Registration Statement No. 333-

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SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

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FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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.)

ddress, including zip code, and telephone number, includin area code, of registrant's principal executive offices)

Steven G. Anderson, President, CEO and Chairman of the Board of Directors
CryoLife, Inc.
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144 (770) 419-3355

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:
B. Joseph Alley, Jr., Esq.
Arnall Golden & Gregory
2800 One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30303-3450
(404) 873-8500

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO PUBLIC: FROM TIME TO TIME AFTER THIS REGISTRATION STATEMENT BECOMES EFFECTIVE, AS DETERMINED BY THE SELLING SHAREHOLDER.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.  $[\ ]$ 

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [ X ]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.  $[\ ]$ 

#### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share (1)	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee(1)
Common Stock \$.01 Par Value	10,395 Shares	\$15.25	\$158,523.75	\$100.00

Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) and based upon the average of the high and low prices for the Company's Common Stock on the Nasdaq National Market on November 15, 1996.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), shall determine.

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INFORMATION CONTAINED HEREIN IS SUBJECT TO COMPLETION OR AMENDMENT. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD NOR MAY OFFERS TO BUY BE ACCEPTED PRIOR TO THE TIME THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS SHALL NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF THESE SECURITIES IN ANY STATE IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH STATE.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED NOVEMBER 21, 1996

CRYOLIFE, INC.

10,395 SHARES

COMMON STOCK

(PAR VALUE, \$.01 PER SHARE)

This Prospectus ("Prospectus") relates to 10,395 shares (the "Shares") of common stock, \$.01 par value per share ("Common Stock"), of CryoLife, Inc., a Florida corporation (the "Company"). The Shares may be offered by a shareholder of the Company (the "Selling Shareholder") from time to time in transactions in the over-the-counter market, in negotiated transactions or a combination of such methods of sale at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices. On November 15, 1996, the closing sales price of the Common Stock on the National Market System, as reported by the National Association of Securities Dealers' Automated Quotation System ("Nasdaq") was \$14.75. The Selling Shareholder may effect such transactions by selling the Shares to or through broker-dealers, and such

broker-dealers may receive compensation in the form of discounts or commissions from the Selling Shareholder and/or the purchasers of the Shares for whom such broker-dealers may act as agents or to whom they sell as principals, or both. See "Selling Shareholder" and "Manner of Distribution."

All of the Shares offered hereunder are to be sold by the Selling Shareholder. None of the proceeds from the sale of the Shares by the Selling Shareholder will be received by the Company. The Company has agreed to bear all expenses (other than discounts or commissions) in connection with the registration and sale of the Shares being offered by the Selling Shareholder.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

THE DATE OF THIS PROSPECTUS IS NOVEMBER \_\_\_\_, 1996.

No person has been authorized to give any information or to make any representations other than those contained in this Prospectus in connection with the offering made by this Prospectus and, if given or made, such information or representations must not be relied upon as having been authorized by the Company. This Prospectus does not constitute an offer to sell, or the solicitation of an offer to buy, the securities offered hereby in any jurisdiction to any person to whom it is unlawful to make an offer or solicitation. Except where otherwise indicated, this Prospectus speaks as of the date hereof. The delivery of this Prospectus shall not, under any circumstances, create any implication that there has been no change in the affairs of the Company since the date hereof.

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### AVAILABLE INFORMATION

The Company is subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in accordance therewith files Annual, Quarterly and Current Reports (on Forms 10-K, 10-Q and 8-K, respectively), proxy statements utilized in the solicitation of shareholders as well as other information with the Securities and Exchange Commission (the "Commission"). Such reports, proxy statements and other information filed by the Company under the Exchange Act can be inspected and copied at the public reference facilities maintained by the Commission at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549 and at the Commission's Regional Offices at 7 World Trade Center, Suite 1300, New York, New York 10048 and Northwestern Atrium Center, 500 West Madison Street, Suite 1400, Chicago, Illinois 60661. Copies of such material can be obtained from the Public Reference Section of the Commission, Washington D.C. at prescribed rates. The Common Stock of the Company is traded on the Nasdaq National Market System. Reports and other information concerning the Company may be inspected at the National Association of Securities Dealers, Inc., 1735 K Street, N.W., Washington, D.C. 20006.

This Prospectus constitutes a part of a Registration Statement on Form S-3 (together with any amendments thereto, the "Registration Statement") filed with the Commission under the Securities Act of 1933, as amended (the "Securities Act") relating to the Shares offered hereby. This Prospectus does not contain all of the information set forth in the Registration Statement and the exhibits and schedules thereto, certain portions of which have been omitted in accordance with the rules and regulations of the Commission. Statements contained in this Prospectus as to the contents of any contract or other document are not necessarily complete, and in each instance reference is made to such copy of such contract or other document filed as an exhibit to the Registration Statement, each statement being qualified in all respects by such reference and the exhibits and schedules thereto. For further information regarding the Company and the Shares offered hereby, reference is hereby made to such Registration Statement and such exhibits and schedules, which may be inspected without charge at the office of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549, and copies of which may be obtained, from the Commission upon payment of the fees prescribed by the Commission.

#### DOCUMENTS INCORPORATED BY REFERENCE

In accordance with the requirements of the Exchange Act, the Company periodically files certain reports and other information with the Commission. The following documents filed with the Commission are hereby incorporated in this Prospectus by reference:

- (a) The Company's Annual Report on Form 10-K, as amended, filed with respect to the year ended December 31, 1995.
- (b) The Company's  $\,$  Quarterly  $\,$  Report on Form 10-Q filed with respect to the quarter ended March 31, 1996.
- (c) The Company's Current Report on Form 8-K filed with the Commission on April 16, 1996.
- (d) The Company's Quarterly Report on Form 10-Q filed with respect to the quarter ended June 30, 1996.
- (e) The Company's Quarterly Report on Form 10-Q filed with respect to the quarter ended September 30, 1996.

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- (f) The description of the Company's Common Stock contained in the Company's registration statement filed under Section 12 of the Securities Exchange Act of 1934, including any amendment or report filed for the purpose of updating such description.
- All documents subsequently filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act prior to the filing of a post-effective amendment to this registration statement which indicates that all of the shares of Common Stock offered have been sold or which deregisters all of such shares then remaining unsold shall be deemed to be incorporated by reference in this registration statement and to be a part hereof from the date of filing of such documents. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this registration statement to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this registration statement.

The Company will provide without charge to each person to whom this Prospectus is delivered, upon the written or oral request of any such person, a copy of any or all of the documents incorporated by reference into this Prospectus, other than exhibits to such documents, unless such exhibits are specifically incorporated by reference herein. Such requests should be addressed to CryoLife, Inc., 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144, Attention: Suzanne Gabbert, Assistant Secretary (770) 419-3355.

### THE COMPANY

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. 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 cryopreservation 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 (all 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. The Company's Common Stock is traded over the Nasdaq National Market System under the ticker symbol "CRYL."

### 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

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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.

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# 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 factors.

## 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 and biological glues, 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. Over the past several years, the overall number of human donors has been relatively constant. 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 and are presently manufactured by a third party under a contract. 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 and to the risk that the Company's manufacturer will not fulfill its contractual obligations, which could, in turn, result in shortages of supplies of porcine heart valves.

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

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community acceptance. With respect to the Company's major products under development, FibRx(R) has progressed through animal trials and is presently undergoing virology 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 service 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.

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### 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 operation 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.

#### 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

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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, development 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.

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 710,000 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.

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## MATERIAL CHANGES

Set forth below is a discussion of all material changes in the Company's affairs which have occurred since December 31, 1995 and which have not been described in a report on Form 10-Q or Form 8-K filed under the Exchange Act and incorporated by reference herein:

Revenues for the third quarter of 1996 were \$10,411,000 an increase of 25% compared to \$8,347,000 for the third quarter of 1995. Net income for the third quarter of 1996 was \$1,261,000 or \$.13 per common share, an increase of 85% compared to \$685,000 or \$.07 per common share for the same period in 1995.

In March 1996, the Company received a \$250,000 payment from Bayer Corporation for a limited term exclusive right to negotiate with the Company for a world-wide license of the Company's FibRx adhesive technology. Termination of negotiations between the two companies was announced on August 30, 1996 and the payment was recorded in the third quarter of 1996. The Company has initiated discussions with additional parties with respect to partnership license agreements for FibRx technology.

The Company entered into a new line of credit agreement with NationsBank during the third quarter of 1996 which increased the Company's aggregate line of credit from \$3,000,000 to \$10,000,000. The purpose of the new line of credit is to assist the Company in facilitating internal growth programs and acquisitions. As of October 31, 1996, approximately \$7.5 million dollars was available to the

Company pursuant to the line of credit.

On September 12, 1996, the Company announced the acquisition of the assets of United Cryopreservation Foundation, Inc. ("UCFI"), a processor and distributor of cryopreserved human heart valves and saphenous veins for transplant. Under the terms of the acquisition, the Company will pay approximately \$2,000,000 over a five year period and will assume certain obligations of UCFI in exchange for assets of UCFI consisting of cryopreservation equipment and storage facilities.

The Company received a \$99,000 Phase One Innovation Research Grant from the National Institutes of Health during the third quarter of 1996. This grant pertains to CryoLife's Synergraft program for the development of a bio-engineered human implantable heart valve. Pursuant to the grant, CryoLife scientists will conduct advanced studies using a porcine heart valve collagen matrix that can be "seeded" with human cells. The goal of the project is to create a non-immunogenic heart valve for use in human heart valve replacement surgery.

The Company signed a licensing agreement during the second quarter of 1996 with Innovacion Cientifica, SA of Buenos Aires, Argentina. Under the terms of the contract, CryoLife received a technology transfer fee of \$50,000 during the third quarter of 1996 and will supply Innovacion Cientificia with CryoLife's patented cryoprotectants, antibiotic treatment and viral inactivation technology. Similar licensing programs are under discussion with medical groups in Spain and Italy.

During the third quarter of 1996, the Company announced a new manufacturing agreement with Tissuemed, Ltd.of Leeds, England, extending European production of the CryoLife-O'Brien advanced design porcine stentless heart valves.

The Company's new 100,000 square foot leased world headquarters laboratory, located in suburban Atlanta, is expected to be ready for occupancy on or about November 25, 1996. It is anticipated that a majority of the Company's departments will complete their relocation to the new facility on or before the end of November 1996.

### USE OF PROCEEDS

The Company will not receive any proceeds from the sale of the Shares offered hereby.

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### SELLING SHAREHOLDER

Set forth below is the name of the Selling Shareholder and the number of Shares being offered by him. To the best of the Company's knowledge, assuming all of the Shares being offered hereby are sold and the Selling Shareholder does not choose to acquire additional Common Stock during the offering period, the Selling Shareholder will own 1000 shares of the issued and outstanding shares of Common Stock upon completion of the offering.

Selling Shareholder	Number of Shares Owned1	Number of Shares Offered
Donald Nixon Ross	11,395	10,395

<sup>1</sup> As of November 15, 1996.

All of the Shares being offered by the Selling Shareholder were acquired in connection with the purchase by the Company from the Selling Shareholder of certain patents, intellectual property rights and other assets. In the agreement dated as of August 15, 1996 (the "Agreement") executed in connection with the purchase, the Company granted certain demand registration rights to the Selling Shareholder. The Company has agreed to bear all expenses (other than commissions and discounts of underwriters, dealers or agents) in connection with the

registration and sale of the Shares being offered by the Selling Shareholder. See "Manner of Distribution."

The Selling Shareholder has requested that the Company use its best efforts to effectuate a registration of the Shares for resale under the Securities Act. In light of this request and in accordance with the Agreement, the Company has filed with the Securities and Exchange Commission a Registration Statement with respect to the resale of the Shares from time to time in the over-the-counter market or in privately negotiated transactions and has agreed to prepare and file such amendments and supplements to the Registration Statement as may be necessary to keep the Registration Statement effective until the earlier of three months from the date hereof or until all of the Shares offered hereby have been sold. This Prospectus forms a part of the Registration Statement.

In connection with the Agreement, the Company has entered into a consulting agreement of even date therewith with the Selling Shareholder which provides that the Selling Shareholder shall make himself available to provide specific consulting services to the Company for a period of five years at a rate of \$15,000 per year plus expenses and an additional \$1,000 for each day on which consulting services are provided by the Selling Shareholder in excess of 24 days. The Selling Shareholder has not held any position or office or had any other material relationship in the with the Company.

### MANNER OF DISTRIBUTION

The Shares covered hereby may be offered and sold from time to time by the Selling Shareholder. The Selling Shareholder will act independently of the Company in making decisions with respect to the timing, manner and size of each sale. Such sales may be made in the over-the-counter market or otherwise, at prices related to the then current market price or in negotiated transactions, including one or more of the following methods: (a) purchases by a broker-dealer as principal and resale by such broker or dealer for its account pursuant to this Prospectus; (b) ordinary brokerage transactions and transactions in which the broker solicits purchasers; and (c) block trades in which the broker-dealer so engaged will attempt to sell the Shares as agent but may position and resell a portion of the block as principal to facilitate the transaction. The Company has been advised by the Selling Shareholder that he has not made any arrangements relating to the distribution of the Shares covered by this Prospectus. In effecting sales, broker-dealers engaged by the Selling Shareholder may arrange for other broker-dealers to participate. Broker-dealers may receive commissions or discounts from the Selling Shareholder in amounts to be negotiated.

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In offering the Shares covered hereby, the Selling Shareholder and any broker-dealers and any other participating broker-dealers who execute sales for the Selling Shareholder may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales, and any profits realized by the Selling Shareholder and the compensation of such broker-dealer may be deemed to be underwriting discounts and commissions. In addition, any Shares covered by this Prospectus which qualify for sale pursuant to Rule 144 or Regulation S may be sold under Rule 144 or Regulation S rather than pursuant to this Prospectus. None of the Shares covered by this Prospectus presently qualify for sale pursuant to Rule 144 or Regulation S, and it is not anticipated that any Shares will so qualify during the effectiveness of the Registration Statement in which this Prospectus is contained.

The Company has advised the Selling Shareholder that during such time as he may be engaged in a distribution of Shares covered hereby, he is required to comply with Rules 10b-6 and 10b-7 under the Exchange Act as described below and, in connection therewith, that he may not engage in any stabilization activity in connection with the Company's Common Stock, is required to furnish to each purchaser and/or broker-dealer through which Shares covered hereby may be offered copies of this Prospectus, and may not bid for or purchase any securities of the Company or attempt to induce any person to purchase any securities of the Company except as permitted under the Exchange Act. The Selling Shareholder has agreed to inform the Company when the distribution of his Shares is completed.

Rule 10b-6 under the Exchange Act prohibits, with certain exceptions, participants in a distribution from bidding for or purchasing, for an account in which the participant has a beneficial interest, any of the securities that are the subject of the distribution. Rule 10b-7 governs bids and purchases made in order to stabilize the price of a security in connection with a distribution of the security.

This offering will terminate on the earlier of three months from the date hereof or the date on which all Shares offered hereby have been sold by the Selling Shareholder.

In order to comply with certain states' securities laws, if applicable, the Shares offered hereby will be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, the Shares may not be sold in certain states unless they have been registered or qualified for sale in such states or an exemption from regulation or qualification is available and is complied with.

### LEGAL MATTERS

The legality of the Shares offered hereby has been passed upon for the Company by Arnall Golden & Gregory.

#### EXPERTS

The consolidated financial statements as of December 31, 1995 and 1994 and for each of the years in the three year period ended December 31, 1995 have been incorporated by reference herein and in the Registration Statement in reliance upon the report of KPMG Peat Marwick LLP, independent certified public accountants, and upon the authority of said firm as experts in accounting and auditing.

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### PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

### ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

A reasonable estimate of the costs to be incurred in connection with this Registration Statement and Prospectus, to be borne entirely by the Registrant, is as follows:

Securities and Exchange Commission Registration Fee	\$ 100.00
Accounting Fees and Expenses	5,000.00
Legal Fees and Expenses	6,500.00
Printing and Publication	1,000.00
Miscellaneous	500.00
TOTAL	\$13,100.00

## ITEM 15. INDEMNIFICATION OF OFFICERS AND DIRECTORS

The Company is a Florida corporation. The following summary is qualified in its entirety by reference to the complete text of the Florida Business Corporation Act (the "FBCA"), the Company's Restated Articles of Incorporation, and the Company's Bylaws.

Under Section 607.0850(1) of the FBCA, a corporation may indemnify any of its directors and officers against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding (including any appeal thereof) (i) if such person acted in good faith and in a manner he or she

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reasonably believed to be in, or not opposed to, the best interests of the corporation, and (ii) with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. In actions brought by or in the right of the corporation, however, Section 607.0850(2) provides that no indemnification shall be made in respect of any claim, issue or matter as to which the director or officer shall have been adjudged to be liable unless, and only to the extent that, the court in which such proceeding was brought, or any other court of competent jurisdiction, shall determine upon application that, despite the adjudication of liability but in view of all circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper. Article X of the Company's Restated Articles of Incorporation and Article VI of the Company's Bylaws require that, if in the judgment of the majority of the Board of Directors (excluding from such majority any director under consideration for indemnification) the criteria set forth under Section 607.0850 have been met, then the Company shall indemnify its directors and officers for certain liabilities incurred in the performance of their duties on behalf of the Company to the maximum extent allowed by Section 607.0850 of the FBCA (formerly Section 607.014 of the Florida General Corporation Act).

The Securities Purchase Agreement dated December 17, 1985 between the Company and certain shareholders of the Company provides that any investors exercising registration rights pursuant to such agreement must indemnify the officers and directors signing the registration statement against any liability arising from statements or omissions made in reliance upon information furnished by such investors to the Company for use in such registration statement.

The registration rights agreement dated August 22, 1991, among the Company, Galen Partners, L.P. ("Galen"), and Galen Partners International, L.P. ("Galen International") provides that if Galen or Galen International exercises its registration rights, then such prospective seller and any underwriter acting on its behalf shall have agreed to indemnify the Company and each officer and director signing such registration statement for

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any liability arising from any untrue statement or omission made in such registration statement in reliance upon written information provided to the Company for use in such registration statement. The registration rights agreement further specifies that the indemnification rights granted therein shall be inoperative if, in connection with an underwritten public offering, an underwriting agreement is executed containing provisions covering indemnification among the partners thereto.

The Company has purchased insurance to insure (i) the Company's directors and officers against damages from actions and claims incurred in the course of their duties, and (ii) the Company against expenses incurred in defending lawsuits arising from certain alleged acts of its directors and officers.

## ITEM 16. EXHIBITS

The following exhibits have been filed (except where otherwise indicated) as part of this Registration Statement:

### EXHIBIT NUMBER

### EXHIBIT

2.1 Sale Agreement dated August 15, 1996 between the Company and Donald Nixon Ross. (Incorporated By Reference To Exhibit 2.1 to the Registrant's Form 10-Q for the Quarter Ended September 30, 1996. The Company has applied for confidential treatment of portions of this Agreement. Accordingly, portions thereof were omitted and filed separately with the Securities and Exchange Commission.)

- Opinion of Arnall Golden & Gregory
- 23.1 Consent of KPMG Peat Marwick LLP

23.2 Consent of Arnall Golden & Gregory (contained in Exhibit 5 hereto)

24.1 Powers of Attorney relating to subsequent amendments (included on the signature page of this Registration Statement)

#### ITEM 17. UNDERTAKINGS

- (a) The undersigned registrant hereby undertakes:
  - (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
    - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
    - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement;
    - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

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Provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant, or otherwise, the Securities and Exchange Commission has informed the registrant that such indemnification is against public policy as expressed in the Act and is therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in

connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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#### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Marietta, State of Georgia on November 15, 1996.

CRYOLIFE, INC.

By:/s/ Steven G. Anderson

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

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Steven G. Anderson and Edwin B. Cordell, Jr. and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Title

PRINCIPAL EXECUTIVE, FINANCIAL & ACCOUNTING OFFICERS AND DIRECTORS:

/s/ Steven G. Anderson	President, Chief Executive Officer and	November 15, 1996
Steven G. Anderson	Chairman of the Board of Directors (Principal Executive Officer)	
/s/ Edwin B. Cordell, Jr.	Vice President and Chief Financial Officer	November 15, 1996
Edwin B. Cordell, Jr.	(Principal Financial and Accounting Officer)	
/s/ Ronald D. McCall	Director	November 15, 1996
Ronald D. McCall		
/s/ Benjamin H. Gray	Director	November 15, 1996
Benjamin H. Gray		
Rodney G. Lacy	Director	November, 1996
/s/ Ronald Charles Elkins, M.D.	Director	November 15, 1996

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# EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
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5	Opinion of Arnall Golden & Gregory
23.1	Consent of KPMG Peat Marwick LLP
23.2	Consent of Arnall Golden & Gregory (contained in Exhibit 5 hereto)
24.1	Powers of Attorney relating to subsequent amendments (included on the signature page of this Registration Statement)

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ARNALL GOLDEN & GREGORY 2800 ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET ATLANTA, GEORGIA 30309-3450

(404) 873-8688

(404) 873-8689

November 21, 1996

CryoLife, Inc. 1655 Roberts Boulevard, NW Kennesaw, GA 30144

Re: Form S-3 Registration Statement

Gentlemen:

We have acted as your counsel in connection with the preparation of the Registration Statement on Form S-3 (the "Registration Statement") filed by CryoLife,Inc., a Florida corporation (the "Company"), with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act"). This Registration Statement relates to an offer by a certain selling stockholder named therein of up to 10,395 shares of the Company's Common Stock, \$.01 par value (the "Shares").

In acting as counsel to you, we have examined and relied upon such corporate records, documents, certificates and other instruments and examined such questions of law as we have considered necessary or appropriate for the purposes of this opinion. Based upon and subject to the foregoing, we advise you that in our opinion the Shares are legally issued, fully paid and non-assessable.

We consent to the filing of this opinion as an exhibit to the Registration Statement and the reference to this firm under the caption "Legal Matters" contained therein and elsewhere in the Registration Statement. This consent is not to be construed as an admission that we are a party whose consent is required to be filed with the Registration Statement under the provisions of the Act.

Sincerely,

ARNALL GOLDEN & GREGORY ARNALL GOLDEN & GREGORY

BJA:dlm 382903.1

# ACCOUNTANTS' CONSENT

The Board of Directors CryoLife, Inc.

We consent to the use of our report incorporated herein by reference and to the reference to our firm under the heading "Experts" in the prospectus.

KPMG MARWICK LLP

Atlanta, Georgia November 20, 1996