CRYOLIFE INC
Form S-3
December 17, 2004

As filed with the Securities and Exchange Commission on December 17, 2004
Registration No. 333-_____

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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 Identifi |

CRYOLIFE, INC.
1655 ROBERTS BOULEVARD, NW
KENNESAW, GEORGIA 30144
(770) 419-3355
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

| | COPIES TO: |
|---|---|
| STEVEN G. ANDERSON, PRESIDENT, CHIEF EXECUTIVE OFFICER AND CHAIRMAN OF THE BOARD OF DIRECTORS<br>CRYOLIFE, INC.<br>1655 ROBERTS BOULEVARD, NW<br>KENNESAW, GEORGIA 30144<br>(770) 419-3355 | T. CLARK FITZGERALD III, ESQ.<br>ARNALL GOLDEN GREGORY LLP<br>2800 ONE ATLANTIC CENTER<br>1201 WEST PEACHTREE STREET<br>ATLANTA, GEORGIA 30309-3450<br>(404) 873-8500 |

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

Approximate Date of Commencement of Proposed Sale to the Public: FROM TIME TO TIME AFTER THE EFFECTIVE DATE OF THIS REGISTRATION STATEMENT.

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, 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 this Form is a post-effective amendment filed pursuant to Rule 462(d) 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 | Proposed Maximum Aggregate Offering Price (1)(2) |
|---|---|
| Preferred Stock (3)<br>Depositary Shares (4)<br>Common Stock (including attached preferred share purchase rights) (5)<br>Total | $ 50,000,000 |

(1) Rule 457(o) under the Securities Act of 1933, as amended, permits the registration fee to be calculated on the basis of the maximum offering price of all of the securities listed and, therefore, the table does not specify by each class information as to the amount to be registered or the proposed maximum offering price per security.

(2) This registration statement also covers an indeterminate amount of securities that may be issued in exchange for, or upon conversion or exercise of, as the case may be, any securities registered hereunder that provide for conversion, exercise or exchange. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder.

(3) An indeterminate amount of preferred stock, depositary shares and common stock may be issued from time to time at indeterminate prices, with an aggregate offering price not to exceed $50,000,000.

(4) The depositary shares registered hereunder will be evidenced by depositary receipts issued pursuant to a depositary agreement. If the registrant elects to offer to the public fractional interests in shares of preferred stock, then depositary receipts will be distributed to those persons

purchasing the fractional interests and the shares will be issued to the depositary under the depositary agreement.

(5) Calculated pursuant to Rule 457(o) at the statutory rate of $117.70 per $1,000,000 of securities registered.

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 OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

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THE INFORMATION IN THIS PROSPECTUS IS INCOMPLETE AND MAY BE CHANGED. THE REGISTRANT MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IT IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

PROSPECTUS

$50,000,000

# CRYOLIFE, INC.

COMMON STOCK
PREFERRED STOCK
DEPOSITARY SHARES

We may from time to time offer and sell common stock, preferred stock and depositary shares.

This prospectus provides you with a general description of the securities that may be offered. Each time securities are sold, we will provide one or more supplements to this prospectus that will contain additional information about the specific offering and the terms of the securities being offered. The supplements may also add, update or change information contained in this prospectus. You should carefully read this prospectus and any accompanying prospectus supplement before you invest in any of our securities.

Our common stock is listed for trading on the New York Stock Exchange under the symbol "CRY." Our executive offices are located at 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144. Our telephone number is (770) 419-3355. The last reported sale price of the common stock on December 16, 2004 was $7.40 per share.

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THIS INVESTMENT INVOLVES RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 6.

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NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is _____, 2004.

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You should rely only on the information included or incorporated by reference in this prospectus and any accompanying prospectus supplement. We have not authorized any dealer, salesman or other person to provide you with additional or different information. This prospectus and any accompanying prospectus supplement are not an offer to sell or the solicitation of an offer to buy any securities other than the securities to which they relate and are not an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make an offer or solicitation in that jurisdiction. You should not assume that the information in this prospectus or any accompanying prospectus supplement or in any document incorporated by reference in this prospectus or any accompanying prospectus supplement is accurate as of any date other than the date of the document

containing the information.



## SUMMARY

This summary highlights information that we believe is especially important concerning our business and this offering. It does not contain all of the information that may be important to your investment decision. You should read the entire prospectus, including the documents incorporated herein by reference, "Risk Factors" and our financial statements and related notes, before deciding to purchase our securities.

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, which we refer to as the "SEC," using a "shelf' registration process. Under this shelf process, we may, over time, sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of $50.0 million. This prospectus provides you with a general description of the securities we may offer pursuant to this prospectus. Each time we sell securities, we will provide one or more prospectus supplements that will contain specific information about the terms of that offering. This prospectus does not contain all of the information included in the registration statement. For a complete understanding of the offering of securities, you should refer to the registration statement relating to this prospectus, including its exhibits. A prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any accompanying prospectus supplement together with the additional information described under the heading "Where You Can Find More Information. "

## ABOUT CRYOLIFE

CryoLife develops and commercializes medical devices which may be implanted into the body during surgery and preserves and distributes human tissues for cardiovascular, vascular and orthopaedic transplant applications. The implantable devices include BioGlue(R) Surgical Adhesive, porcine heart valves, and grafts of bovine tissue processed using our proprietary SynerGraft(R) technology.

CryoLife's proprietary BioGlue Surgical Adhesive, designed for cardiovascular, vascular, pulmonary, and general surgical applications, is a polymer based on bovine blood clotting protein and an agent for linking together proteins. CryoLife can distribute BioGlue throughout the United States and more than 40 other countries for designated applications. In the U.S., BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. In Europe, CryoLife distributes BioGlue under CE Mark product certification for vascular applications, pulmonary indications, such as the repair of air leaks in lungs, and soft tissue repair procedures. CryoLife has also received approval and distributes BioGlue for vascular, pulmonary and soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in Australia, and in several countries in South America and Asia.

CryoLife distributes preserved human cardiovascular, vascular and orthopaedic tissue to implanting institutions throughout the United States, Canada and Europe. We preserve human tissue using special freezing techniques, or cryopreservation. Management believes the cryopreserved human tissues it distributes offer specific advantages over mechanical, synthetic, and animal-derived alternatives. Depending on the alternative, these advantages include more natural blood flow properties for our cryopreserved heart valves, the elimination of a long-term need for drug therapy to prevent excessive blood clotting, and a reduced risk of catastrophic failure, thromboembolism (stroke), or calcification.

Through its continuing research and development activities, CryoLife endeavors to use its expertise in protein chemistry, biochemistry, cell biology, and immunology and its understanding of the cardiovascular, vascular, and orthopaedic surgery medical specialties, to acquire and develop useful implantable products and technologies. We seek to identify market areas that can benefit from preserved living tissues and other related technologies, to develop innovative techniques and products within these areas, to secure their commercial protection, to establish their efficacy and then to market these techniques and products. In order to expand CryoLife's service and product offerings, we are in the process of developing or investigating several technologies and products. The products in development have not been subject to completed clinical trials, and have not received FDA or other regulatory approval, so we are not certain if we will derive any revenues from them. CryoLife generally performs significant research and development work before offering its services and products, building on either existing non-proprietary



knowledge or acquired technology and know-how. Our tissue preservation services were developed based on work done some years before. Our BioGlue product was developed by us from a substance originally developed by a third party and acquired by us. In addition we continue to explore technologies that may further enhance the safety of our tissue processing.

CryoLife is using the technology underlying its BioGlue surgical adhesive as the base for several potential products in development. Other potential applications for BioGlue surgical adhesive in the U.S. include hernia repair and sealing the membranes surrounding the brain and spinal cord. BioGlue also has the potential to be used as a replacement for the soft tissue in spinal discs. One of our subsidiaries is developing a new drug delivery technology that has potential uses in the areas of cancer therapy, fibrinolysis (blood clot dissolving), and other drug delivery applications.

CryoLife also distributes its SynerGraft processed bovine vascular graft and a porcine heart valve, the CryoLife-O'Brien(R) aortic heart valve. The SynerGraft process involves the depopulation of cells leaving a matrix of protein fibers that has the potential to be repopulated with the recipient's cells. CryoLife believes that this process increases graft longevity, and improves the biocompatibility and functionality of the tissue. CryoLife markets the SynerGraft bovine vascular graft in Europe and the Middle East. CryoLife's porcine valves contain minimal amounts of synthetic materials, compared to many other fixed porcine heart valves. This decreases the risk of endocarditis, a debilitating and potentially fatal infection. CryoLife currently markets this valve in Europe and certain other territories outside the U.S.

CryoLife's business is subject to a number of risks, including the possibility of FDA actions, additional expenses and losses from product recalls, possible losses from ongoing product liability, securities and other litigation,

regulatory action, adverse publicity and lower demand for CryoLife products resulting from product recalls and other FDA activity, inability to obtain sufficient insurance coverage, possible inability to protect the intellectual property rights in our technology, the possible inability to obtain necessary regulatory approvals, and possible future lack of capital.

Food and Drug Administration (FDA) Activity.

In August 2002 the FDA issued an order, which we refer to as the FDA Order, regarding several types of tissue processed by CryoLife. Non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife from October 3, 2001 to September 5, 2002 was required to be retained until recalled, destroyed, the safety was confirmed, or an agreement was reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA. Pursuant to the FDA Order, CryoLife placed tissue subject to the FDA Order under quality assurance quarantine and recalled the subject tissues (i.e. processed since October 3, 2001) that had been distributed but not implanted. In addition, CryoLife ceased processing non-valved cardiac, vascular, and orthopaedic tissues. In September 2002, CryoLife and the FDA reached an agreement permitting CryoLife to immediately resume processing and limited distribution of its non-valved cardiac and vascular tissues. The Company made changes to its procedures, and now processes most of the tissues that were subject to the FDA recall.

The FDA subsequently issued several notices on its Form 483, called Notices of Observation, which set forth its observations at the conclusion of an inspection of our processing facility. The observations included several as to documentation and procedures. The most recent Notice of Observations was issued in February 2004.

During 2003, we received other notices from the FDA stating that the FDA had determined that non-valved cardiovascular tissue processed using CryoLife's SynerGraft technology would be regulated as medical devices and would require additional premarket approval authorization for continued distribution of these tissues. FDA also notified CryoLife that the application of the SynerGraft technology to allograft heart valves (CryoValve SG), currently regulated as Class II medical devices, was considered to be a major manufacturing change requiring a 510(k) submission.

CryoLife submitted the required 510(k) for CryoValve SG and has received two requests for additional information from FDA. While most of the requested



information has been provided, CryoLife is seeking to resolve certain other requests, involving bench-testing and additional clinical trials, through administrative procedures at the FDA.

CryoLife has also appealed the designation of non-valved cardiovascular tissue processed using CryoLife's SynerGraft technology as medical devices. CryoLife has provided extensive clinical and preclinical evidence of the safety and effectiveness of SynerGraft cardiovascular tissue. Discussions with the Agency to resolve this issue are ongoing.

There can be no assurance that the outstanding issues with respect to the CryoValve SG 510(k) or the designation of SynerGraft cardiovascular tissue will be resolved favorably. In the meantime, CryoLife has voluntarily suspended the use of the SynerGraft technology in the processing of allograft heart valves and other cardiovascular tissue. Additionally, CryoLife discontinued labeling vascular (blood vessel) grafts as suitable for use in arteriovenous access

because FDA has determined that this indication is a "non-homologous" use that would require premarket approval as a medical device.

Until the issues surrounding the SynerGraft treated tissues are resolved, CryoLife will employ its traditional processing methods on cardiovascular and vascular tissues. Distribution of allograft heart valves and vascular tissue processed using CryoLife's traditional processing protocols will continue. CryoLife currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue on hand.

Products Liability Litigation and Insurance Coverage.

As of December 15, 2004 we were aware of ten pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, four allege product liability claims arising out of our orthopaedic tissue services, four allege product liability claims arising out of our allograft heart valve tissue services, one alleges product liability claims arising from BioGlue, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine when it was a subsidiary of CryoLife.

Of the ten open lawsuits a total of four are covered by CryoLife's insurance coverage as follows: two lawsuits by the 2000/2001 insurance policy, one by the 2003/2004 insurance policy and one by the 2004/2005 insurance policy. For the 2000/2001 insurance policy year CryoLife maintained claims-made insurance policies which CryoLife believes to be adequate to defend against the suits filed during this period. As of September 30, 2004 the Company accrued $100,000 for the remaining retention levels related to the 2000/2001 insurance policy year. The Company believes its 2003/2004 and 2004/2005 insurance policies to be adequate to defend against the covered suits filed during these time periods.

Of the ten open lawsuits the remaining six are not covered by CryoLife's insurance policies as either these lawsuits relate to the 2002/2003 insurance policy year for which CryoLife has used all of its insurance coverage, aggregating $25 million, or they were asserted in periods after the coverage in the related incident year had lapsed. Other product liability claims have been asserted against CryoLife that have not resulted in lawsuits. We are monitoring these claims.

CryoLife performed an analysis as of September 30, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of September 30, 2004 CryoLife had accrued a total of $1.8 million for pending product liability claims and recorded zero representing amounts to be recovered from CryoLife's insurance carriers. The $1.8 million accrual is included as a component of accrued expenses and other current liabilities on the September 30, 2004 Summary Consolidated Balance Sheet. This amount represents CryoLife's estimate of the probable losses related to six of the ten pending product liability claims. CryoLife has not recorded an accrual for the remaining four product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. Prior to 2004, CryoLife recorded accruals for the uninsured portion of product liability claims for which the amount of probable loss was reasonably estimable. Had CryoLife recorded the total amounts of the reasonably estimable probable losses as a liability and recorded an asset for the estimated amount recoverable from the insurance carrier, the impact on the financial statements as of December 31, 2003 would not have been material. CryoLife's product

liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. CryoLife is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as many of the claims do not specify the damages sought and CryoLife does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products sold. In July 2004, the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2004 and December 31, 2004. Based on an actuarial valuation performed in July 2004 as of June 30, 2004 and December 31, 2004, the Company estimated that its liability for unreported product liability claims was $8.0 million as of June 30, 2004 and would be $8.7 million as of December 31, 2004. In accordance with EITF 03-8, the Company has accrued a prorated amount of $8.4 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2004. The $8.4 million balance is included as a component of accrued expenses and other current liabilities of $4.3 million and other long-term liabilities of $4.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as $14.6 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2004, $1.8 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The $1.8 million insurance recoverable is included as a component of other receivables of $700,000 and other assets of $1.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries related to unreported product liability claims related to services performed and products sold prior to September 30, 2004. Actual results may differ from this estimate.

If CryoLife is unable to settle the claims for amounts within its ability to pay or one or more of the product liability claims in which CryoLife is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed CryoLife's available insurance coverage and liquid assets. Failure by CryoLife to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of CryoLife.

RECENT DEVELOPMENTS

CryoLife is a nominal defendant in a purported shareholder derivative action against the individuals who were directors of the Company at the time of the FDA Order as detailed in our prior SEC filings. In early December, the court denied the defendant's motion to dismiss. See "Risk Factors-CryoLife's Insurance Coverage May Be Insufficient-Shareholder Derivative Action" for more details.

On December 14, 2004, CryoLife announced that Albert E. Heacox, Ph.D. has assumed the position of Senior Vice President of Research and Development of CryoLife, Inc. He replaces Kirby S. Black, Ph.D. Reporting to Dr. Heacox will be CryoLife's Research and Development Laboratory, Product and Process Engineering and Aurazyme Pharmaceuticals' Research Department. In his new position he will continue to report to Steven G. Anderson, President and CEO of CryoLife.



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CryoLife, Inc. was incorporated January 19, 1984 in Florida. All references to "CryoLife," the "Company," "we," "us" or "our" in this prospectus mean CryoLife, Inc., a Florida corporation, and all entities owned or controlled by CryoLife, Inc., except where it is made clear that the term means only the parent company.

Our principal executive offices are located at 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144. Our telephone number is (770) 419-3355 and our Web site is located at www.cryolife.com. Information contained on our Web site is not part of this prospectus.



## RISK FACTORS

You should carefully consider the following risk factors and all other information contained in this prospectus before you make any investment decisions with respect to our securities.

If any of the adverse events described in the following factors actually occur, or if we do not accomplish those events or objectives described in the risk factors as necessary to meet our expectations, our business, financial condition and operating results could be materially and adversely affected, the value of your securities could decline and you could lose all or part of your investment.

## RISKS RELATING TO OUR BUSINESS

### OVERVIEW

CryoLife has faced extraordinary challenges since it received, on August 13, 2002, an FDA order calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife since October 3, 2001 (the "FDA Order"). The recall resulted in the destruction of much of CryoLife's tissue, required that it adjust revenue for tissue recall returns, curtailed its processing activities, subjected it to intense FDA scrutiny and additional regulatory requirements that increased cost while CryoLife suffered decreased revenues due to lack of processing ability and decreased market demand for its services. During the same year, CryoLife was the subject of intense adverse media attention in connection with allegations that tissue processed by CryoLife had infected a man in Minnesota and caused his

death. CryoLife also became the subject of shareholders' class action and derivative shareholder suits, both of which remain pending. Products liability cases and claims increased to unprecedented numbers for CryoLife, using all of its related 2002/2003 insurance policy year insurance coverage and taxing its other resources. While many cases and claims have been settled, several remain unresolved. Since 2002, a U.S. Senate committee has inquired into safety in the tissue processing industry, making inquiries of CryoLife. The SEC has initiated and continues to pursue a formal investigation of CryoLife. The combined effect of these challenges has been to reduce Company revenues, increase its costs to process tissues and its operating expenses and strain management resources. Although CryoLife has now resumed processing and distribution of the tissues subject to the FDA recall and resolved many of the products liability suits pending against it, the foregoing factors will continue to challenge CryoLife in its efforts to increase sales and return to profitability. No assurances can be made that CryoLife will succeed in those efforts in a timely fashion.

THE COMPANY HAS EXPERIENCED OPERATING ISSUES AND NEGATIVE CASH FLOW. THE COMPANY MUST ADDRESS THE UNDERLYING CAUSES.

The Company expects that its operations will continue to generate negative cash flows throughout the remainder of 2004 and at least the first half of 2005 due to:

- The anticipated lower preservation services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activity, and related events,
- The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,
- An expected use of cash related to the defense and resolution of lawsuits and claims, and
- The legal and professional costs related to ongoing FDA compliance.

Although the impact of these factors has been offset in part by the success of BioGlue, the Company's long term liquidity and capital requirements will depend upon numerous factors, including:

- The success of BioGlue and other products using related technology,
- The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,
- The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,



- The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline, and
- The amount and the timing of the resolution of the remaining outstanding product liability claims and other claims against the Company.

IF THE COMPANY IS UNABLE TO ADDRESS THE CAUSES OF ITS OPERATING LOSSES AND NEGATIVE CASH FLOWS, IT WILL NEED TO RAISE ADDITIONAL CAPITAL WHICH MAY NOT BE AVAILABLE.

If the Company is unable to address these issues and continues to experience negative cash flows, the Company anticipates that it will require

additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements. The Company may elect to obtain financing prior to that time depending on the availability and terms of the financing agreement. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows. These challenges are addressed in greater detail elsewhere in this prospectus.

THE FDA ORDER AND SUBSEQUENT FDA ACTIVITY CONTINUE TO ADVERSELY IMPACT CRYOLIFE'S BUSINESS, INCLUDING REDUCING DEMAND FOR ITS SERVICES AND INCREASING PROCESSING COSTS

On August 13, 2002 CryoLife received an order from the FDA calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife at its headquarters since October 3, 2001 based upon allegations that CryoLife violated FDA regulations in its handling of such tissue and alleged contamination through CryoLife's processing of such tissue that resulted in 14 post-transplant infections including one death. A significant portion of CryoLife's current revenues is derived from the preservation of human tissues. Revenues from human tissue preservation services for the six months ended June 30, 2002, the last period ending prior to the issuance of the FDA Order, were 78% of CryoLife's revenues, or approximately $37.8 million. During the third quarter of 2004, these revenues were approximately $7.0 million or 43% of third quarter revenues.

The FDA Order, subsequent FDA activity and resulting adverse publicity have had a material adverse effect on CryoLife's business, financial condition, results of operations and cash flows. CryoLife has experienced decreases in revenues and incurred losses and there is a possibility that CryoLife may not generate sufficient cash from operations to fund its operations over the long-term.

CryoLife has continued to experience a reduced demand for its tissues due to the adverse publicity generated from the recall and from decisions by implanting physicians' or risk managers at implanting institutions to use human tissue services provided by CryoLife's competitors. In addition, as a result of the FDA Order, subsequent FDA activity, and changes in CryoLife's processing, the costs of such processing have increased and are likely to remain high as compared to cost levels prior to the FDA Order. Although they have decreased somewhat beginning the second quarter of 2004, these high costs could have a material adverse effect on CryoLife's business, results of operations and financial position and may continue to do so.

The success of CryoLife's tissue preservation services depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. Any material reduction in the supply of donated human tissue could restrict CryoLife's growth. CryoLife relies primarily upon the efforts of third party procurement agencies and tissue banks (most of which are not-for-profit) and others to educate the public and foster a willingness to donate tissue. Because of the adverse publicity associated with the FDA Order and subsequent FDA activity and uncertainty regarding future tissue processing, some procurement agencies stopped sending tissue to CryoLife for processing. If CryoLife's relationships with procurement agencies continue to be adversely affected or CryoLife is unable to obtain tissues from procurement agencies that have ceased sending tissue to CryoLife for processing, CryoLife may be unable to obtain adequate supplies of donated tissues to operate profitably.

REVENUE FROM ORTHOPAEDIC TISSUE PRESERVATION SERVICES IS MINIMAL AND MAY NOT RETURN

We have received only minimal revenue from the preservation of orthopaedic

tissue since August 14, 2002. For the year ended December 31, 2001, human tissue preservation services revenues for orthopaedic tissue were $22.5 million, which



represented 26% of CryoLife's revenues. For the six months ended June 30, 2002, (the last period ending prior to the FDA Order) revenues for preservation services for orthopaedic tissue were $11.5 million which represented 24% of CryoLife's revenues. For the year ended December 31, 2003, revenues from preservation services for orthopaedic tissue were $1.1 million, which represented 2% of CryoLife's revenues. For the nine months ended September 30, 2004, they were $1.7 million, or 4% of revenues.

The demand for orthopaedic tissue from CryoLife may not return to the levels in existence before the FDA Order, even though CryoLife has resumed processing. As a result, this portion of CryoLife's business may be discontinued or may only continue at substantially reduced levels. Either of these results would result in a continued significant decrease in CryoLife's preservation services revenues and have an adverse impact on its ability to return to profitability.

PHYSICIANS MAY BE RELUCTANT TO IMPLANT CRYOLIFE'S PRESERVED TISSUES

Some physicians or implanting institutions have been reluctant to choose CryoLife's preserved tissues for use in implantation, due to a perception that they may not be safe or to a belief that the implanting physician or hospital may be subject to a heightened liability risk if CryoLife's tissues are used. In addition, for similar reasons, hospital risk managers may forbid implanting surgeons to utilize CryoLife's tissues where alternatives are available. Several risk managers and physicians have refused to use our products due to these concerns. If additional implanting hospitals or physicians representing significant revenues refuse to use tissues preserved by us, and we are unable to replace the revenues lost, our preservation services revenues and profits would be materially adversely affected.

PRODUCTS AND SERVICES NOT INCLUDED IN THE FDA RECALL MAY COME UNDER INCREASED FDA SCRUTINY

Although CryoLife's heart valve tissues, BioGlue Surgical Adhesive and bioprosthetic devices were not included in the FDA recall, the processing and manufacturing facilities for these products may come under increased scrutiny from the FDA. A negative review from the FDA of these processing and manufacturing facilities could have a material adverse effect on CryoLife's business, results of operations and financial position.

ADVERSE PUBLICITY MAY REDUCE DEMAND FOR PRODUCTS AND SERVICES NOT AFFECTED BY THE FDA RECALL

Even though CryoLife's heart valve tissues, BioGlue Surgical Adhesive and bioprosthetic devices were not included in the FDA Order, there is a possibility that surgeons or risk managers at institutions that use such products may be reluctant to use such products because of the adverse publicity associated with the FDA Order. Decreased demand for such products, particularly BioGlue, could have a material adverse effect on CryoLife's business, results of operations and financial position.

WE MAY BE UNABLE TO ADDRESS THE CONCERNS RAISED BY THE FDA IN ITS FORM 483 NOTICES OF OBSERVATIONS

The FDA issued new Form 483 Notices of Observations in February and October

2003, and another in February 2004. If CryoLife's responses to the FDA's observations contained in these notices, or any future notices, are deemed unsatisfactory, the FDA could take further action, which could have a material adverse effect on the Company's business, results of operations, financial position or cashflows. Further action by the FDA could include additional recalls of products, requiring us to do additional testing, beginning to require prescriptions for products where they are not currently required, halting the shipping or processing of products, or requiring additional approvals for marketing our products or services.

THE FDA HAS NOTIFIED CRYOLIFE OF ITS BELIEF THAT MARKETING OF CRYOVALVE SG AND CRYOVEIN SG REQUIRE ADDITIONAL REGULATORY SUBMISSIONS AND/OR APPROVALS

During 2003, FDA notified CryoLife that the application of the SynerGraft technology to allograft heart valves (CryoValve SG), currently regulated as Class II medical devices, was considered to be a major manufacturing change requiring a 510(k) submission. CryoLife submitted a 510(k) for CryoValve SG and has received two requests for additional information from FDA. While most of the requested information has been provided, CryoLife is seeking to resolve certain



other requests, involving bench-testing and additional clinical trials, through administrative procedures at the FDA. There can be no assurance that the FDA will agree with CryoLife or that CryoValve SG 510(k) will be cleared in the foreseeable future.

FDA has also determined that non-valved cardiovascular tissues processed using CryoLife's SynerGraft technology should be regulated as medical devices and will require additional premarket approval authorization for continued distribution of these tissues. CryoLife appealed the designation of SynerGraft-processed cardiovascular tissue as medical devices. Discussions with the FDA to resolve this issue are ongoing. There can be no assurance that the designation of SynerGraft cardiovascular tissue will be resolved favorably.

REGULATORY ACTION OUTSIDE OF THE U.S. MAY ALSO AFFECT CRYOLIFE'S BUSINESS

After the issuance of the FDA Order, Health Canada also issued a recall on the same types of tissue. In addition, other countries have inquired as to the tissues exported by the Company, although these inquiries are now, to CryoLife's knowledge, complete. In the event additional regulatory concerns are raised by other countries, CryoLife may be unable to export tissues to those countries. Revenue from international human tissue preservation services was $721,000 for the year ended December 31, 2003 and $363,000 for the nine months ended September 30, 2004.

CRYOLIFE IS THE SUBJECT OF AN ONGOING SEC INVESTIGATION

As previously disclosed, there is an ongoing SEC investigation. CryoLife has cooperated with this investigation both before and after issuance of the formal order of investigation in June 2003, and intends to continue doing so. CryoLife voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife shares on August 14, 2002, before trading was halted pending CryoLife's press release reporting the FDA Order. These individuals were not and are not executive officers of CryoLife. The formal order of investigation indicates that the SEC's scope includes whether, during 2002, among other things, CryoLife or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate

controls. The investigation could also encompass matters not specifically identified in the formal order. As of the date hereof, the SEC has had no discussions with CryoLife representatives as to whether or against whom it will seek relief, or the nature of any relief that may be sought. At present, CryoLife is unable to predict the ultimate focus or outcome of the investigation, or when it will be completed. An unfavorable outcome could have a material adverse effect on CryoLife's reputation, business, financial position, results of operations, and cash flows.

CRYOLIFE'S INSURANCE COVERAGE MAY BE INSUFFICIENT

Product Liability Claims

In the normal course of business as a medical device and services company, CryoLife has product liability complaints filed against it. Following the FDA Order, products liability lawsuits increased to unprecedented numbers for CryoLife. CryoLife maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period.

For the 2000/2001 and 2001/2002 insurance policy years, CryoLife maintained claims-made insurance policies, which CryoLife believes to be adequate to defend against the suits filed during this period. For the 2002/2003 insurance policy year, CryoLife maintained claims-made insurance policies with three carriers. CryoLife used all of its insurance coverage, aggregating $25.0 million, for the 2002/2003 insurance policy year, as well as funds of its own, to resolve claims outstanding in the relevant policy period. CryoLife continues to attempt to resolve the remaining litigation.



CryoLife's September 30, 2004, consolidated balance sheet reflects a liability for the estimated cost of resolving these claims. The amounts recorded were estimates, and do not reflect actual settlement arrangements or final judgments, the latter of which could include punitive damages, nor do they represent cash set aside for the purpose of making payments. CryoLife's September 30, 2004 consolidated balance sheet also reflects an $8.4 million liability, included as a component of accrued expenses and other current liabilities, for the estimated cost of resolving unreported product liability claims. CryoLife's product liability insurance policies do not include coverage for any punitive damages.

If CryoLife is unsuccessful in arranging acceptable settlements of product liability claims, there may not be sufficient insurance coverage and liquid assets to meet these obligations. Additionally, if one or more of the product liability claims in which CryoLife is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed CryoLife's available insurance coverage and liquid assets. If CryoLife is unable to meet required future cash payments to resolve the outstanding product liability claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of CryoLife.

Class Action Lawsuit

Several putative class action lawsuits were filed in July through September

2002 against CryoLife and certain officers of CryoLife, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that CryoLife made misrepresentations and omissions relating to product safety and CryoLife's alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. CryoLife and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the United States District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003, the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. At present, the case remains in the expert discovery phase. Although CryoLife carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment in excess of CryoLife's available insurance coverage could have a material adverse effect on CryoLife's financial position, results of operations, and cash flows. At this time, CryoLife is unable to predict the outcome of this litigation.

Shareholder Derivative Action

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names CryoLife as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to CryoLife by causing or allowing CryoLife to engage in certain inappropriate practices that caused CryoLife to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that CryoLife's Board of Directors take certain actions in response to her allegations. On January 16, 2003 another purported derivative suit alleging claims similar to those of the Lichtenberger suit was filed in the Superior Court of Fulton County by complainant Robert F. Frailey. As in the Lichtenberger suit, the filing of the complaint in the Frailey action was preceded by a demand letter sent on Frailey's behalf to CryoLife's Board of Directors. Both complaints seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of CryoLife. As previously disclosed, CryoLife's Board of Directors has established an independent committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel evaluated the consolidated amended complaint, and concluded that its prior report and



determination addressed the material allegations contained in the consolidated amended complaint. Based on the report of the independent committee, the Company moved to dismiss the derivative action in May 2004. In an order dated December 1, 2004, the Court denied the motion to dismiss. The case will proceed into the discovery phase. The committee reiterated its previous conclusions and

determinations, including that maintaining the derivative litigation is not in the best interests of CryoLife. At this time, CryoLife is unable to predict the outcome of this litigation.

INSURANCE COVERAGE MAY BE DIFFICULT OR IMPOSSIBLE TO OBTAIN IN THE FUTURE AND IF OBTAINED, THE COST OF INSURANCE COVERAGE IS LIKELY TO BE MUCH MORE EXPENSIVE THAN IN THE PAST

Due in part to the current litigation, the FDA Order and subsequent FDA activity, CryoLife may be unable to obtain satisfactory insurance coverage in the future, causing CryoLife to be subject to additional future exposure from product liability claims. Additionally, if insurance coverage is obtained, the insurance rates may be significantly higher than in the past, and may provide less coverage, which may adversely impact CryoLife's profitability. For example, CryoLife paid a higher fee for its 2003/2004 policy year products liability insurance coverage, which also had a higher retention level and a lower overall limit. Unlike the prior year's policy, the 2003/2004 policy did not cover any claims which arose prior to the insurance policy year. The 2004/2005 policy is a two-year claims-made policy, covering claims arising since the commencement of the 2003/2004 policy year.

INTENSE COMPETITION MAY AFFECT CRYOLIFE'S ABILITY TO RECOVER FROM THE FDA ORDER

CryoLife faces competition from other companies that process human tissue, as well as companies that market mechanical valves and synthetic and animal tissue for implantation and companies that market surgical adhesives and surgical sealants. Management believes that at least four tissue banks offer preservation services for allograft heart valves and many companies offer processed porcine heart valves and mechanical heart valves. A few companies dominate portions of the mechanical, porcine and bovine heart valve markets, including St. Jude Medical, Inc., Medtronic, Inc. and Edwards Life Sciences. CryoLife is aware that a few companies have surgical adhesive products under development. Competitive products may also be under development by other large medical device, pharmaceutical and biopharmaceutical companies. Many of CryoLife's competitors have greater financial, technical, manufacturing and marketing resources than CryoLife and are well established in their markets. CryoLife plans to increase fees and prices on a number of its services and products during the first quarter of 2005. The increase may provide an opportunity for CryoLife's competitors to gain market share. If the Company is unable to increase prices as planned and retain or improve its market share, its revenue and return to profitability may be adversely affected.

We believe that our cryopreserved tissues compete favorably with other entities that cryopreserve human tissue on the basis of technology, customer service, and quality assurance. As a result of the decrease in CryoLife's procurement and processing yields of human tissue since the FDA Order in 2002, the decrease in cardiovascular, vascular, and orthopaedic tissue shipments, and the lack of orthopaedic tissue shipments for a period of time, our competitors have been favorably impacted and CryoLife believes it has lost some market share. As compared to mechanical, porcine, and bovine heart valves, we believe that the human heart valves cryopreserved by CryoLife compete on the factors set forth above, as well as by providing a tissue that is the preferred replacement alternative with respect to certain medical conditions, such as pediatric cardiac reconstruction, valve replacements for women in their child-bearing years, and valve replacements for patients with endocarditis. Additionally, although fees charged for human tissue cryopreserved by CryoLife are initially higher than fees charged for mechanical alternatives, these alternatives typically require that the patient take anti-coagulation drug therapy for the lifetime of the implant. As a result of the costs associated with anti-coagulants, mechanical valves are generally, over the life of the implant, more expensive than tissue cryopreserved by CryoLife. However, management believes that, to date, price has not been a significant competitive factor.

CryoLife's BioGlue product competes with other surgical adhesives and surgical sealants, including Baxter Healthcare's Tisseel, FloSeal and CoSeal products. Competitive products may also be under development by other large medical device, pharmaceutical, and biopharmaceutical companies. CryoLife believes its BioGlue product competes favorably because of its inherent sealing capabilities, high tensile strength and ease of use.

There can be no assurance that CryoLife's products and services will be able to compete successfully with the products of these or other companies. Any products developed by CryoLife that gain regulatory clearance or approval would have to compete for market acceptance and market share. Failure of CryoLife to



compete effectively could have a material adverse effect on CryoLife's business, financial condition, results of operations and cash flows. The FDA Order and related adverse publicity had an adverse effect on CryoLife's competitive position, which had a material adverse effect on CryoLife's results of operations. The FDA Order and subsequent FDA activity may continue to have an adverse effect on CryoLife's competitive position, which may continue to have a material adverse effect on CryoLife's results of operations. As a result, CryoLife's competitors may gain competitive advantages that may be difficult to overcome.

CRYOLIFE MAY NOT BE SUCCESSFUL IN OBTAINING NECESSARY CLINICAL RESULTS AND REGULATORY APPROVALS FOR PRODUCTS AND SERVICES IN DEVELOPMENT, AND SUCH PRODUCTS AND SERVICES MAY NOT ACHIEVE MARKET ACCEPTANCE

CryoLife's growth and profitability will depend, in part, upon its ability to complete development of and successfully introduce new products and services, including new applications of its BioGlue and related technology and applications applying its SynerGraft technology. Developing new products and services to a commercially acceptable form is uncertain, and obtaining required regulatory approval is time consuming and costly.

Although CryoLife has conducted pre-clinical studies on its products under development which indicate that such products may be effective in a particular application, there can be no assurance that the results obtained from expanded clinical studies will be consistent with earlier trial results or be sufficient for CryoLife to obtain any required regulatory approvals or clearances. There can be no assurance that CryoLife will not experience difficulties that could delay or prevent the successful development, introduction and marketing of new products, that regulatory clearance or approval of these or any new products will be granted on a timely basis, if ever, or that the new products will adequately meet the requirements of the applicable market or achieve market acceptance.

The completion of the development of any of CryoLife's products remains subject to all of the risks associated with the commercialization of new products based on innovative technologies, including unanticipated technical or other problems, manufacturing difficulties and the possible insufficiency of the funds allocated for the completion of such development. Consequently, CryoLife's products under development may not be successfully developed or manufactured or, if developed and manufactured, such products may not meet price or performance objectives, be developed on a timely basis or prove to be as effective as competing products.

The inability to successfully complete the development of a product, application or service, or a determination by CryoLife, for financial, technical

or other reasons, not to complete development of any product, application or service, particularly in instances in which CryoLife has made significant capital expenditures, could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. CryoLife's research and development efforts are time consuming and expensive and there can be no assurance that these efforts will lead to commercially successful products or services. Even the successful commercialization of a new service or product in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity and continuing research and development and education costs. The introduction of new human tissue services or products may require significant physician training and years of clinical evidence derived from follow-up studies on human implant recipients in order to gain acceptance in the medical community.

INVESTMENTS IN NEW TECHNOLOGIES OR DISTRIBUTION RIGHTS MAY NOT BE SUCCESSFUL

CryoLife may invest in new technology licenses or distribution rights that may not succeed in the marketplace. In such cases, CryoLife may be unable to recover its initial investment in the license, distribution right or purchase of initial inventory, which may adversely impact CryoLife's profitability.

FUNDING FOR THE ACT TECHNOLOGY MAY NOT BE AVAILABLE

The ACT (Activation Control Technology) is a reversible linker technology that has potential uses in the areas of cancer therapy, fibrinolysis (blood clot dissolving) and other drug delivery applications. The reversible linker technology joins a drug to another molecule. This link can be reversed by normal hydrolysis or the application of an energy source. If the molecule to which the drug is linked concentrates at the site of a tumor, or if an energy source is



applied at that site, then a drug can be concentrated at the site of a tumor and the link reversed. By concentrating active drug at the site rather than throughout the body there could be a greater opportunity to kill the tumor and minimize harm to the patient. In February 2001 CryoLife formed AuraZyme, a wholly-owned subsidiary, in order to seek a corporate collaboration or to complete a potential private placement of equity or equity-oriented securities to fund the commercial development of the ACT. CryoLife has been seeking such funding since 1998. This strategy is designed to allow CryoLife to continue development of this technology without incurring additional research and development expenditures, other than through AuraZyme. There can be no guarantee that such funding can be obtained on acceptable terms, if at all. If such funding is not obtained, CryoLife may be unable to effectively test and develop the ACT, and may therefore be unable to determine its effectiveness. Even if such financing is obtained, there is no guarantee that the ACT will in fact prove to be effective in the above applications. In addition, any new financing may cause dilution to the ownership interests of current CryoLife shareholders, or may include restrictive covenants that could adversely affect CryoLife or its business.

SYNERGRAFT-TREATED TISSUES MAY NOT DEMONSTRATE EXPECTED BENEFITS

CryoLife processes bovine tissues with the SynerGraft technology and processed human tissues with that technology until February 2003, following the receipt of the informal FDA letter. The process involves antigen reduction, which is the depopulation of the cells of the tissue to be implanted, leaving a matrix of protein fibers that has the potential to be repopulated with the recipient's cells. If successful, we believe that such repopulation may increase graft longevity and improve the biocompatibility and functionality of such

tissue, resulting in the implanted tissue behaving more like the recipient's own tissue. In animal studies, explanted SynerGraft treated allograft heart valves have been shown to repopulate with the hosts' cells. However, should such tissues implanted in humans not consistently and adequately repopulate with the human host cells, the higher priced SynerGraft-treated tissues may not demonstrate benefits over the CryoLife standard processing technology. This could have a material adverse effect on future expansion plans and could limit future growth.

CRYOLIFE IS DEPENDENT ON ITS KEY PERSONNEL

CryoLife's business and future operating results depend in significant part upon the continued contributions of its key technical personnel and senior management, many of who would be difficult to replace. CryoLife'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 operations. Competition for such personnel is intense and there can be no assurance that CryoLife will be successful in attracting and retaining such personnel. CryoLife's key employees include its management team, consisting of Steven G. Anderson, President, Chief Executive Officer, and Chairman; D. Ashley Lee, CPA, Executive Vice President, Chief Operating Officer and Chief Financial Officer; Sidney B. Ashmore, Vice President, Marketing; David M. Fronk, Vice President, Clinical Research; Albert E. Heacox, PhD, Senior Vice President, Research and Development; and Thomas J. Lynch, JD, PhD, Vice President, Regulatory Affairs and Quality Assurance. CryoLife has employment agreements with these key personnel. Mr. Anderson's employment agreement contains a provision providing an evergreen two year term, and provides for payment of $900,000 if his employment is terminated other than for cause, death, disability or by him for good reason. The others expire in August 2005 or September 2005, except for Mr. Lynch's which expires in august 2006. They provide for payments ranging from $240,000 to $360,000 if employment is terminated other than for cause, death, disability or by the employee for good reason. Other than a $1.5 million life insurance policy on Mr. Anderson, CryoLife does not have key life insurance on these individuals. The loss of key employees, the failure of any key employee to perform adequately or CryoLife's inability to attract and retain skilled employees as needed could have a material adverse effect on CryoLife's business, financial condition, results of operations and cash flows.

OUR CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2001 AND INCLUDED IN CRYOLIFE'S 10-K WERE AUDITED BY ARTHUR ANDERSEN LLP, WHICH WAS FOUND GUILTY OF OBSTRUCTION OF JUSTICE AND THE SUBJECT OF ADDITIONAL LITIGATION

Arthur Andersen LLP has been found guilty of obstruction of justice with respect to its activities in connection with Enron Corp. and may be the subject of additional litigation. Arthur Andersen LLP has also ceased practicing before the SEC. Arthur Andersen LLP or any successor in interest may have insufficient assets to satisfy any claims that may be made by investors with respect to the financial statements as of and for the year ending December 31, 2001 included in



CryoLife's Form 10-K for the year ending December 31, 2003 and incorporated into this prospectus.

In addition, Arthur Andersen LLP has not consented to the inclusion of their report dated March 27, 2002 in CryoLife's Form 10-K for the year ending December 31, 2003, and as a result, only a copy of such report has been included. Because Arthur Andersen LLP has not consented to the inclusion of

their report in our Form 10-K for the year ending December 31, 2003 which is incorporated into this prospectus, claimants may not be able to recover against Arthur Andersen LLP for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen LLP or any omissions to state a material fact required to be stated therein.

## RISKS RELATED TO CRYOLIFE AND OUR INDUSTRY

### EXTENSIVE GOVERNMENT REGULATION MAY ADVERSELY AFFECT THE ABILITY TO DEVELOP AND SELL PRODUCTS AND SERVICES

Government regulation in the U.S., the EEA and other jurisdictions can determine the success of CryoLife's efforts to market and develop its services and products and those of its competitors. Allograft heart valves such as those processed by CryoLife are currently regulated as Class II medical devices by the FDA and are subject to significant regulatory requirements, including Quality System Regulations and record keeping requirements. Changes in regulatory treatment or the adoption of new statutory or regulatory requirements are likely to occur, which could adversely impact the marketing or development of these products or could adversely affect market demand for these products. Other allograft tissues processed and distributed by CryoLife are currently regulated as "human tissue" under rules promulgated by the FDA pursuant to the Public Health Services Act. These rules establish requirements for donor testing and screening of human tissue and record keeping relating to these activities and impose certain registration and product listing requirements on establishments that process or distribute human tissue or cellular-based products. The FDA has finalized a regulation that will implement good tissue practices, akin to good manufacturing practices, followed by tissue banks and processors of human tissue. It is anticipated that these good tissue practices regulations when made effective will enhance regulatory oversight of CryoLife and other processors of human tissue.

BioGlue Surgical Adhesive is regulated as a Class III medical device and CryoLife believes that its ACT may be regulated as a biologic or drug by the FDA. The ACT has not been approved for commercial distribution in the U.S. or elsewhere. Fixed porcine heart valve products are classified as Class III medical devices. CryoLife may not obtain the FDA approval required to distribute its porcine heart valve products in the U.S. Distribution of these products within the EC is dependent upon CryoLife maintaining the CE Mark for this product and its ISO 13485 certifications, of which there can be no assurance.

Most of CryoLife's products and services in development and those of CryoLife's competitors if successfully developed, will require regulatory approvals from the FDA and perhaps other regulatory authorities before they may be commercially distributed. The process of obtaining required regulatory approvals from the FDA normally involves clinical trials and the preparation of an extensive premarket approval ("PMA") application and often takes many years. The process is expensive and can vary significantly based on the type, complexity and novelty of the product. There can be no assurance that any products developed by CryoLife or its competitors, independently or in collaboration with others, will receive the required approvals for manufacturing and marketing.

Delays in obtaining U.S. or foreign approvals could result in substantial additional cost and adversely affect a company's competitive position. The FDA may also place conditions on product approvals that could restrict commercial applications of such products. Product marketing approvals or clearances may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Delays imposed by the governmental clearance process may materially reduce the period during which a company such as CryoLife has the exclusive right to commercialize patented products.

Also, delays or rejections may be encountered during any stage of the regulatory approval process based upon the failure of the clinical or other data to demonstrate compliance with, or upon the failure of the product to meet, the regulatory agency's requirements for safety, efficacy and quality, and those requirements may become more stringent due to changes in applicable law,



regulatory agency policy or the adoption of new regulations. Clinical trials may also be delayed due to unanticipated side effects, inability to locate, recruit and qualify sufficient numbers of patients, lack of funding, the inability to locate or recruit clinical investigators, the redesign of clinical trial programs, the inability to manufacture or acquire sufficient quantities of the particular product or any other components required for clinical trials, changes in development focus and disclosure of trial results by competitors.

Even if regulatory approval is obtained for any products or services offered by CryoLife or one of its competitors, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. Products or services marketed pursuant to FDA or foreign oversight or approvals are subject to continuing regulation. In the U.S., devices and biologics must be manufactured in registered establishments (and, in the case of biologics, licensed establishments) and must be produced in accordance with Quality System Regulations. Manufacturing facilities and processes are subject to periodic FDA inspection. 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 applicable FDA requirements, which may be ambiguous, could result in civil and criminal enforcement actions, warnings, citations, product recalls or detentions and other penalties and could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. As noted above, the FDA Order and subsequent FDA activity had, and may continue to have such an effect.

In addition, The National Organ Transplant Act ("NOTA") prohibits the acquisition or transfer of human organs for "valuable consideration" for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, processing, preservation, quality control and storage of human organs. There can be no assurance that restrictive interpretations of NOTA will not be adopted in the future that will challenge one or more aspects of industry methods of charging for preservation services. Laboratory operations of CryoLife and its competitors 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.

More restrictive state laws or regulations may be adopted in the future and they could have a material adverse effect on CryoLife's business, financial condition, results of operations and cash flows.

UNCERTAINTIES RELATED TO PATENTS AND PROTECTION OF PROPRIETARY TECHNOLOGY MAY ADVERSELY AFFECT THE VALUE OF INTELLECTUAL PROPERTY

CryoLife owns several patents, patent applications and licenses relating to its technologies, which it believes provide important competitive advantages. There can be no assurance that CryoLife'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 CryoLife, or, if instituted, that such challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of a patent could be substantial. Furthermore, there can be no assurance that competitors will not independently develop similar technologies or duplicate CryoLife's technologies or design around the patented aspects of CryoLife's technologies. There can be no assurance that CryoLife's proposed technologies will not infringe patents or other rights owned by others.

In addition, under certain of CryoLife's license agreements, if CryoLife fails to meet certain contractual obligations, including the payment of minimum royalty amounts, such licenses may become nonexclusive or terminable by the licensor, which could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows. Additionally, CryoLife protects its proprietary technologies and processes in part by confidentiality agreements with its collaborative partners, employees and consultants. There can be no assurance that these agreements will not be breached, that CryoLife will have adequate remedies for any breach or that CryoLife's trade secrets will not otherwise become known or independently discovered by competitors, any of which could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows.



UNCERTAINTIES REGARDING FUTURE HEALTH CARE REIMBURSEMENT MAY AFFECT THE AMOUNT AND TIMING OF REVENUES

Even though CryoLife does not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand for CryoLife's cryopreserved tissue and other services and products. CryoLife's preservation services with respect to its cardiac, vascular, and orthopaedic tissues may be particularly susceptible to third-party cost containment measures. For example, the initial cost of a cryopreserved allograft heart valve generally exceeds the cost of a mechanical, synthetic or animal-derived valve. CryoLife is unable to predict what changes will be made in the reimbursement methods and policies utilized by third-party health care payors or their effect on CryoLife.

Changes in the reimbursement methods and policies utilized by third-party health care payors, including Medicare, with respect to cryopreserved tissues provided for implant by CryoLife and other Company services and products, could have a material adverse effect on CryoLife. 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 CryoLife to maintain price levels sufficient for realization of an appropriate return on its investment in developing new products.

Government, hospitals, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products approved for marketing by the FDA and by refusing in some cases to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval. If adequate coverage and reimbursement levels are not provided by government and other third-party payors for uses of CryoLife's new products and services, market acceptance of these products would be adversely affected, which could have a material adverse effect on CryoLife's business, financial condition, results of operations and cash flows.

RAPID TECHNOLOGICAL CHANGE COULD CAUSE SERVICES AND PRODUCTS TO BECOME OBSOLETE

The technologies underlying products and services offered by CryoLife and its competitors are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. There can be no assurance that others will not develop products or processes with significant advantages over the products and processes that CryoLife or a competitor offers or is seeking to develop. Any such occurrence could have a material adverse effect on the business, financial condition, results of operations, and cash flows of CryoLife or its competitors.

RISKS RELATED TO CRYOLIFE'S CAPITAL STOCK

SECURITIES PRICES FOR CRYOLIFE SHARES HAVE BEEN, AND MAY CONTINUE TO BE, VOLATILE

The trading price of CryoLife's common stock has been subject to wide fluctuations and may continue to be volatile in the future. Trading price fluctuations can be caused by a variety of factors, including regulatory actions such as the FDA Order, recent product liability claims, variations in operating results, announcement of technological innovations or new products by CryoLife or its competitors, governmental regulatory acts, developments with respect to patents or proprietary rights, general conditions in the medical device or service industries, actions taken by government regulators, changes in earnings estimates by securities analysts or other events or factors, many of which are beyond CryoLife's control. If CryoLife's revenues or operating results in future quarters fall below the expectations of securities analysts and investors, the price of CryoLife's common stock would likely decline further, perhaps substantially. Changes in the trading price of CryoLife's common stock may bear no relation to CryoLife's actual operational or financial results. If CryoLife's share prices do not meet the requirements of the New York Stock Exchange, CryoLife's shares may be delisted. CryoLife's closing stock price in the period January 1, 2002 to December 16, 2004 has ranged from a high of $31.31 to a low of $1.89.



ANTI-TAKEOVER PROVISIONS MAY DISCOURAGE OR MAKE MORE DIFFICULT AN ATTEMPT TO OBTAIN CONTROL OF CRYOLIFE

CryoLife's Articles of Incorporation and Bylaws contain provisions that may discourage or make more difficult any attempt by a person or group to obtain control of CryoLife, 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, CryoLife is subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of CryoLife's common stock. Further, pursuant to the terms of a shareholder rights plan adopted in 1995, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire CryoLife on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. These provisions could potentially deprive our stockholders of opportunities to sell shares of our stock at above-market prices. Please read "Description of Capital Stock-Anti-Takeover Provisions."

COMMON STOCK DIVIDENDS ARE NOT LIKELY TO BE PAID IN THE FORESEEABLE FUTURE

CryoLife has not paid, and does not presently intend to pay, cash dividends

on our common stock. Future credit agreements may contain financial covenants, including covenants to maintain certain levels of net worth and certain leverage ratios, which could have the effect of restricting the amount of dividends that CryoLife may pay on its common stock. It is not likely that any cash dividends on its common stock will be paid in the foreseeable future.

WE MAY NOT BE ABLE TO PAY CASH DIVIDENDS ON OUR CAPITAL STOCK

Under Florida law, no distibutions may be paid on capital stock, if after giving it effect: (a) the corporation would not be able to pay its debts as they become due in the usual course of business; or (b) the corporation's total assets would be less than the sum of its total liabilities plus (unless the articles of incorporation permit otherwise) the amount that would be needed, if the corporation were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of shareholders whose preferential rights are superior to those receiving the distribution. Unless we return to profitably, our ability to pay cash dividends on our capital stock requires the availability of adequate net assets. Further, even if adequate net assets are available to pay cash dividends on the common stock (if declared) and preferred stock, we may not have sufficient liquidity to pay dividends on our preferred stock or common stock, as the case may be.



## FORWARD LOOKING STATEMENTS

This prospectus includes and incorporates by reference "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. Forward-looking statements give our current expectations or forecasts of future events. The words "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future" and other similar expressions generally identify forward-looking statements, including, in particular, statements regarding future services, market expansion, revenues, cost savings, regulatory activity, available funds and capital resources, and pending litigation. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates. Such forward-looking statements reflect the views of our management at the time such statements are made and are subject to a number of risks, uncertainties, estimates and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under "Risk Factors" and elsewhere in this prospectus.

All statements, other than statements of historical facts, included herein that address activities, events or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

- adequacy of product liability insurance to defend against lawsuits;
- the outcome of lawsuits filed against the Company, and of the SEC investigation;
- the impact of the FDA Order and subsequent FDA activity, including the FDA's letters regarding the SynerGraft process and measures taken by

the Company as a result, on future revenues, profits and business operations;

- the effect of the FDA Order and subsequent FDA activity on sales of BioGlue;
- the impact of the FDA's Form 483 Notices of Observation;
- the estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies, as well as the estimates of the amounts accrued for product loss claims incurred but not reported;
- future costs of human tissue preservation services, including the Company's ability to reduce its costs of tissue preservation services;
- the Company's competitive position, including the impact of price increases;
- product demand and market growth;
- the potential of the ACT for use in cancer therapies, fibrinolysis (blood clot dissolving), and other drug delivery applications;
- the impact on the Company of adverse results of surgery utilizing tissue processed by it; and
- other statements regarding future plans and strategies, anticipated events or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including the risk factors discussed in this prospectus and other factors, many of which are beyond the



control of CryoLife. Consequently, all of the forward-looking statements made in this prospectus are qualified by these cautionary statements and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

## USE OF PROCEEDS

Except as may otherwise be described in an accompanying prospectus supplement, the net proceeds from the sale of the securities offered pursuant to this prospectus and any accompanying prospectus supplement will be used for general corporate purposes. Any specific allocation of the net proceeds of an offering of securities to a specific purpose will be determined at the time of the offering and will be described in an accompanying prospectus supplement.

RATIO OF EARNINGS TO FIXED CHARGES

For purposes of determining the ratio of earnings to combined fixed charges and preferred dividends, earnings are defined as net income (loss) before income taxes, extraordinary items, amortization of capitalized interest and fixed charges, less capitalized interest. Fixed charges consist of interest (whether expensed or capitalized), amortization of debt expenses and discount or premium relating to any indebtedness and the portion of rental expense determined to be representative of the interest factor. For this purpose, we assumed one-third of rental expense should be included in fixed charges.

| | YEAR ENDED DECEMBER 31, | | | |
|---|---|---|---|---|
| | 1999 | 2000 | 2001 | 2002 |
| | (DOLLARS IN THOUSANDS) | | | |
| Ratio of earnings to fixed charges..... | 8.53 | 16.53 | 8.81 | (a) |
| Deficiency of earnings to fixed charges and preferred stock dividends..... | $ N/A | $ N/A | $ N/A | $(41,376) |

(a) Earnings for this period were insufficient to cover fixed charges.



DESCRIPTION OF CAPITAL STOCK

DESCRIPTION OF CAPITAL STOCK

The Company is authorized to issue up to 75,000,000 shares of Common Stock, $.01 par value, and 5,000,000 shares of Preferred Stock, $.01 par value. As of December 17, 2004, there were 23,415,175 shares of Common Stock outstanding net of 1,388,432 treasury shares. They were held by approximately 572 shareholders of record and no shares of Preferred Stock outstanding.

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

COMMON STOCK

Holders of Common Stock are entitled to one vote per share of Common Stock held of record on all matters to be voted upon by the Company's shareholders generally. Holders of Common Stock are not entitled to cumulative voting rights. As a result, the holders of a majority of the shares of Common Stock voting for the election of directors may elect all of the Company's directors if they choose to do so, and, in such event, the holders of the remaining shares of Common Stock will not be able to elect any person or persons to the Board of Directors. See "Selling Shareholders."

Holders of Common Stock are entitled to receive, on a pro rata basis, such dividends and distributions, if any, as may be declared from time to time by the

Board of Directors out of funds legally available therefor, subject to any preferential dividend right of any issued and outstanding shares of Preferred Stock. In the event of liquidation, dissolution or winding up of the Company, after payment of creditors, holders of Common Stock are entitled to share ratably in all assets, subject to the payment of any liquidation preference of any issued and outstanding shares of Preferred Stock. The shares of Common Stock currently outstanding are validly issued, fully paid and non-assessable.

PREFERRED STOCK

The Board of Directors of the Company is empowered, without approval of the Company's shareholders, to cause shares of Preferred Stock (the "Preferred Stock") to be issued in one or more series and to fix and determine the relative rights and preferences of the shares of any such series, subject to the limits of Florida law. Because the Board of Directors has the power to establish the preferences and rights of each series, it may afford the holders of any series of Preferred Stock preferences, powers and rights, voting or otherwise, senior to the rights of holders of Common Stock. The issuance of Preferred Stock could have the effect of delaying or preventing a change in control of CryoLife.

While providing desirable flexibility for possible acquisitions and other corporate purposes, and eliminating delays associated with a shareholder vote on specific issuances, the issuance of preferred stock could adversely affect the voting power of holders of common stock, as well as dividend and liquidation payments on both common and preferred stock. It also could have the effect of delaying, deferring or preventing a change in control.

The prospectus supplement relating to an offering of preferred stock will specify the terms of any series of preferred stock offered by it including:

- the series, the number of shares offered and the liquidation value of the preferred stock;
- the price at which the preferred stock will be issued;
- the dividend rate, the dates on which the dividends will be payable and other terms relating to the payment of dividends on the preferred stock;
- the liquidation preference of the preferred stock;



- whether the preferred stock is redeemable or subject to a sinking fund, and the terms of any such redemption or sinking fund;
- whether the preferred stock is convertible into or exchangeable for any other securities, and the terms of any such conversion or exchange; and
- any additional rights, preferences, qualifications, limitations or restrictions of the preferred stock.

The description of the terms of the preferred stock to be set forth in an applicable prospectus supplement will not be complete and will be subject to and qualified in its entirety by reference to the statement of resolution relating to the applicable series of preferred stock. The registration statement of which this prospectus forms a part will include the statement of resolution as an exhibit or incorporate it by reference.

STOCK OPTIONS AND RESTRICTED STOCK AWARDS

As of December 17, 2004, the Company had issued and outstanding options to purchase an aggregate of 2,308,755 shares of Common Stock (net of forfeitures, expirations and cancellations) pursuant to its Stock Option Plans, at exercise prices between $2.20 and $31.99. Of such options, approximately 1,269,837 were exercisable as of December 17, 2004.

On November 2, 2004, the Compensation Committee granted 55,000 shares of restricted stock to senior management. Of these, 20,000 shares vested immediately. The remainder vest 1/12 each month, commencing December 1, 2004. If a recipient of an award leaves the employ of the Company before an award is fully vested, the unvested shares are forfeited.

ARTICLES OF INCORPORATION AND BYLAWS

Certain provisions of the Articles of Incorporation and Bylaws of the Company, which are summarized below, could have the effect of making it more difficult to change the composition of the Company's Board of Directors or for any person or entity to acquire control of the Company.

SPECIAL MEETINGS

Pursuant to the Company's Articles of Incorporation and Bylaws, special meetings of the shareholders may be called only by the President or Secretary at the request in writing of a majority of the Board of Directors then in office or at the request in writing of shareholders owning not less than 50% of all votes entitled to be cast at the special meeting.

PROHIBITION OF SHAREHOLDER ACTION WITHOUT MEETING

Under the Company's Articles of Incorporation, the shareholders may not take action by written consent. Any and all action by the shareholders is required to be taken at the annual shareholders' meeting or at a special shareholders' meeting. See "Risk Factors--Anti-Takeover Provisions."

ANTI-TAKEOVER STATUTES

The Company is subject to several anti-takeover provisions of the FBCA that apply to a public corporation organized under Florida law unless the corporation has elected to opt out of such provision in its Articles of Incorporation or (depending on the provision in question) its Bylaws. The Company has not elected to opt out of these provisions. The Common Stock of the Company is subject to the "affiliated transaction" and "control-share acquisition" provisions of the FBCA, which are Sections 607.0901 and 607.0902, respectively. These provisions provide that, subject to certain exceptions, an "affiliated transaction" must be approved by the holders of two-thirds of the voting shares other than those beneficially owned by an "interested shareholder" and that "control shares" acquired in specified shareholders, excluding holders of shares defined as "interested shares." These provisions of the FBCA may have the effect of making it more difficult for any person or group to acquire the Company or substantial amounts of the Company's Common Stock. See "Risk Factors--Anti-Takeover Provisions."



ABILITY TO CONSIDER OTHER CONSTITUENCIES

The Directors of the Company are subject to the "general standards for

Directors" provisions set forth in Section 607.0830 of the FBCA. These provisions provide that, among other things, in discharging his or her duties and determining what is in the best interests of the Company, a Director may consider such factors as the Director deems relevant, including the long-term prospects and interests of the Company and its shareholders, and the social, economic, legal or other effects of any proposed action on the employees, suppliers or customers of the Company, the communities in which the Company operates and the economy in general. Consequently, in connection with any proposed corporate action, the Board of Directors is empowered to consider interests of other constituencies in addition to the interests of the Company's shareholders. Shareholders should be aware that Directors who take into account these other factors may make decisions which are less beneficial to the shareholders than if the law did not permit consideration of such other factors.

SHAREHOLDER RIGHTS PLAN

In November 1995, the Board of Directors of the Company established a rights plan, pursuant to which one preferred share purchase right (a "Right") is attached to each outstanding share of Common Stock. The description and terms of the Rights are set forth in a Rights Agreement dated as of November 27, 1995, between the Company and Chemical Mellon Shareholder Services, the original "Rights Agent." The agreement was amended effective June 1, 1997, when the Company's Board appointed American Stock Transfer and Trust Company successor Rights Agent.

Each Right currently entitles the registered holder, upon a "Distribution Date" (defined below), to purchase from the Company .0333 of a share of Series A Junior Participating Preferred Stock, par value $.01 per share (the "Preferred Stock") for $100.00, subject to adjustment as described below. In addition, if any person or group of affiliated or associated persons becomes an Acquiring Person (defined below), each Right, other than Rights beneficially owned by the Acquiring Person (which will thereafter be void), will thereafter entitle its holder to receive upon exercise (in lieu of Preferred Stock) a number of shares of Company Common Stock having a market value of two times the exercise price of the Right. After accounting for the Company's 1996 and 2000 stock splits, the exercise price would be $33.33, subject to further adjustment upon certain events.

Currently, each Right is non-exercisable and is evidenced only by the certificate of Common Stock to which it is attached. The Rights will not be exercisable and will not be evidenced by separate certificates ("Right Certificates") until the Distribution Date. Certificates will be issued upon the "Distribution Date," which will occur on the earlier of:

- 10 days following a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired beneficial ownership of 15% or more of the outstanding Common Stock; or

- 10 business days following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would cause the offeror to become an Acquiring Person (except that the Board of Directors may extend the 10-business-day period before a person or group becomes an Acquiring Person).

Until the Distribution Date (or earlier redemption or expiration of the Rights), the Rights are transferable only with the Common Stock. During this period, newly issued Common Stock certificates contain a legend that evidences the Right, and transfer of any certificate for Common Stock also constitutes the transfer of the Rights associated with the Common Stock represented by such certificate.

Upon the Distribution Date, Right Certificates will be mailed to holders of record of the Common Stock as of the close of business on the Distribution Date. From that date, all Rights will be evidenced by Right Certificates and generally exercisable. The Rights will expire on November 27, 2005 (the "Expiration Date"), unless the Expiration Date is extended or unless the Rights are earlier redeemed or exchanged by the Company.



The Purchase Price payable and the number of shares of Preferred Stock or other securities or property issuable upon exercise of the Rights are subject to adjustment from time to time (to prevent dilution) upon any of the following events:

- a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Stock;
- the grant to holders of the Preferred Stock of certain rights or warrants to subscribe for or purchase Preferred Stock at a price, or securities convertible into Preferred Stock with a conversion price less than the then-current market price of the Preferred Stock; or
- upon the distribution to holders of the Preferred Stock of evidences of indebtedness or assets (excluding regular periodic cash dividends paid out of earnings or retained earnings or dividends payable in Preferred Stock) or of subscription rights or warrants (other than those referred to above).

With certain exceptions, no adjustment in the Purchase Price will be required until cumulative adjustments require an adjustment of at least 1% in such Purchase Price.

The number of outstanding Rights and the number of shares of Preferred Stock issuable upon exercise of each Right (presently .0333 of a share) are also subject to adjustment in the event of:

- a stock split of the Common Stock;
- a stock dividend on the Common Stock payable in Common Stock; or
- subdivision, consolidation or combination of the Common Stock.

Such adjustments are made only if the triggering event occurs before the Distribution Date. Such an adjustment was made following the Company's 1996 and 2000 stock splits. Currently, there is one Right attached to each share of Common Stock, and each Right entitles its holder, after the Rights become exercisable, to purchase .0333 of a share of Preferred Stock. The exercise price payable to acquire Common Stock is also subject to adjustment. Currently, each Right entitles its holder to purchase, after the Rights become exercisable, $66.66 worth of Common Stock for $33.33.

Shares of Preferred Stock will not be redeemable. The Preferred Stock will be entitled to a preferential quarterly dividend equal to the greater of $.10 per share and (after adjustment for the stock splits) approximately 3.33 times the dividend declared per share of Common Stock. In the event of liquidation, any holders of the Preferred Stock will be entitled to a preferential liquidation payment equal to the greater of $10.00 per share and approximately 3.33 times the payment made per share of Common Stock. Each share of Preferred Stock will be entitled to one vote, voting together with the Common Stock. In

the event of any merger, consolidation or other transaction in which Common Stock is exchanged, Preferred Stock will be entitled to receive approximately 3.33 times the amount received per share of Common Stock.

Based on the terms of the Preferred Stock, including its dividend, liquidation and voting rights, the value of .0333 of a share of Preferred Stock (before stock splits or other adjustments) purchasable upon exercise of each Right should approximate the value of one share of Common Stock.

If the Company is acquired in a merger or other business combination transaction, or if 50% or more of its consolidated assets or earning power is sold after a person or group has become an "Acquiring Person," proper provision will be made so that each holder of a Right, other than Rights beneficially owned by the Acquiring Person (which will thereafter be void), will thereafter have the right to receive, upon the exercise thereof at the then current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right.

At any time after any person or group becomes an Acquiring Person and prior to the acquisition by such person or group of 50% or more of the outstanding Common Stock of the Company, the Board of Directors of the Company may exchange



the Rights (other than Rights owned by such person or group which will have become void), in whole or in part, at an exchange ratio of one share of Common Stock per Right.

The Company is not obligated to issue fractional shares of Preferred Stock (other than fractions which are integral multiples of one one-tenth of a Preferred Share). If the Company issues fractional shares of Preferred Stock, it may issue depositary receipts to represent such fractional shares. The Company may also provide in lieu of fractional shares an amount of cash based on the market price of the Preferred Stock on the last trading day prior to the date of exercise.

At any time prior to the acquisition by a person or group of affiliated or associated persons of beneficial ownership of 15% or more of the outstanding Common Stock, the Board of Directors of the Company may redeem the Rights in whole, but not in part. The "Redemption Price," after adjustment for the Company's stock splits, is approximately $.00033 per Right, subject to further adjustment for future stock splits, stock dividends and similar transactions. The redemption of the Rights may be made effective at such time, on such basis, and with such conditions as the Board of Directors in its sole discretion may establish. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights, with respect to the Rights, will be to receive the Redemption Price.

The terms of the Rights may be amended by the Board of Directors of the Company without the consent of the holders of the Rights, including an amendment to lower certain beneficial ownership thresholds described above to not less than the sum of .001% and the largest percentage of the outstanding Common Shares then known to the Company to be beneficially owned by any person or group of affiliated or associated persons, except that from and after such time as any person or group of affiliated or associated persons becomes an Acquiring Person no such amendment may adversely affect the interests of the holders of the Rights. Until a Right is exercised, the holder thereof, as such, will have no rights as a shareholder of the Company, including, without limitation, the right to vote or to receive dividends.

The description of the Rights contained herein is qualified in its entirety by reference to the Rights Agreement, which is incorporated by reference into the registration statement of which this Prospectus forms a part.

SHAREHOLDER ACTION

Except as otherwise provided by law or in our articles of incorporation or bylaws, the approval by holders of a majority of the shares of common stock present in person or represented by proxy at a meeting and entitled to vote is sufficient to authorize, affirm, ratify or consent to a matter voted on by shareholders. The FBCA General Corporation Act requires the approval of the holders of a majority of the outstanding stock entitled to vote for certain extraordinary corporate transactions, such as a merger, sale of substantially all assets, dissolution or amendment of the articles of incorporation.

TRANSFER AGENT AND REGISTRAR

The Transfer Agent and Registrar for the Common Stock is American Stock Transfer & Trust Company. It is located at 40 Wall Street, 46th Floor, New York, NY 10005, and its telephone number is (718) 921-8200.



## DESCRIPTION OF DEPOSITARY SHARES

GENERAL

We may offer fractional shares of preferred stock, rather than full shares of preferred stock. If we decide to offer fractional shares of preferred stock, we will issue receipts for depositary shares. Each depositary share will represent a fraction of a share of a particular series of preferred stock. The prospectus supplement will indicate that fraction. The shares of preferred stock represented by depositary shares will be deposited under a depositary agreement between us and a bank or trust company that meets certain requirements and is selected by us (the "Bank Depositary"). Each owner of a depositary share will be entitled to all the rights and preferences of the preferred stock represented by the depositary share. The depositary shares will be evidenced by depositary receipts issued pursuant to the depositary agreement. Depositary receipts will be distributed to those persons purchasing the fractional shares of preferred stock in accordance with the terms of the offering.

We have summarized selected provisions of a depositary agreement and the related depositary receipts. The summary is not complete. The forms of the deposit agreement and the depositary receipts relating to any particular issue of depositary shares will be filed with the SEC on a Current Report on Form 8-K prior to our offering of the depositary shares, and you should read such documents for provisions that may be important to you.

DIVIDENDS AND OTHER DISTRIBUTIONS

If we pay a cash distribution or dividend on a series of preferred stock represented by depositary shares, the Bank Depositary will distribute such dividends to the record holders of such depositary shares. If the distributions are in property other than cash, the Bank Depositary will distribute the property to the record holders of the depositary shares. If the Bank Depositary, however, determines that it is not feasible to make the distribution of property, the Bank Depositary may, with our approval, sell such property and distribute the net proceeds from such sale to the record holders of the

depositary shares.

REDEMPTION OF DEPOSITARY SHARES

If we redeem a series of preferred stock represented by depositary shares, the Bank Depositary will redeem the depositary shares from the proceeds received by the Bank Depositary in connection with the redemption. The redemption price per depositary share will equal the applicable fraction of the redemption price per share of the preferred stock. If fewer than all the depositary shares are redeemed, the depositary shares to be redeemed will be selected by lot or pro rata as the Bank Depositary may determine.

VOTING THE PREFERRED STOCK

Upon receipt of notice of any meeting at which the holders of the preferred stock represented by depositary shares are entitled to vote, the Bank Depositary will mail the notice to the record holders of the depositary shares relating to such preferred stock. Each record holder of these depositary shares on the record date (which will be the same date as the record date for the preferred stock) may instruct the Bank Depositary as to how to vote the preferred stock represented by such holder's depositary shares. The Bank Depositary will endeavor, insofar as practicable, to vote the amount of the preferred stock represented by such depositary shares in accordance with such instructions, and we will take all action which the Bank Depositary deems necessary in order to enable the Bank Depositary to do so. The Bank Depositary will abstain from voting shares of the preferred stock to the extent it does not receive specific instructions from the holders of depositary shares representing such preferred stock.



AMENDMENT AND TERMINATION OF THE DEPOSITARY AGREEMENT

The form of depositary receipt evidencing the depositary shares and any provision of the depositary agreement may be amended by agreement between the Bank Depositary and us. However, any amendment that materially and adversely alters the rights of the holders of depositary shares will not be effective unless such amendment has been approved by the holders of at least a majority of the depositary shares then outstanding. The depositary agreement may be terminated by the Bank Depositary or us only if (i) all outstanding depositary shares have been redeemed or (ii) there has been a final distribution in respect of the preferred stock in connection with any liquidation, dissolution or winding up of our company and such distribution has been distributed to the holders of depositary receipts.

CHARGES OF BANK DEPOSITARY

We will pay all transfer and other taxes and governmental charges arising solely from the existence of the depositary arrangements. We will pay charges of the Bank Depositary in connection with the initial deposit of the preferred stock and any redemption of the preferred stock. Holders of depositary receipts will pay other transfer and other taxes and governmental charges and any other charges, including a fee for the withdrawal of shares of preferred stock upon surrender of depositary receipts, as are expressly provided in the depositary agreement to be for their accounts.

WITHDRAWAL OF PREFERRED STOCK

Upon surrender of depositary receipts at the principal office of the Bank

Depositary, subject to the terms of the depositary agreement, the owner of the depositary shares may demand delivery of the number of whole shares of preferred stock and all money and other property, if any, represented by those depositary shares. Partial shares of preferred stock will not be issued. If the depositary receipts delivered by the holder evidence a number of depositary shares in excess of the number of depositary shares representing the number of whole shares of preferred stock to be withdrawn, the Bank Depositary will deliver to such holder at the same time a new depositary receipt evidencing the excess number of depositary shares. Holders of preferred stock thus withdrawn may not thereafter deposit those shares under the depositary agreement or receive depositary receipts evidencing depositary shares therefor.

RESIGNATION AND REMOVAL OF BANK DEPOSITARY

The Bank Depositary may resign at any time by delivering to us notice of its election to do so, and we may at any time remove the Bank Depositary. Any such resignation or removal will take effect upon the appointment of a successor Bank Depositary and its acceptance of such appointment. Such successor Bank Depositary must be appointed within 60 days after delivery of the notice of resignation or removal and must be a bank or trust company meeting the requirements of the depositary agreement.

## PLAN OF DISTRIBUTION

Any of the securities being offered hereby may be sold in any one or more of the following ways from time to time:

- through agents;
- to or through underwriters;
- through dealers; or
- directly by us.

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices.

Offers to purchase securities may be solicited by agents designated by us from time to time. Any such agent involved in the offer or sale of the securities in respect of which this prospectus is delivered will be named, and any commissions payable by us to such agent will be set forth, in the applicable



prospectus supplement. Unless otherwise indicated in such prospectus supplement, any such agent will be acting on a reasonable best efforts basis for the period of its appointment. Any such agent may be deemed to be an underwriter, as that term is defined in the Securities Act, of the securities so offered and sold. We may periodically engage agents or underwriters in connection with at-the-market offerings or negotiated transactions involving our common stock.

If securities are sold by means of an underwritten offering, we will execute an underwriting agreement with an underwriter or underwriters at the time an agreement for such sale is reached, and the names of the specific managing underwriter or underwriters, as well as any other underwriters, the respective amounts underwritten and the terms of the transaction, including commissions, discounts and any other compensation of the underwriters and

dealers, if any, will be set forth in the applicable prospectus supplement which will be used by the underwriters to make resales of the securities in respect of which this prospectus is being delivered to the public. If underwriters are utilized in the sale of any securities in respect of which this prospectus is being delivered, such securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at fixed public offering prices or at varying prices determined by the underwriters at the time of sale. Securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more underwriters. If any underwriter or underwriters are utilized in the sale of securities, unless otherwise indicated in the applicable prospectus supplement, the underwriting agreement will provide that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters with respect to a sale of such securities will be obligated to purchase all such securities if any are purchased.

We may grant to the underwriters options to purchase additional securities, to cover over-allotments, if any, at the price at which securities are first offered to the public (with additional underwriting commissions or discounts), as may be set forth in the prospectus supplement relating thereto. If we grant any over-allotment option, the terms of such over-allotment option will be set forth in the prospectus supplement for such securities.

If a dealer is utilized in the sale of the securities in respect of which this prospectus is delivered, we will sell such securities to the dealer as principal. The dealer may then resell such securities to the public at varying prices to be determined by such dealer at the time of resale. Any such dealer may be deemed to be an underwriter, as such term is defined in the Securities Act, of the securities so offered and sold. The name of the dealer and their terms of the transaction will be set forth in the prospectus supplement relating thereto.

Offers to purchase securities may be solicited directly by us and the sale thereof may be made by us directly to institutional investors or others, who may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale thereof. The terms of any such sales will be described in the prospectus supplement relating thereto.

If so indicated in the applicable prospectus supplement, we may authorize agents and underwriters to solicit offers by certain institutions to purchase securities from us at the public offering price set forth in the applicable prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in the applicable prospectus supplement. Such delayed delivery contracts will be subject to only those conditions set forth in the applicable prospectus supplement. A commission indicated in the applicable prospectus supplement will be paid to underwriters and agents soliciting purchases of securities pursuant to delayed delivery contracts accepted by us.

Agents, underwriters and dealers may be entitled under relevant agreements with us to indemnification by us against certain liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which such agents, underwriters and dealers may be required to make in respect thereof.

Each series of securities will be a new issue and, other than our common stock, which is listed on The New York Stock Exchange, will have no established trading market. We may elect to list any series of securities on an exchange, and in the case of common stock, on any additional exchange, but, unless otherwise specified in the applicable prospectus supplement, we shall not be obligated to do so. No assurance can be given as to the liquidity of the trading

market for any of the securities.

Agents, underwriters and dealers may be customers of, engage in transactions with, or perform services for, us and our subsidiaries in the ordinary course of business.



## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy and information statements and other information with the Securities and Exchange Commission. We have filed a registration statement on Form S-3 with the SEC to register under the Securities Act the common stock offered hereby. This prospectus constitutes a part of that registration statement. As allowed by the SEC's rules, this prospectus does not contain all the information set forth in the registration statement, certain parts of which have been omitted in accordance with the rules and regulations of the SEC. Please refer to the registration statement and related exhibits and schedules filed therewith for further information with respect to us and the common stock offered hereby. Although the prospectus describes the material provisions of documents referenced herein and filed as exhibits, statements contained herein concerning the provisions of any such document are not necessarily complete. In each instance, reference is made to the copy of such document filed as an exhibit to the registration statement or otherwise filed by us with the SEC and each such statement is qualified in its entirety by such reference.

The following documents, which we have filed with the SEC (file number 001-13165), are incorporated by reference in and made a part of this prospectus:

- The Registrant's Annual Report on Form 10-K filed with respect to the Registrant's fiscal year ended December 31, 2003.
- The Registrant's Current Reports on Forms 8-K filed on January 7, January 26, February 9, February 26, May 10, August 5, October 29, November 4, November 8, November 22, and December 10, 2004.
- The Registrant's Quarterly Reports on Form 10-Q filed with respect to the three month periods ended March 31, 2004, June 30, 2004, and September 30, 2004.

We are also incorporating by reference any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering. We also are incorporating any filings under these sections filed after the date of the initial filing of this registration statement and prior to the effectiveness of the registration statement. These documents will be deemed to be incorporated by reference in this prospectus and to be a part of it from the date they are filed with the SEC. You may read and copy any document we file at the SEC's public reference room located at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our SEC filings are also available to the public from commercial document retrieval services and at the Web site maintained by the SEC at http://www.sec.gov. This information is also available without charge upon written or oral request to:

CryoLife, Inc.
Attn: Secretary
1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144

(770) 419-3355

You should rely only on the information provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. We may not make an offer of the common stock in any state where the offer is not permitted. The delivery of this prospectus does not, under any circumstances, mean that there has not been a change in our affairs since the date of this prospectus. It also does not mean that the information in this prospectus is correct after this date.

## LEGAL MATTERS

The validity of the common stock (including any common stock issuable upon the conversion of any preferred stock), preferred stock (including any preferred stock underlying any depositary shares) and the depositary shares offered by this prospectus have been passed upon for us by Arnall Golden Gregory LLP. Legal counsel to any underwriters may pass upon legal matters for such underwriters.



## EXPERTS

The consolidated financial statements and the related financial statement schedules as of December 31, 2003 and 2002 and for the years then ended incorporated in this prospectus by reference from the Annual Report on Form 10-K of CryoLife, Inc. for the year ended December 31, 2003 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's change in its method of accounting for goodwill and other intangible assets to conform with Statement of Financial Accounting Standards No. 142), which is incorporated herein by reference and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated statements of income, changes in shareholders' equity, and cash flows of CryoLife, Inc. for the year ended December 31, 2001 have been audited by Arthur Andersen LLP, independent public accountants, as indicated in their report dated March 27, 2002.

We could not obtain, after reasonable efforts, the written consent of Arthur Andersen LLP to its being named in this Form S-3 as having audited our financial statements for the year ended December 31, 2001, as required by Section 7 of the Securities Act. Accordingly, Arthur Andersen LLP may not have any liability under Section 11 of the Securities Act for false or misleading statements or omissions contained in this prospectus, including the financial statements, and any claims against Arthur Andersen LLP related to such false or misleading statements or omissions may be limited.

CRYOLIFE, INC.

$50,000,000

COMMON STOCK
PREFERRED STOCK
DEPOSITARY SHARES

---

PROSPECTUS

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DECEMBER __, 2004

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

All expenses, other than fees and expenses of legal or other advisors to the selling shareholders, will be paid by CryoLife. Such expenses are as follows:*

| | |
|---|---|
| SEC registration fee..... | $ 5,885 |
| NYSE listing fee..... | 25,000 |
| Printing expenses..... | 10,000 |
| Accounting fees and expenses..... | 25,000 |
| Legal fees and expenses..... | 50,000 |
| Miscellaneous..... | 15,115 |
| Total..... | $ 131,000 |

*The amounts set forth, except for the filing fees for the SEC, are estimated.

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

The Registrant 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 Registrant's Restated Articles of Incorporation, and the Registrant'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 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 Registrant's Restated Articles of Incorporation and Article VI of the Registrant'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 Registrant shall indemnify its directors and officers for certain liabilities incurred in the performance of their duties on behalf of the Registrant to the maximum extent allowed by Section 607.0850 of the FBCA (formerly Section 607.014 of the Florida General Corporation Act).

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



ITEM 16. EXHIBITS

| Exhibit No. | Exhibit |
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| | |
|---|---|
| 3.1 | Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.) |
| 3.2 | ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to the Registrant's Report on Form 8-K filed November 8, 2004.) |
| 3.3 | Articles of Amendment to the Articles of Incorporation of CryoLife. (Incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000.) |
| 4.1 | Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (Commission File No. 33-56388). ) |
| 4.2 | Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.) |
| 4.3 | Rights Agreement between the Company and Chemical Mellon Shareholder Services, L.L.C., as Rights Agent, dated as of November 27, 1995. (Incorporated by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.) |
| 4.4 | First Amendment to Rights Agreement, effective June 1, 1997, executed by the Company and American Stock Transfer & Trust Company, as successor Rights Agent. (Incorporated by reference to the Registrant's Registration Statement on Form S-3 (Commission File No. 333-112673.)) |
| 4.5+ | Form of Depositary Agreement. |
| 4.6+ | Form of Depositary Receipt. |
| 5.1* | Opinion of Arnall Golden Gregory LLP regarding legality of the common stock and preferred stock. |
| 5.2* | Opinion of Arnall Golden Gregory LLP regarding legality of the depositary shares. |
| 12.1* | Computation of Ratio of Earnings to Fixed Charges |
| 23.1* | Consent of Arnall Golden Gregory LLP (included as part of Exhibit 5 hereto). |
| 23.2* | Consent of Deloitte & Touche LLP. |
| 23.3* | Notice regarding consent of Arthur Andersen LLP. |
| 24.1* | Power of Attorney (included in the signature pages of this registration statement.) |

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* Filed with this Form S-3

\+ To be filed by amendment or as an exhibit to a current report on Form 8-K of the Registrant.

ITEM 17. UNDERTAKINGS

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. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(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.

provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by registrants pursuant to section 13 or section 15(d) of the Exchange Act 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.

(4) That, for purposes of determining 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 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to 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.

(5) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission 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.



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 Kennesaw, State of Georgia on December 17, 2004.

CRYOLIFE, INC.

By: /s/ Steven G. Anderson
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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 D. Ashley Lee 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.

PRINCIPAL EXECUTIVE, FINANCIAL & ACCOUNTING OFFICERS AND DIRECTORS:
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| Name | Title | D |
|---|---|---|
| /s/ Steven G. Anderson | President, Chief Executive Officer and Chairman of the Board of Directors | Decemb |

| | | |
|---|---|---|
| Steven G. Anderson | (Principal Executive Officer) | |
| /s/ D. Ashley Lee<br>D. Ashley Lee | Executive Vice President, Chief Operating Officer and Chief Financial Officer (Principal Financial and Accounting Officer) | Decemb |
| /s/ Thomas F. Ackerman<br>Thomas F. Ackerman | Director | Decemb |
| /s/ Dan Bevevino<br>Dan Bevevino | Director | Decemb |
| /s/ John M. Cook<br>John M. Cook | Director | Decemb |
| /s/ Ronald Charles Elkins, M.D.<br>Ronald Charles Elkins, M.D. | Director | Decemb |
| /s/ Virginia C. Lacy<br>Virginia C. Lacy | Director | Decemb |
| /s/ Ronald D. McCall<br>Ronald D. McCall | Director | Decemb |
| /s/ Bruce J. Van Dyne, M.D.<br>Bruce J. Van Dyne, M.D. | Director | Decemb |



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* Filed with this Form S-3

\+ To be filed by amendment or as an exhibit to a current report on Form 8-K of the Registrant.