company cryopreserves human saphenous 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 1993, 1994, and 1995 were $4.7 million, $5.5 million, and $6.8 million, respectively, accounting for 22%, 23%, and 23% 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 1993, 1994, and 1995 were $604,000, $593,000, and $1,456,000, respectively, accounting for 3%, 2%, and 5%, 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. 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 1993, 1994, and 1995 were $497,000 $268,000, and $263,000, respectively. Stented porcine valve sales totaled $423,000 in 1993 and $146,000 in 1994. Accordingly, total Company revenues attributable to porcine heart valve sales in 1993, 1994, and 1995 were $920,000, $414,000, and $263,000 respectively, accounting for 4%, 2%, 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. Currently, porcine valve sales represent significantly all of the Company's export sales. The Company will also investigate the process for IDE and PMA approval of stentless porcine heart valves in the United States.

Inventories of porcine heart valves were $424,200 at December 31, 1995, a decrease of $432,000 from the previous year. This decrease represents both sales of porcine valves and reductions of the carrying value of stented valves.

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 Marietta, 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 and the SynerGraft, the Company's business currently depends on the availability of sufficient quantities of tissue from human donors. Over the past several years, the overall number of human donors has been relatively constant. 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 that may disqualify the tissue for preservation. Blood samples from each tissue donor are subjected to a variety of tests to screen for infectious diseases. Samples of the tissue are also sent to independent laboratories for pathology testing. Following removal of the tissue to be preserved, a separate sterilization 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. It is management s intention to introduce two new preserved human tissues during 1996. One is the development of preservation techniques for human pericardial tissue that will be used by thoracic surgeons during lung reduction surgery for emphysema patients. Also, the Company is developing the techniques for the recovery, preservation and transplantation of human mitral heart valves.

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:

FibRx (registered) - 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 has progressed through animal trials and is presently undergoing virology validation procedures mandated by the FDA prior to the approval for human clinical trials. It is anticipated that the applications to begin human clinical trials for FibRx will be submitted to the FDA in the fourth quarter of

1996.

On March 18, 1996 the Company signed an agreement with Bayer Corporation Pharmaceutical Division to negotiate the terms and conditions of a worldwide license for FibRx. Management believes that the successful conclusion of a license with Bayer to accelerate introduction of FibRx in both the U.S. and world markets.

BioGlue (trademark) - 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. During March 1996, the Company acquired the technology underlying the BioGlue. Management believes that BioGlue has the potential to replace sutures and surgical staples in many standard surgical procedures. BioGlue is progressing through animal and toxicity evaluations. It is anticipated that applications to begin clinical trials for BioGlue will be submitted to the FDA during the fourth quarter of 1996.

SynerGraft (registered) - 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 1993, 1994, and 1995, the Company expended approximately $1.4 million, $2.0 million, and $2.6 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 6%, 8%, and 9%, 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.

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.

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.

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 81 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 cryopreservation service fees received by the Company that are attributable to physicians in their territory.

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.

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 no tissue banks process 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.

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 Company's business.

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 17 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 8 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 (i) light-sensitive enzyme inhibitors and (ii) a protein-based bio-adhesive. The remaining duration of the Company's patents ranges from 7 to 16 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, FibRx and SynerGraft are registered trademarks of the Company, and BioGlue and CryoLife-O'Brien are trademarks of the Company.

EMPLOYEES

The Company presently has approximately 160 employees. These employees include 10 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.

PART IV.

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

The following exhibits are filed herewith or incorporated by reference:

Exhibit Number	Description
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, 1975
3.3*	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 31,1993.)
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 Newmarket 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).)
10.2*	Lease by and between Newmarket Partners I, Laing Properties, Inc. and Laing Management Company, General Partner, as Landlord, and the Company as Tenant, dated July 23, 1993. (Incorporated by reference to Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
10.3*	1993 Employee Stock Incentive Plan adopted on July 6, 1993. (Incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
10.4*	1989 Incentive Stock Option Plan for the Company, adopted March 23, 1989 (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.5*	Incentive Stock Option Plan, dated as of April 5, 1984. (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.6*	Form of Stock Option Agreement and Grant under the Incentive Stock Option and Employee Stock Incentive Plans. (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.7*	CryoLife, Inc. Profit Sharing 401(k) Plan,

	as adopted on December 17, 1991. (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.8*	Form of Supplemental Retirement Plan, by and between the Company and its Officers -- Parties to Supplemental Retirement Plans: Steven G. Anderson, Robert T. McNally, Gerald B. Seery, James C. Vander Wyk, Albert E. Heacox, 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
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.
10.9(f)*	Employment Agreement, by and between the Company and James C. Vander Wyk, Ph.D.
10.10*	Amended and Restated Loan Agreement, by and between Bank South, N.A., and the Company, dated February 20, 1992, as modified by that First Modification of Amended and Restated Loan Agreement, by and between the parties, dated May 12, 1992, as modified by that Second Modification of Amended and Restated Loan Agreement, by and between the parties, dated November 12, 1992, and related

	Revolving Line Note dated February 20, 1992 and Consolidated Term Note dated February 20, 1992. (Incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.11*	Third Modification of Amended and Restated Loan Agreement, dated as of May 31, 1993. (Incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1993.)
10.12*	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).)
10.13*	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).)
10.14*	Technology Acquisition Agreement between the Company and Nicholas Kowanko, Ph.D., dated March 14, 1996.
10.15*	Technology Option Agreement, by and between the Company and Colorado State University Research Foundation, dated March 1, 1991. (Incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.16*	Option Agreement, by and between the Company and Duke University, dated July 9, 1990, as amended by that Option Agreement Extension, by and between the parties, dated July 9, 1991. (Incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)
10.17*	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).)
10.18*	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.)
10.19*	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.)
10.20*	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.)
10.21*	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.)
10.22*	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.)
10.23*	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.)
10.24*	Sale and Assignment Agreement between the Company and Osteotech, Inc.
10.25*	Option Letter between the Company and Bayer Corporation Pharmaceutical Division, dated

March 18, 1996.

10.26*	Lease Agreement between the Company and Amli Land Development - I Limited Partnership, dated April 18, 1995.
10.27*	Preoccupancy and Construction Agreement between the Company and Amli Land Development - I Limited Partnership dated April 18, 1995.
10.28*	Funding Agreement between the Company and Amli Land Development - I Limited Partnership dated April 18, 1995.
10.29*	Employee Stock Purchase Plan dated May 22, 1995.
11.1*	Statement re: Computation of Per Share Earnings.
13.1*	1995 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	Accountants' Consent.

* previously filed

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.

May 9, 1996 By: STEVEN G. ANDERSON

_____

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

the Board of Directors

EXHIBIT 23.1

ACCOUNTANTS' CONSENT

The Board of Directors
CryoLife, Inc.

We consent to incorporation by reference in the registration statements (Nos. 33-83996 and 33-84048) on Form S-8 of CryoLife, Inc. of our reports dated February 14, 1996, except as to Note 13, which is as of March 18, 1996, relating to the consolidated balance sheets of CryoLife, Inc. and subsidiaries as of December 31, 1995 and 1994, and the related consolidated statements of income, shareholders' equity, and cash flows and related schedule for each of the years in the three-year period December 31, 1995, which reports appear in the December 31, 1995 annual report on Form 10-K of CryoLife, Inc.

KPMG PEAT MARWICK LLP
KPMG PEAT MARWICK LLP

Atlanta, Georgia
May 9, 1996