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CRYOLIFE INC  
Form 424B3  
May 18, 2004

Prospectus Supplement filed under Rule 424(b)(3)  
Registration Number 333-112673

PROSPECTUS

3,444,000 SHARES

CRYOLIFE, INC.

COMMON STOCK

This prospectus relates to the potential offer and sale from time to time of up to 3,444,000 shares of our common stock by the shareholders identified on pages 18-20 of this prospectus or in any accompanying supplement to this prospectus.

We will not receive any of the proceeds from the sale of shares of common stock by the selling shareholders.

Our common stock is traded on The New York Stock Exchange under the symbol "CRY." The last reported sale price of the common stock on May 17, 2004 was \$5.05 per share.

THIS INVESTMENT INVOLVES RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 5.

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 May 18, 2004.

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### SUMMARY

This summary highlights information that we believe is especially important concerning our business and this offering of common stock. 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 invest in the common stock.

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

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, a reduced incidence of reoperation, and a reduced risk of catastrophic failure, thromboembolism (stroke), or calcification.

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.

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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.

Through its continuing research and development activities, CryoLife endeavors to use its expertise in biochemistry, cell biology, immunology, and protein chemistry 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.

In December 2003 we announced that CryoLife and Clearant are working together to develop and validate a process to incorporate the use of the Clearant technology in the processing of some of our orthopaedic tissue. Our research and development strategy is to allocate available resources among CryoLife's core market areas based on the size of the potential market for any specific product candidate and the estimated development time and cost required to bring the product to market.

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.

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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 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

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possibility of further FDA actions, additional expenses and losses from product recalls, possible losses from ongoing product liability, securities and other litigation, 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 non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order on quality assurance quarantine and recalled the non-valved cardiac, vascular, and orthopaedic tissues subject to the FDA Order (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 life-saving 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 as to documentation and procedures that need to be addressed. The most recent Notice of Observations was issued in February 2004.

During 2003, we received other notices from the FDA stating that the FDA believed that cardiovascular tissue processed using CryoLife's SynerGraft technology required additional premarket approval authorization and that the tissues should be regulated as medical devices. CryoLife voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular and vascular tissue. Additionally, CryoLife discontinued labeling blood vessel grafts, referred to as vascular grafts, for use in arteriovenous access. The FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SynerGraft treated tissues are resolved, CryoLife will employ its traditional processing methods on these 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 May 10, 2004 we were aware of ten pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, six allege product liability claims arising out of our orthopaedic tissue services, three allege product liability claims arising out of our allograft heart valve tissue services, 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.

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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 and two by the 2003/2004 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 March 31, 2004 the Company has an accrual of \$100,000 for the remaining retention levels related to the 2000/2001 insurance policy year. The Company believes its 2003/2004 insurance policy to be adequate to defend against the two covered suits filed during this time period.

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 March 31, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of March 31, 2004 CryoLife had accrued a total of \$5.1 million for pending product liability claims and recorded \$1.1 million representing amounts to be recovered from CryoLife's insurance carriers. These amounts represent CryoLife's estimate of the probable losses and anticipated recoveries related to these pending product liability claims. 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. The amount recorded as a receivable is reflective of the estimated amount recoverable from the Company's insurance carrier, based on the Company's estimate of the liability and analysis of the policy terms. The Company believes that these amounts are fully collectible. Prior to March 31, 2004, the Company recorded accruals for the uninsured portion of product liability claims for which the amount of probable loss was reasonably estimable. Had the Company 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.

### RECENT DEVELOPMENTS

#### Recent Sale of Common Stock

On January 27, 2004, CryoLife closed on a \$21.5 million private placement of 3,444,000 shares of common stock. Net proceeds from the offering were approximately \$19.9 million. The proceeds from the sale of the common stock will be used for general corporate purposes.

#### Products Liability Insurance

On April 1, 2004, the Company bound coverage for the 2004/2005 insurance policy year. The Company will maintain a two-year claims made insurance policy, meaning claims incurred during the period April 1, 2003, through March 31, 2005, and reported during the period April 1, 2004, through March 31, 2005, are covered by this policy.

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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](http://www.cryolife.com). Information contained in our Web site is not part of this prospectus.

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### SELECTED CONSOLIDATED FINANCIAL DATA

The following Selected Consolidated Financial Data should be read in conjunction with our Consolidated Financial Statements and Notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information incorporated herein by reference. The selected data presented below for and as of the end of the years ended December 31, 2002 and 2003 are derived from our Consolidated Financial Statements that were audited by Deloitte and Touche LLP, independent auditors, and which are incorporated herein by reference. The selected data presented below as of and for each of the years in the three-year period ended December 31, 2001, are derived from our Consolidated Financial Statements that were audited by Arthur Andersen LLP, independent auditors. The historical results are not necessarily indicative of future results of operations. The selected consolidated statement of operations data for the three months ended March 31, 2004 and 2003 and the selected consolidated balance sheet data as of March 31, 2004 are derived from our unaudited consolidated financial statements, which, in our opinion, include all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation.

### SELECTED FINANCIAL INFORMATION

(in thousands, except percentages and per share data)

OPERATIONS	THREE MONTHS ENDED: MARCH 31		YEAR ENDED DECEMBER 31,		
	2004	2003	2003	2002	2001
Revenues	\$ 15,086	\$ 15,920	\$ 59,532	\$ 77,795	\$ 87,671
Net (loss)/income	(7,026)	(434)	(32,294)	(27,761)	9,166
Research and development as a percentage of revenues	6.1%	5.8%	6.1%	5.9%	5.4%
(LOSS)/EARNINGS PER SHARE <sup>1</sup>					
Basic	\$ (.32)	\$ (.02)	\$ (1.64)	\$ (1.43)	\$ 0.49
Diluted	\$ (.32)	\$ (.02)	\$ (1.64)	\$ (1.43)	\$ 0.47

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	MARCH 31, 2004	DECEMBER 31,		
		2003	2002	2001
Total assets	\$ 87,517	\$ 75,027	\$ 106,414	\$ 129,310
Working capital	29,088	14,790	39,385	66,668
Long Term Liabilities	5,692	5,716	4,552	10,071
Shareholder's equity	61,241	48,338	79,800	101,439
Current ratio 2	2:1	2:1	3:1	5:1

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- 1 Reflects adjustment for 3-for-2 stock split effected December 27, 2000.
  - 2 Current assets divided by current liabilities.

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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 trading price of our common stock could decline and you could lose all or part of your investment.

RISKS RELATING TO OUR BUSINESS

OVERVIEW

CryoLife has faced extraordinary challenges since 2002. 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

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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 return to the sales and profitability it enjoyed prior to 2002. No assurances can be made that CryoLife will succeed in those efforts in the near future. These risks are addressed in greater detail below and elsewhere in this prospectus.

THE AUGUST 2002 FDA ORDER ON HUMAN TISSUE AND SUBSEQUENT FDA ACTIVITY CONTINUE TO ADVERSELY IMPACT CRYOLIFE'S BUSINESS, INCLUDING DEMAND FOR ITS SERVICES AND 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 fourth quarter of 2003, these revenues were approximately \$4.9 million or 39% of fourth 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 profits 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 the types of tissues subject to the FDA Order 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

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FDA Order. Although CryoLife expects them to decrease somewhat beginning in the second quarter of 2004, these high costs could have a material adverse effect on CryoLife's business, results of operations and financial position.

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.



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THE FDA ORDER AND SUBSEQUENT ACTIVITY HAVE HAD AND CONTINUE TO HAVE AN ADVERSE IMPACT ON LIQUIDITY AND CAPITAL RESOURCES

Based upon the lower levels of revenues and profits since the FDA Order, FDA activity, and associated adverse publicity, CryoLife expects that its cash and cash equivalents will continue to decrease over the near term and working capital could decrease from levels now on hand. As a result of the FDA Order CryoLife recorded a reduction to pretax income of \$12.6 million in the quarter ended June 30, 2002. The reduction was comprised of a net \$8.9 million increase to cost of human tissue preservation services, a \$2.4 million reduction to revenues (and accounts receivable) for the estimated return of the tissues subject to recall by the FDA Order, and a \$1.3 million accrual recorded in general, administrative, and marketing expenses consisting of an accrual for retention levels under CryoLife's product liability and directors' and officers' insurance policies of \$1.2 million and for estimated expenses for packaging and handling for the return of affected tissues under the FDA Order of \$75,000. The net increase of \$8.9 million to cost of preservation services was comprised of a \$10.0 million write-down of deferred preservation costs for tissues subject to the FDA Order, offset by a \$1.1 million decrease in cost of preservation services due to the estimated tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the \$10.0 million write-down).

In the quarter ended September 30, 2002 CryoLife recorded a reduction to pretax income of \$24.6 million as a result of the FDA Order. The reduction was comprised of a net \$22.2 million increase to cost of human tissue preservation services, a \$1.4 million write-down of goodwill, and a \$1.0 million reduction to revenues (and accounts receivable) for the estimated return of the tissues shipped during the third quarter subject to recall by the FDA Order. The net \$22.2 million increase to cost of preservation services was comprised of a \$22.7 million write-down of deferred preservation costs, offset by a \$535,000 decrease in cost of preservation services due to the estimated and actual tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the \$22.7 million write-down).

In the quarter ended March 31, 2003 CryoLife recorded a favorable adjustment of \$848,000 to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002. The adjustment increased cardiac tissue revenues by \$92,000, vascular tissue revenues by \$711,000, and orthopaedic tissue revenues by \$45,000 in the first quarter of 2003. In the quarter ended September 30, 2003 CryoLife recorded a favorable adjustment of \$52,000 to reverse the remaining unused portion of the estimated tissue recall returns due to lower overall actual tissue returns under the FDA Order than were estimated. Although vascular and orthopaedic returns were lower than expected, cardiac returns were higher than expected. Therefore, the \$52,000 adjustment decreased cardiac tissue revenues by \$7,000 and increased vascular tissue revenues by \$41,000 and orthopaedic tissue revenues by \$18,000 in the third quarter of 2003. We determined that no additional accruals were necessary for tissue returns under the FDA Order. Therefore, as of December 31, 2003 there was no accrual for estimated return of tissues subject to recall by the FDA Order.

Although CryoLife has reduced its level of operations and the number of personnel, there is a possibility that CryoLife may not have sufficient funds to fund its primary capital requirements or to meet its operating and development needs in the long-term.

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

We have received only nominal 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 three months ended March 31, 2004, they were \$309,000, or 2% of revenues. The demand for orthopaedic tissue from CryoLife may remain minimal and may never 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 have to be permanently discontinued or may only continue at substantially reduced levels. Any of these occurrences would result in a continued significant decrease in CryoLife's preservation services revenues and profitability in the future as compared to prior to the FDA Order.

PHYSICIANS MAY BE RELUCTANT TO IMPLANT CRYOLIFE'S PRESERVED TISSUES

There is a risk that physicians or implanting institutions will be 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 SCRUTINY

Although CryoLife's heart valve processing services, 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. As of the date of this prospectus, we have not received any correspondence or conversations from the FDA suggesting higher scrutiny.

DEMAND FOR HEART VALVES PROCESSED BY CRYOLIFE HAS DECREASED AND MAY CONTINUE TO DECREASE

Some physicians and implanting institutions have remained reluctant to choose CryoLife's allograft heart valves for use in implantation, perhaps due to a perception that they may not be safe or to a belief that the implanting institutions or hospitals may be subject to a heightened liability risk if CryoLife's preserved tissues are used, especially if alternatives are available. Demand for CryoLife's allograft heart valves could decrease. In such an event, CryoLife's preservation services revenues and profits would be materially adversely affected.

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

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### THE FDA RECALL

Even though CryoLife's BioGlue, porcine heart valves and bovine vascular grafts (of which the porcine and bovine products are not sold in the U.S.) 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 are deemed unsatisfactory, the FDA could take further action, which could have a material adverse effect on the Company's

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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

On February 20, 2003 CryoLife received a letter from the FDA stating that a 510(k) premarket notification for the CryoValve SG was required before the product can be marketed. The letter also contended that a premarket approval application was required in order to market the CryoVein SG when used for A-V (arteriovenous) access. The agency's position is that femoral veins used for A-V access are medical devices that require premarket approval. CryoLife submitted a 510(k) premarket notification for the CryoValve SG, and received a response requesting additional information. There can be no assurance as to when clearance will be obtained, if at all.

### 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.

### 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

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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 reach settlements of the remaining litigation. CryoLife's March 31, 2004, consolidated balance sheet reflects a liability for the estimated cost of resolving these claims, and an asset representing amounts recoverable from insurance companies. 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 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.

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### 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 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. The committee reiterated its previous conclusions and

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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.

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

CryoLife faces competition from other companies that cryopreserve human tissue, as well as companies that market mechanical valves and synthetic and animal tissue for implantation and companies that market wound closure products. 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.

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 of human tissue, 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 since the FDA Order in 2002. This interruption in our services may make it difficult for CryoLife to regain the level of revenues reported prior to the FDA Order. 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. Although human tissue cryopreserved by CryoLife is initially higher priced than 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 will compete with other surgical adhesives and

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surgical sealants, including Baxter Healthcare's Tiseel, FloSeal and CoSeal products. Competitive products may also be under development by other large medical device, pharmaceutical, and biopharmaceutical companies, including 3M and Johnson & Johnson. 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

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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, including new applications of its BioGlue 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 many of its products under development which indicate that such products may be effective in a particular application, there can be no assurance that the results obtained from expanded clinical studies will be consistent with earlier trial results or be sufficient for 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 or application, or a determination by CryoLife, for financial, technical or other reasons, not to complete development of any product or application, particularly

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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

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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, especially in light of the recent FDA Order. 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 BENEFITS SUFFICIENT TO JUSTIFY THE PRICE

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 increases graft longevity and improves the biocompatibility and functionality of such



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tissue, such that the implanted tissue behaves similar to 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 employers include its management team, consisting of Steven G. Anderson, President, Chief Executive Officer, and Chairman; Sidney B. Ashmore, Vice President, Marketing; Kirby S. Black, PhD, Senior Vice President, Research and Development; David M. Fronk, Vice President, Clinical Research; Albert E. Heacox, PhD, Senior Vice President, Laboratory Operations; D. Ashley Lee, CPA, Vice President, Finance, Chief Financial Officer, and Treasurer; Thomas J. Lynch, JD, PhD, Vice President, Regulatory Affairs and Quality Assurance; and James C. Vander Wyk, PhD, Vice President, Product Integrity. 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 September 2004, August 2005 or September 2005, and 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. Mr. Lynch's agreement also provides for an automatic one year extension to August 1, 2006 unless notice is given 30 days prior to August 1, 2004. 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 HAS BEEN 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

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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 proposed and is refining 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 promulgated will enhance regulatory oversight of CryoLife and other processors of human tissue. See "Risk Factor - The FDA Has Notified CryoLife of Its Belief that Marketing of CryoValve SG and CryoVein SG Require Additional Regulatory Submissions and/or Approvals."

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 its CE Mark ISO 9001, and 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

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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

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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

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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.

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### 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

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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 COMMON 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 recently and may continue to be subject to such volatility 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 May 13, 2004 has ranged from a high of \$31.31 to a low of \$1.89.

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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.

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DIVIDENDS ARE NOT LIKELY TO BE PAID IN THE FORESEEABLE FUTURE

CryoLife has not paid, and does not presently intend to pay, cash dividends. 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. It is not likely that any cash dividends will be paid in the foreseeable future.

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### FORWARD LOOKING STATEMENTS

This prospectus, and the information incorporated herein by reference, contains forward-looking statements and information made or provided by us that are based on the beliefs of our management as well as estimates and assumptions made by and information currently available to our management. 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 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:

- o the impact of recent accounting pronouncements;
- o adequacy of product liability insurance to defend against lawsuits;
- o the outcome of lawsuits filed against the Company;
- o the impact of the FDA Order and subsequent FDA activity on future revenues, profits and business operations;
- o the effect of the FDA Order and subsequent FDA activity on sales of BioGlue;
- o future tissue procurement levels;
- o expected future impact of BioGlue on revenues;
- o the impact of the FDA's Form 483 Notices of Observation;
- o the estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance

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policies, as well as the estimates of the amounts accrued for product loss claims incurred but not reported;

- o future costs of human tissue preservation services;
- o changes in liquidity and capital resources;
- o the outcome of any evaluation of allograft heart valves by the FDA;
- o the Company's competitive position;
- o estimated dates relating to the Company's proposed regulatory submissions;
- o the Company's expectations regarding the adequacy of current financing arrangements;
- o product demand and market growth;

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- o the potential of the ACT for use in cancer therapies, fibrinolysis (blood clot dissolving), and other drug delivery applications;
- o the impact on the Company of adverse results of surgery utilizing tissue processed by it;
- o the expected receipt of tax refunds; and
- o 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

This prospectus relates to the offer and sale of our common stock by the shareholders named herein. We will not receive any proceeds from the sale of the common stock. We will pay all expenses related to the registration of the common stock except underwriting discounts and commissions and fees and expenses of counsel for the selling shareholders.

### SELLING SHAREHOLDERS

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The shareholders named below have contractual rights requiring us to register the resale of their shares. The following table states the name of each shareholder who may sell under this prospectus and, for each shareholder, the number of shares of our common stock beneficially owned as of May 10, 2004, and the percentage of our stock that number represents; the number of shares which may be sold using this prospectus; and the number of shares of common stock that will be beneficially owned after the completion of this offering (assuming the sale of all shares offered), and the percentage of our common stock that number represents.

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NAMES OF SHAREHOLDERS	BENEFICIAL OWNERSHIP PRIOR TO THE OFFERING		NUMBER OF SHARES OFFERED
	SHARES	PERCENTAGE	
Atlas Equity I, Ltd. (2).....	250,000	1.1%	250,000
BlackRock Funds, Small Cap Growth Equity Portfolio (3) (10).....	757,500	3.3%	600,000
Capital Ventures International (4).....	500,000	2.2%	500,000
Deephaven Small Cap Growth Fund LLC (5) (10).	400,000	1.7%	400,000
MFS Series I Trust on behalf of MFS New Discovery Fund (NDF) (6) (10).....	569,200	2.5%	119,500
MFS/Sun Life Trust Series on behalf of New Discovery Series (NWD) (6) (10).....	106,600	*	22,000
MFS Variable Insurance Trust on behalf of MFS New Discovery Series (VND) (6) (10)....	218,100	*	48,500
The Riverview Group LLC (7) (10).....	160,000	*	160,000
Smithfield Fiduciary LLC (8) (10).....	994,800	4.3%	944,000
UBS O'Connor LLC f/b/o O'Connor PIPES Corporate Master Strategies Ltd. (9).....	400,000	1.7%	400,000

\*Less than 1% of the outstanding shares

(1) Assumes that all common stock offered will be sold, that we will not issue additional shares before the offering is completed, and that the shareholder will not acquire more shares, or sell shares, before completion of the offering.

(2) Balyasny Asset Management, L.P. ("Balyasny") is the investment manager of Atlas Equity I, Ltd. ("Atlas"). Balyasny has discretionary authority to vote and dispose of the shares held by Atlas and may be deemed to beneficially own the shares held by Atlas. By virtue of his majority ownership of the equity interest in Balyasny, Dmitry Balyasny may be deemed to beneficially own the shares of the Company's common stock beneficially owned by Atlas. The address for Balyasny and Dmitry Balyasny is 181 W. Madison, Suite 3600, Chicago, IL 60602, Attn: Dmitry Balyasny.



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(3) BlackRock Funds is a registered investment company. Its investment manager is BlackRock Advisors, Inc., a registered investment adviser. The address for this shareholder is c/o BlackRock Advisors, Inc., 100 Bellevue Parkway, Wilmington, DE 19809, Attn: Thomas Downey.

(4) Heights Capital Management, Inc., the authorized agent of Capital Ventures International ("CVI"), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares. The business address for this shareholder is 425 California Street, Suite 1100, San Francisco, CA 94104.

(5) Deephaven Small Cap Growth Fund LLC is a private investment fund that is owned by all of its investors and managed by Deephaven Capital Management LLC. Deephaven Capital Management LLC, of which Mr. Colin Smith is the Chief Executive Officer, has voting and investment control over the shares that are owned by Deephaven Small Cap Growth Fund LLC. The address for this shareholder is 130 Chesire Lane, Suite 102, Mennetonka, MN 55305, Attn: Jared R. Lewis.

(6) These shareholders have appointed Massachusetts Financial Services Company, d/b/a MFS Investment Management ("MFS") as their investment adviser. As investment adviser, MFS has sole voting and investment power over all of the shares beneficially held by these shareholders. As of May 10, 2004, MFS or a subsidiary of MFS, as investment adviser and not beneficially, had sole or shared voting and/or investment power over, in the aggregate, 1,400,210 shares on behalf of these and other client accounts for which MFS or a subsidiary of MFS acts as investment adviser. The address for all of these shareholders (or the investment adviser) is c/o Massachusetts Financial Services Company, 500 Boylston Street, Boston, Massachusetts 02116.

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(7) The sole member of Riverview is Millennium Holding Group, L.P., a Delaware limited partnership ("Holding"). Millennium Management, LLC, a Delaware limited liability company ("Millennium Management"), is the general partner of Holding. Israel A. Englander ("Mr. Englander") is the sole managing member of Millennium Management. The foregoing should not be construed in and of itself as an admission by any of Holding, Millennium Management or Mr. Englander as to beneficial ownership of the shares owned by Riverview. The address for this shareholder is 666 Fifth Avenue, 8th Floor, New York, NY 10103, Attn: Terry Feeney.

(8) Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and consequently has voting control and investment discretion over securities held by Smithfield. Glenn Dubin and Henry Swieca control Highbridge. Each of Highbridge, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield. The address for this shareholder is c/o Highridge Capital Management LLC, 9 West 57th Street, 27th Floor, New York, NY 10019, Attn: Ari J. Storch/Adam J. Chill.

(9) UBS O'Connor LLC ("UBS") is the investment manager for PIPES Corporate Strategies Master Ltd (the selling security holder), which is a wholly owned

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subsidiary of UBS AG which is traded on NYSE. UBS AG is the managing member of UBS, and in that capacity directs its operations. The address for this shareholder is 1 North Wacker Drive, 32nd Floor, Chicago, Illinois 60606, Attn: Jeff Richmond.

(10) This selling shareholder has represented to CryoLife that, although it is affiliated with a broker or dealer, the selling shareholder purchased the securities shown in the ordinary course of business, and at the time of the purchase of the securities, the selling shareholder had no agreements or understandings, directly or indirectly, with any person to distribute the securities.

### PLAN OF DISTRIBUTION

The shareholders named herein may offer and sell shares of common stock offered by this prospectus during the two year period ending on the second anniversary of the closing of the private placement of our common stock in one or more of the following transactions:

- o on The New York Stock Exchange or any other securities exchange or quotation service that lists the common stock for trading;
- o in the over-the-counter market;
- o in transactions other than on such exchanges or in the over-the-counter market;
- o in negotiated transactions;
- o through the writing of options, whether such options are listed on an options exchange or otherwise;
- o ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- o block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- o an exchange distribution in accordance with the rules of the applicable exchange;
- o privately negotiated transactions;
- o short sales, swaps, or other derivative shares at a stipulated price per share;
- o pursuant to Rule 144; and

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- o a combination of any such methods of sale.

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The selling shareholders may offer and sell the shares using any other method permitted pursuant to applicable law. The named shareholders may sell their shares at market prices prevailing at the time of sale, at prices related to such prevailing market prices, at negotiated prices or at fixed prices. The transactions listed above may include block transactions. These shareholders have advised us that they have no arrangements with any underwriters or broker-dealers relating to the distribution of the shares covered by this prospectus.

The shareholders may sell their shares directly to purchasers, use broker-dealers to sell their shares or may sell their shares to broker-dealers acting as principals. If this happens, broker-dealers may either receive discounts or commissions from the shareholders, or they may receive commissions from purchasers of shares for whom they acted as agents, or both. If a broker-dealer purchases shares as a principal, it may resell the shares for its own account under this prospectus. We will pay all registration fees and expenses for the common stock offered by this prospectus.

The shareholders and any underwriter, agent, broker or dealer that participates in sales of common stock offered by this prospectus may be deemed "underwriters" within the meaning of Section 2(11) under the Securities Act of 1933 and any discounts, concessions, commissions or fees received by them and any profit on the resale of the securities sold by them may be considered underwriting discounts or commissions under the Securities Act. We have agreed to indemnify the shareholders named herein against certain liabilities arising under the Securities Act from sales of common stock. Selling shareholders may agree to indemnify any agent, broker or dealer that participates in sales of common stock against liabilities arising under the Securities Act from sales of common stock.

The selling shareholders and any underwriter, agent, broker or dealer that participates in sales of common stock offered by this prospectus will be subject to the prospectus delivery requirements of the Securities Act, which may include delivery through the facilities of The New York Stock Exchange pursuant to Rule 153 under the Securities Act.

The selling shareholders and other persons participating in the sale or distribution of the securities may be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated under the Exchange Act, including Regulation M. Under Regulation M, in connection with a distribution of securities effected by or on behalf of the selling security holder, it is unlawful for such person, or any affiliated purchaser of such person, directly or indirectly, to bid for, purchase, or attempt to induce any person to bid for or purchase, a covered security during the applicable restricted period. These restrictions may affect the marketability of the securities and the ability of any person or entity to engage in market-making activities with respect to the securities. Generally, Regulation M provides an exemption from these restrictions if the CryoLife common stock has a public float of at least \$150 million and an average daily trading volume of at least \$1 million for a 60 consecutive calendar day period ending within 10 days preceding the determination of the offering price in any distribution of the shares under this registration statement. However, this exemption does not apply to any selling shareholder who is deemed to be an affiliate of CryoLife at the time of the distribution.

In addition, the selling shareholders may from time to time sell short our common stock and, in such instances, this prospectus may be delivered in connection with such short sales and the shares of common stock offered under this prospectus may be used to cover such short sales. Any short sales and purchases to cover short positions may be subject to the Regulation M restrictions mentioned above.

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Instead of selling common stock under this prospectus, shareholders may sell common stock in compliance with the provisions of Rule 144 under the Securities Act, if available.

With respect to a particular offering of the common stock, to the extent required, an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement of which this prospectus is a part will be prepared and will set forth the following information:

- o the specific shares of common stock to be offered and sold;
- o the names of the selling shareholders;

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- o the respective purchase prices and public offering prices and other material terms of the offering;
- o the names of any participating agents, broker-dealers or underwriters; and
- o any applicable commissions, discounts, concessions and other items constituting compensation from the selling shareholders.

In addition, upon CryoLife being notified by a selling shareholder that a permitted transferee to which the right to utilize this prospectus, as determined in accordance with the stock purchase agreements which granted registration rights to the selling shareholders, has been transferred intends to sell more than 500 shares, a post effective amendment or supplement to this prospectus will be filed, as appropriate.

Shareholders who sell shares using this prospectus may also include persons who obtain common stock from one of the named shareholders as a gift, for no consideration upon dissolution of a corporation, partnership or limited liability company, on foreclosure of a pledge or in another private transaction; provided, however, that if a permitted transferee intends to sell more than 500 shares of such CryoLife common stock, the filing of a supplement to this prospectus will be required.

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### 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 April 23, 2004, there were 23,251,881 shares of Common Stock outstanding held by approximately 434 shareholders of record and no shares of Preferred Stock outstanding.

The following summary is qualified in its entirety by reference to the

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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. The Board of Directors has no present plans to issue any shares of Preferred Stock.

### STOCK OPTIONS

As of December 31, 2003, the Company has issued and outstanding options to purchase an aggregate of 2,523,000 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 1,293,000 were exercisable as of December 31, 2003.

### 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

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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

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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.

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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:

- o 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
- o 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:

- o a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Stock;
- o 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
- o 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).

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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:

- o a stock split of the Common Stock;
- o a stock dividend on the Common Stock payable in Common Stock; or
- o 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

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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.



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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.

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### 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.

### 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

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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:

- o The Registrant's Annual Report on Form 10-K filed with respect to the Registrant's fiscal year ended December 31, 2003.
- o The Registrant's Current Reports on Forms 8-K filed on January 7, January 26, February 9, February 26, and May 11, 2004.
- o The Registrant's Quarterly Report on Form 10-Q filed with respect to the three month period ended March 31, 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: Chief Financial Officer  
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.

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### LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus has been passed upon for CryoLife by Arnall Golden Gregory LLP, Atlanta, Georgia.

### EXPERTS

The consolidated financial statements and the related financial statement

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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, independent auditors, 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.

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CRYOLIFE, INC.

3,444,000 SHARES COMMON STOCK

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PROSPECTUS  
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May 18, 2004