

Edgar Filing: CRYOLIFE INC - Form S-3

CRYOLIFE INC  
Form S-3  
February 10, 2004

As filed with the Securities and Exchange Commission on February 10, 2004  
Registration No. 333-\_\_\_\_\_

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

FORM S-3  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933  
-----

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

FLORIDA

59-2417093

-----  
(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer Identification No.)

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

STEVEN G. ANDERSON, PRESIDENT,  
CHIEF EXECUTIVE OFFICER  
AND CHAIRMAN OF THE BOARD OF DIRECTORS  
CRYOLIFE, INC.  
1655 ROBERTS BOULEVARD, NW  
KENNESAW, GEORGIA 30144  
(770) 419-3355

COPIES TO:  
T. CLARK FITZGERALD III, ESQ.  
ARNALL GOLDEN GREGORY LLP  
2800 ONE ATLANTIC CENTER  
1201 WEST PEACHTREE STREET  
ATLANTA, GEORGIA 30309-3450  
(404) 873-8622

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

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

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

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

Edgar Filing: CRYOLIFE INC - Form S-3

registration statement for the same offering. [ ]

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

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

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

Title of securities to be registered	Amount to be Registered	Proposed maximum offering price per share	Proposed maximum aggregate offering price
Common Stock, \$0.01 par value	3,444,000 Shares	\$6.745	\$23,229,780

\* The offering price for such shares is estimated pursuant to Rule 457(c) and (h) under the Securities Act of 1933, as amended, solely for the purpose of calculating the registration fee and is based upon the average of the high and low prices of the Registrant's common Stock on February 6, 2004 as listed on the New York Stock Exchange.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OR UNTIL THIS REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(A), MAY DETERMINE.

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

SUBJECT TO COMPLETION, DATED FEBRUARY 10, 2004

PROSPECTUS

3,444,000 SHARES

CRYOLIFE, INC.

# Edgar Filing: CRYOLIFE INC - Form S-3

## 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 16 - 17 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 February 9, 2004 was \$7.11 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 February \_\_\_\_\_, 2004.

## TABLE OF CONTENTS

	PAGE
SUMMARY.....	1
SELECTED CONSOLIDATED FINANCIAL DATA.....	4
RISK FACTORS.....	5
FORWARD LOOKING STATEMENTS.....	15
USE OF PROCEEDS.....	16
SELLING SHAREHOLDERS.....	16
PLAN OF DISTRIBUTION.....	18
DESCRIPTION OF CAPITAL STOCK.....	21
WHERE YOU CAN FIND MORE INFORMATION.....	25
LEGAL MATTERS.....	26

EXPERTS.....26

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, Inc., incorporated January 19, 1984 in Florida, preserves and distributes human tissues for cardiovascular, vascular and orthopedic transplant applications and develops and commercializes implantable medical devices, including its BioGlue(R) Surgical Adhesive, glutaraldehyde-fixed stentless porcine heart valves, and SynerGraft(R) processed bovine vascular grafts for use as arteriovenous access devices. 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 orthopedic surgery medical specialties, to develop useful implantable products and technologies.

The Company distributes preserved human cardiovascular, vascular and orthopedic tissue throughout the United States, Canada and Europe. 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 a more natural hemodynamic functionality with respect to cryopreserved heart valves, the elimination of a long-term need for anti-coagulation drug therapy, 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 serum albumin and a cross-linking agent. CryoLife can distribute BioGlue throughout the United States and more than 40 other countries for designated applications. In the U.S. BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. In Europe, CryoLife distributes BioGlue under CE Mark product certification for vascular applications, pulmonary indications, such as the repair of air leaks in lungs, and soft tissue repair procedures. CryoLife has also received approval and distributes BioGlue for vascular, pulmonary and soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in Australia, and in several countries in South America and Asia.

CryoLife is using the protein hydrogel 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 dura mater sealing. BioGlue also has the potential to be used as a replacement for spinal disc nuclei. A Company subsidiary is developing a reversible linker 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 glutaraldehyd-fixed stentless porcine heart valve, the

## Edgar Filing: CRYOLIFE INC - Form S-3

CryoLife-O'Brien(R) aortic heart valve. The SynerGraft process involves the depopulation of cells leaving a collagen matrix 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 glutaraldehyde fixed 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.

1

### RECENT DEVELOPMENTS

#### PIPE Offering

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 \$20.0 million. The proceeds from the sale of the common stock will be used for general corporate purposes.

#### Financial Results

On January 7, 2004, CryoLife announced that:

- o Aggregate revenues for 2003 were approximately \$59.6 million.
- o Aggregate revenues for the fourth quarter of 2003 were approximately \$12.8 million.
- o BioGlue revenues were approximately \$27.8 million for the full year 2003 and approximately \$7.8 million in the fourth quarter of 2003. BioGlue revenues increased 33% over full year 2002.
- o Tissue processing revenues were approximately \$30.8 million for the full year 2003 and approximately \$4.9 million in the fourth quarter of 2003.
- o Cardiac tissue processing revenues were approximately \$17.1 million for the full year 2003 and approximately \$2.8 million in the fourth quarter of 2003.
- o Vascular tissue processing revenues were approximately \$12.6 million for the full year 2003 and approximately \$2.0 million in the fourth quarter of 2003.
- o Orthopedic tissue processing revenues were approximately \$1.1 million for the full year 2003 and approximately \$166,000 in the fourth quarter of 2003.

CryoLife has an ongoing, comprehensive program to increase the number of tissues available for distribution to patients who require reconstructive cardiac, vascular, and orthopedic surgeries. This program includes recently implemented initiatives with tissue procurement organizations, operating a newly created, in-house pathology department, and several tissue processing improvements. While CryoLife expects to realize the positive impact of these initiatives beginning in the second quarter of 2004, the Company believes there

## Edgar Filing: CRYOLIFE INC - Form S-3

will be an increase in tissue processing costs through the first quarter of 2004.

As of December 31, 2003, CryoLife had approximately \$11 million in cash, cash equivalents, and marketable securities. These funds have now been supplemented by the net proceeds of the PIPE offering. CryoLife also expects to receive tax refunds of approximately \$2.4 million during 2004.

CryoLife has not completed the preparation of its 2003 financial statements and additional definitive information with respect to 2003 is not yet available. This "Recent Developments" section should not be read to confirm the accuracy of the company's prior guidance with respect to 2003.

Food and Drug Administration.

The FDA inspected CryoLife in October of 2003 in response to a reported orthopedic infection and issued a Form 483 Notice of Observations. The observation in the October 2003 483, which was a reissuance of a previous observation, required CryoLife to complete the validation of its processing operations and procedures for decontaminating tissues, written procedures for the prevention of infectious disease contamination during processing, and its anti-microbial solution. CryoLife submitted its response to the October 2003 483 on October 28, 2003. The submissions include the completed validation report for its anti-microbial solution.

2

Products Liability Litigation and Insurance Coverage.

During 2003, the insurance carriers with the second and third layers of coverage totaling \$15 million for the 2002/2003 policy year tendered their remaining limits of approximately \$13.2 million to CryoLife and made the funds available to be applied to settle all claims outstanding in the relevant policy period. CryoLife continues to attempt to reach settlements of the remaining outstanding litigation.

During 2003 and through January, 2004, CryoLife resolved, or reached agreements in principle to resolve, 22 product liability cases and claims related to the 2002-2003 insurance policy year. CryoLife believes it has sufficient insurance coverage to defend against the four suits related to periods prior to its 2002/2003 insurance policy year. CryoLife currently has two lawsuits pending related to the 2002-2003 insurance policy year and three lawsuits pending related to subsequent periods. There are other claims that have not resulted in lawsuits.

As of September 30, 2003, CryoLife had accrued \$16.7 million in the aggregate for the uninsured portion of estimated potential legal fees and settlement costs related to the Company's product liability lawsuits and potential claims that have been incurred, but not reported. CryoLife is evaluating this accrual to determine if it should be increased or decreased.

-----

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

## Edgar Filing: CRYOLIFE INC - Form S-3

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.

3

### 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 year ended December 31, 2002 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 data set forth below with respect to our Consolidated Balance Sheet and Statement of Operations as of and for the year ended December 31, 1998 are derived from our Consolidated Financial Statements that were audited by Ernst & Young LLP, independent auditors. The historical results are not necessarily indicative of future results of operations. The selected consolidated statement of income data for the nine months ended September 30, 2003 and 2002 and the selected consolidated balance sheet data as of September 30, 2003 are derived from our unaudited consolidated financial statements, which, in our opinion, include all adjustments (consisting of only normal, recurring adjustments) necessary for a fair presentation.

#### SELECTED FINANCIAL INFORMATION

(in thousands, except percentages and per share data)

	NINE MONTHS ENDED: SEPTEMBER 30		YEAR ENDED DECEMBER 31		
	2003	2002	2002	2001	2000
<b>OPERATIONS</b>					
Revenues	\$ 46,730	\$ 65,624	\$ 77,795	\$ 87,671	\$ 77,096
Net (loss)/income	(25,050)	(22,064)	(27,761)	9,166	7,817
Research and development as a percentage of revenues	6.1%	5.6%	5.9%	5.4%	6.8%
<b>(LOSS)/EARNINGS PER SHARE 1</b>					
Basic	\$ (1.27)	\$ (1.14)	\$ (1.43)	\$ 0.49	\$ 0.42
Diluted	\$ (1.27)	\$ (1.14)	\$ (1.43)	\$ 0.47	\$ 0.41

## Edgar Filing: CRYOLIFE INC - Form S-3

	SEPT. 30, 2003	----- 2002	2001	DECEMBER 31 2000
Total assets	\$ 86,523	\$ 106,414	\$ 129,310	\$ 112,009
Working capital	20,251	37,816	66,668	69,063
Long Term Liabilities	5,030	2,752	10,071	12,192
Shareholder's equity	55,319	79,800	101,439	89,395
Current ratio 2	2:1	3:1	5:1	8:1

1 Reflects adjustment for 3-for-2 stock split effected December 27, 2000.

2 Current assets divided by current liabilities.

4

### 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.

SINCE 2002 CRYOLIFE HAS FACED SEVERAL EXTRAORDINARY CHALLENGES, INCLUDING THE 2002 FDA RECALL ORDER, DECREASED REVENUES, AND INCREASED EXPENSES, AND MAY NOT BE SUCCESSFUL IN ADDRESSING THEM

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 orthopedic 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 a shareholders' class action suit and a derivative shareholder suit, 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



### Edgar Filing: CRYOLIFE INC - Form S-3

tissue processing industry, making inquiries of CryoLife. The SEC has initiated and continues to pursue a formal investigation of CryoLife. The combined effect of these challenges has been to reduce Company revenues, increase its costs to process tissues and operating expense 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.

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 orthopedic 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 \$20.0 million. During the fourth quarter of 2003, these revenues were approximately \$4.9 million or 52% 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 FDA Order. Although CryoLife expects them to decrease somewhat beginning in the

5

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 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.

## Edgar Filing: CRYOLIFE INC - Form S-3

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. 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.

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

The Company has received only nominal revenue from the preservation of orthopedic tissue since August 14, 2002. For the year ended December 31, 2001, human tissue preservation services revenues for orthopedic 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 orthopedic tissue were \$11.9 million (prior to the reduction for estimated tissue recall returns), which represented 23% of CryoLife's revenues. For the year ended December 31, 2003, revenues for preservation services for orthopedic tissue were \$1.1 million, which represented 2% of CryoLife's revenues. The demand for orthopedic 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. If a significant number of implanting hospitals or physicians refused to use tissues preserved by the Company, CryoLife's 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 manufacturing facilities could have a material adverse effect on CryoLife's business, results of operations and financial position.

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

## Edgar Filing: CRYOLIFE INC - Form S-3

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 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 FEBRUARY 2003 FORM 483 NOTICE OF OBSERVATIONS OR ITS OCTOBER 2003 FORM 483 NOTICE OF OBSERVATIONS

The FDA issued new Form 483 Notice of Observations in February 2003 and October 2003. 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 business, results of operations, financial position or cashflows.

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.

CRYOLIFE IS THE SUBJECT OF AN ONGOING SEC INVESTIGATION

CryoLife is the subject of an ongoing SEC investigation. An adverse finding by the SEC could have a material adverse effect on CryoLife's business financial position, results of operations, and cash flows. At the present time, CryoLife is unable to predict the outcome of this matter.

CRYOLIFE'S INSURANCE COVERAGE MAY BE INSUFFICIENT

## Edgar Filing: CRYOLIFE INC - Form S-3

### 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

7

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 recorded a liability on its September 30, 2003, consolidated balance sheet and a corresponding expense for the estimated cost of resolving these claims and reflecting the uninsured portion of the estimated liability. The amounts recorded were estimates, and did not reflect actual settlement arrangements or final judgments, the latter of which could include punitive damages. CryoLife's product liability insurance policies do not include coverage for any punitive damages. If CryoLife is unsuccessful in arranging acceptable settlements of product liability claims, there may not be sufficient insurance coverage and liquid assets to meet these obligations. Additionally, if one or more of the product liability claims in which CryoLife is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed CryoLife's available insurance coverage and liquid assets. If CryoLife is unable to meet required future cash payments to resolve the outstanding product liability claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of CryoLife.

### Class Action Lawsuit

Several putative class action lawsuits were filed in July through September 2002 against CryoLife and certain officers of CryoLife, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that CryoLife failed to disclose its 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. CryoLife carries directors' and officers' liability insurance policies, which CryoLife presently believes to be adequate to defend against this action. Nonetheless, an adverse judgment in excess of CryoLife's insurance coverage could have a material adverse effect on CryoLife's financial position, results of operations, and cash

## Edgar Filing: CRYOLIFE INC - Form S-3

flows.

### 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 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

8

amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of the Company. An adverse decision in the case could have a material adverse effect on CryoLife.

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

Because of 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.

INTENSE COMPETITION MAY AFFECT CRYOLIFE'S ABILITY TO RECOVER FROM THE FDA ORDER AND DEVELOP ITS SURGICAL ADHESIVE BUSINESS

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,

## Edgar Filing: CRYOLIFE INC - Form S-3

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.

There can be no assurance that CryoLife's products and services will be able to compete successfully with the products of these or other companies. Any products developed by CryoLife that gain regulatory clearance or approval would have to compete for market acceptance and market share. Failure of CryoLife to compete effectively could have a material adverse effect on CryoLife's business, financial condition, results of operations and cash flows. The FDA Order and related adverse publicity had an adverse effect on CryoLife's competitive position, which had a material adverse effect on CryoLife's results of operations. The FDA Order and subsequent FDA activity may continue to have an adverse effect on CryoLife's competitive position, which may continue to have a material adverse effect on CryoLife's results of operations. As a result, CryoLife's competitors may gain competitive advantages that may be difficult to overcome.

RAPID TECHNOLOGICAL CHANGE COULD CAUSE CRYOLIFE'S SERVICES AND PRODUCTS TO BECOME OBSOLETE

The technologies underlying CryoLife's products and services are subject to rapid and profound technological change. CryoLife expects competition to intensify 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 offers or is seeking to develop. Any such occurrence could have a material adverse effect on CryoLife's business, financial condition, results of operations, and cash flows.

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

9

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

## Edgar Filing: CRYOLIFE INC - Form S-3

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 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. In February 2001 CryoLife formed AuraZyme, a wholly-owned subsidiary, in order to seek a corporate collaboration or to complete a potential private placement of equity or equity-oriented securities to fund the commercial development of the ACT. CryoLife has been seeking such funding since 1998. This strategy is designed to allow CryoLife to continue development of this technology without incurring additional research and development expenditures, other than through AuraZyme. There can be no guarantee that such funding can be obtained on acceptable terms, if at all, 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.

### UNCERTAINTIES REGARDING THE SYNERGRAFT TECHNOLOGY

CryoLife processes bovine tissues with the SynerGraft technology and processed human tissues with the SynerGraft technology until February 22, 2003, following the receipt of the informal February FDA letter. In animal studies, explanted SynerGraft treated allograft heart valves have been shown to repopulate with the hosts' cells. However, should SynerGraft-treated tissues implanted in humans not consistently and adequately repopulate with the human host cells, the SynerGraft-treated tissues may not have the improved longevity over the CryoLife standard processing technology that CryoLife currently expects. This could have a material adverse effect on future expansion plans and could limit future growth.

EXTENSIVE GOVERNMENT REGULATION MAY ADVERSELY AFFECT CRYOLIFE'S 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 products. The allograft heart valves to which CryoLife applies its preservation services 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, 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, 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 to CryoLife and adversely affect CryoLife's competitive position. The FDA may also place conditions on product approvals that could restrict commercial applications of such products. Product marketing approvals or clearances may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Delays imposed by the governmental clearance process may materially reduce the period during which CryoLife has the exclusive right to commercialize patented products.

Also, delays or rejections may be encountered during any stage of the



## Edgar Filing: CRYOLIFE INC - Form S-3

regulatory approval process based upon the failure of the clinical or other data to demonstrate compliance with, or upon the failure of the product to meet, the regulatory agency's requirements for safety, efficacy and quality, and those requirements may become more stringent due to changes in applicable law, regulatory agency policy or the adoption of new regulations. Clinical trials may also be delayed due to unanticipated side effects, inability to locate, recruit and qualify sufficient numbers of patients, lack of funding, the inability to locate or recruit clinical investigators, the redesign of clinical trial programs, the inability to manufacture or acquire sufficient quantities of the particular product or any other components required for clinical trials, changes in CryoLife's or its collaborative partners' development focus and disclosure of trial results by competitors.

Even if regulatory approval is obtained for any of CryoLife's products or services, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. Products or services marketed by CryoLife 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

11

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 CryoLife's methods of charging for its preservation services. CryoLife's laboratory operations are subject to the U.S. Department of Labor, Occupational Safety and Health Administration and Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations governing the processing, transportation and storage of human organs and tissue.

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 AFFECT THE VALUE OF CRYOLIFE'S INTELLECTUAL PROPERTY

CryoLife owns several patents, patent applications and licenses relating to its technologies, which it believes provide important competitive advantages. There can be no assurance that CryoLife's pending patent applications will issue

## Edgar Filing: CRYOLIFE INC - Form S-3

as patents or that challenges will not be instituted concerning the validity or enforceability of any patent owned by CryoLife, or, if instituted, that such challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of a patent could be substantial. Furthermore, there can be no assurance that competitors will not independently develop similar technologies or duplicate CryoLife's technologies or design around the patented aspects of CryoLife's technologies. There can be no assurance that CryoLife's proposed technologies will not infringe patents or other rights owned by others.

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

### UNCERTAINTIES REGARDING FUTURE HEALTH CARE REIMBURSEMENT MAY AFFECT THE AMOUNT AND TIMING OF CRYOLIFE'S 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 orthopedic 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

12

for CryoLife to maintain price levels sufficient for realization of an appropriate return on its investment in developing new products.

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

CRYOLIFE IS DEPENDENT ON ITS KEY PERSONNEL

## Edgar Filing: CRYOLIFE INC - Form S-3

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 operation. Competition for such personnel is intense and there can be no assurance that CryoLife will be successful in attracting and retaining such personnel. 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 TWO YEARS ENDED DECEMBER 31, 2001 AND FOR THE YEAR ENDED DECEMBER 31, 2000 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 and for the year ended December 31, 2000 included in CryoLife's Form 10-K for the year ending December 31, 2002 and incorporated into this prospectus.

In addition, Arthur Andersen LLP has not consented to the inclusion of their report dated March 27, 2002 in CryoLife's Form 10-K for the year ending December 31, 2002, 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, 2002 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.

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 January 22, 2004 has ranged from a high of \$31.31 to a low of \$1.89.

## Edgar Filing: CRYOLIFE INC - Form S-3

### 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.

### 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.

14

### 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:

## Edgar Filing: CRYOLIFE INC - Form S-3

- 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 February 2003 FDA 483 and October 2003 FDA 483;
- o the estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies, as well as the estimates of the amounts accrued for product loss claims incurred but not reported at December 31, 2002 or September 30, 2003;
- 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;

15

- 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

## Edgar Filing: CRYOLIFE INC - Form S-3

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

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 January 31, 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.

16

NAMES OF SHAREHOLDERS	BENEFICIAL OWNERSHIP PRIOR TO THE OFFERING		NUMBER OF SHARES OFFERED
	SHARES	PERCENTAGE	
Atlas Equity I, Ltd. (2).....	250,000	*	250,000
BlackRock Funds, Small Cap Growth Equity Portfolio (3) (12).....	600,000	2.6%	600,000
Capital Ventures International (4).....	500,000	2.2%	500,000
Deephaven Small Cap Growth Fund LLC (5) (12).	400,000	1.7%	400,000
MFS Series I Trust on behalf of MFS New Discovery Fund (6) (12).....	598,300	2.6%	119,500
MFS/Sun Life Series Trust on behalf of New Discovery Series (7) (12).....	111,000	*	22,000
MFS Variable Insurance Trust on behalf of MFS New Discovery Series (8) (12).....	218,100	*	48,500
The Riverview Group LLC (9) (12).....	160,000	*	160,000
Smithfield Fiduciary LLC (10) (12).....	944,000	4.1%	944,000
UBS O'Connor LLC f/b/o O'Connor PIPES Corporate Strategies Ltd. (11).....	400,000	1.7%	400,000

## Edgar Filing: CRYOLIFE INC - Form S-3

-----  
\*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 before completion of the offering.

(2) Balyasny Asset Management, LLC ("Balyasny") is the manager of Atlas Equity I, Ltd. ("Atlas"). By virtue of its ownership of 100% of the equity interest in Atlas, Balyasny may be deemed to beneficially own the shares held by Atlas. By virtue of his majority ownership of the equity interest in Balyasny, which owns 100% of the equity interest in Atlas, Dmitry Balyasny may be deemed to beneficially own the shares of the Company's Common Stock beneficially owned by Atlas Fund, LLC. The address for this shareholder is 181 W. Madison, Suite 3600, Chicago, IL 60602, Attn: Dmitry Balyasny.

(3) BlackRock Funds is a registered investment company. Its investment manager is BlackRock Advisors, 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, 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) The shareholder is a registered investment company. Massachusetts Financial Services Company ("MFSC"), a registered investment advisor, has sole investment and voting power over these shares. Through this and other investment funds, and private client accounts, MFSC may be deemed to have voting and investment power over an aggregate of 1,498,010 shares of CryoLife common stock. Clump & Co. acts as a nominee and is the record holder of these shares. The address for this shareholder is c/o Massachusetts Financial Services Company, 500 Boylston Street, Boston, Massachusetts 02116.

(7) The shareholder is a registered investment company. MFSC has sole investment and voting power over these shares. Through this and other investment funds, and private client accounts, MFSC may be deemed to have voting and investment power

over an aggregate of 1,498,010 shares of CryoLife common stock. Inletbluff & Co. acts as a nominee and is the record holder of these shares. The address for this shareholder is c/o Massachusetts Financial Services Company, 500 Boylston Street, Boston, Massachusetts 02116.

### Edgar Filing: CRYOLIFE INC - Form S-3

(8) The shareholder is a registered investment company. MFSC has sole investment and voting power over these shares. Through this and other investment funds, and private client accounts, MFSC may be deemed to have voting and investment power over an aggregate of 1,498,010 shares of CryoLife common stock. Newwind & Co. acts as a nominee and is the record holder of these shares. The address for this shareholder is c/o Massachusetts Financial Services Company, 500 Boylston Street, Boston, Massachusetts 02116.

(9) 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.

(10) 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.

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

(12) 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 PIPE offering 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



## Edgar Filing: CRYOLIFE INC - Form S-3

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;

18

- 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
- o a combination of any such methods of sale.

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.

## Edgar Filing: CRYOLIFE INC - Form S-3

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.

19

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;
- 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

## Edgar Filing: CRYOLIFE INC - Form S-3

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.

20

### 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 January 31, 2004, there were 23,225,566 shares of Common Stock outstanding held by approximately 431 shareholders of record and no shares of Preferred Stock outstanding.

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

#### COMMON STOCK

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

Holders of Common Stock are entitled to receive, on a pro rata basis, such dividends and distributions, if any, as may be declared from time to time by the Board of Directors out of funds legally available therefor, subject to any preferential dividend right of any issued and outstanding shares of Preferred Stock. In the event of liquidation, dissolution or winding up of the Company, after payment of creditors, holders of Common Stock are entitled to share ratably in all assets, subject to the payment of any liquidation preference of any issued and outstanding shares of Preferred Stock. The shares of Common Stock currently outstanding are validly issued, fully paid and non-assessable.

#### PREFERRED STOCK

The Board of Directors of the Company is empowered, without approval of the Company's shareholders, to cause shares of Preferred Stock (the "Preferred Stock") to be issued in one or more series and to fix and determine the relative rights and preferences of the shares of any such series, subject to the limits of Florida law. Because the Board of Directors has the power to establish the preferences and rights of each series, it may afford the holders of any series of Preferred Stock preferences, powers and rights, voting or otherwise, senior to the rights of holders of Common Stock. The issuance of Preferred Stock could have the effect of delaying or preventing a change in control of CryoLife. The Board of Directors has no present plans to issue any shares of Preferred Stock.

#### STOCK OPTIONS

## Edgar Filing: CRYOLIFE INC - Form S-3

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.

21

### SPECIAL MEETINGS

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

### PROHIBITION OF SHAREHOLDER ACTION WITHOUT MEETING

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

### ANTI-TAKEOVER STATUTES

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

### ABILITY TO CONSIDER OTHER CONSTITUENCIES

The Directors of the Company are subject to the "general standards for Directors" provisions set forth in Section 607.0830 of the FBCA. These provisions provide that, among other things, in discharging his or her duties and determining what is in the best interests of the Company, a Director may consider such factors as the Director deems relevant, including the long-term prospects and interests of the Company and its shareholders, and the social, economic, legal or other effects of any proposed action on the employees, suppliers or customers of the Company, the communities in which the Company operates and the economy in general. Consequently, in connection with any

## Edgar Filing: CRYOLIFE INC - Form S-3

proposed corporate action, the Board of Directors is empowered to consider interests of other constituencies in addition to the interests of the Company's shareholders. Shareholders should be aware that Directors who take into account these other factors may make decisions which are less beneficial to the shareholders than if the law did not permit consideration of such other factors.

### SHAREHOLDER RIGHTS PLAN

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

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

22

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

## Edgar Filing: CRYOLIFE INC - Form S-3

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).

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 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.

## Edgar Filing: CRYOLIFE INC - Form S-3

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

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

At any time after any person or group becomes an Acquiring Person and prior to the acquisition by such person or group of 50% or more of the outstanding Common Stock of the Company, the Board of Directors of the Company may exchange the Rights (other than Rights owned by such person or group which will have become void), in whole or in part, at an exchange ratio of one share of Common Stock per Right.

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

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

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

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

## Edgar Filing: CRYOLIFE INC - Form S-3

### 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 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, 2002.
- o The Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.
- o The Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, as amended.
- o The Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003.
- o The Registrant's Current Reports on Forms 8-K filed on April 3, May 1, July 15, August 5, August 11, August 21 and November 4, 2003, as well as January 7, January 26 and February 9, 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



## Edgar Filing: CRYOLIFE INC - Form S-3

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.

25

### 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 schedules as of December 31, 2002 and for the year 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, 2002 have been audited by Deloitte & Touche LLP, independent auditors, as stated in their reports (which reports express an unqualified opinion and with respect to the report on the consolidated financial statements for the year ended December 31, 2002 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 are incorporated herein by reference and have been so incorporated in reliance upon the reports 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.

26

CRYOLIFE, INC.

3,444,000 SHARES COMMON STOCK

-----  
PROSPECTUS  
-----

FEBRUARY \_\_, 2004

PART II  
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

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

SEC registration fee.....	\$	2,944
NYSE listing fee.....		40,186
Printing expenses.....		10,000
Accounting fees and expenses.....		25,000
Legal fees and expenses.....		50,000

Edgar Filing: CRYOLIFE INC - Form S-3

Miscellaneous.....	11,870
	-----
Total.....	\$ 140,000
	=====

-----

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

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

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

Under Section 607.0850(1) of the FBCA, a corporation may indemnify any of its directors and officers against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding (including any appeal thereof) (i) if such person acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and (ii) with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. In actions brought by or in the right of the corporation, however, Section 607.0850(2) provides that no indemnification shall be made in respect of any claim, issue or matter as to which the director or officer shall have been adjudged to be liable unless, and only to the extent that, the court in which such proceeding was brought, or any other court of competent jurisdiction, shall determine upon application that, despite the adjudication of liability but in view of all circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such court shall deem proper. Article X of the Registrant's Restated Articles of Incorporation and Article VI of the Registrant's Bylaws require that, if in the judgment of the majority of the Board of Directors (excluding from such majority any director under consideration for indemnification) the criteria set forth under Section 607.0850 have been met, then the Registrant shall indemnify its directors and officers for certain liabilities incurred in the performance of their duties on behalf of the Registrant to the maximum extent allowed by Section 607.0850 of the FBCA (formerly Section 607.014 of the Florida General Corporation Act).

The Agreement and Plan of Merger dated March 5, 1997, between Registrant and Ideas for Medicine, Inc. ("IFM") and certain stockholders of IFM provides that any investors exercising registration rights pursuant to such agreement must indemnify the officers and directors signing the registration statement against any liability arising from statements or omissions made in reliance upon information furnished by such investors to the Registrant for use in such registration statement.

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

## Edgar Filing: CRYOLIFE INC - Form S-3

### ITEM 16. EXHIBITS

Exhibit No. -----	Exhibit -----
3.1	Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003).
3.2	ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter year ended March 31, 2003).
3.3	Articles of Amendment to the Articles of Incorporation of CryoLife. (Incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000).
4.1	Form of Certificate for the Company's Common Stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Registrant's Registration Statement on Form S-1 (Commission File No. 33-56388).
4.2	Form of Certificate for the Company's Common Stock (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997).
4.3	Rights Agreement between the Company and Chemical Mellon Shareholder Services, L.L.C., as Rights Agent, dated as of November 27, 1995. (Incorporated by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000).
4.4*	First Amendment to Rights Agreement, effective June 1, 1997, executed by the Company and American Stock Transfer & Trust Company, as successor Rights Agent.
5*	Opinion of Arnall Golden & Gregory, LLP regarding legality
23.1*	Consent of Arnall Golden & Gregory, LLP (included as part of Exhibit 5 hereto).
23.2*	Consent of Deloitte & Touche LLP
23.3*	Notice regarding consent of Arthur Andersen LLP

-----  
\* Filed with this Form S-3.

### ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

- (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most

## Edgar Filing: CRYOLIFE INC - Form S-3

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

II-2

"Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for purposes of determining liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(5) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

Edgar Filing: CRYOLIFE INC - Form S-3

II-3

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Kennesaw, State of Georgia on February 10, 2004.

CRYOLIFE, INC.

By: /s/ Steven G. Anderson

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

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

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

PRINCIPAL EXECUTIVE, FINANCIAL & ACCOUNTING OFFICERS AND DIRECTORS:

-----

Name -----	Title -----	Date -----
/s/ Steven G. Anderson ----- Steven G. Anderson	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	February 10, 2004
/s/ D. Ashley Lee ----- D. Ashley Lee	Vice President of Finance, Treasurer and Chief Financial Officer (Principal Financial and Accounting Officer)	February 10, 2004
/s/ Thomas F. Ackerman ----- Thomas F. Ackerman	Director	February 10, 2004

Edgar Filing: CRYOLIFE INC - Form S-3

----- Dan Bevevino	Director	February __, 2004
/s/ John M. Cook ----- John M. Cook	Director	February 10, 2004
----- Ronald Charles Elkins, M.D.	Director	February __, 2004
/s/ Virginia C. Lacy ----- Virginia C. Lacy	Director	February 10, 2004
/s/ Ronald D. McCall ----- Ronald D. McCall	Director	February 10, 2004
/s/ Bruce J. Van Dyne, M.D. ----- Bruce J. Van Dyne, M.D.	Director	February 10, 2004

II-4

EXHIBIT INDEX

Exhibit No. -----	Exhibit -----
3.1	Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003).
3.2	ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter year ended March 31, 2003).
3.3	Articles of Amendment to the Articles of Incorporation of CryoLife. (Incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000).
4.1	Form of Certificate for the Company's Common Stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Registrant's Registration Statement on Form S-1 (Commission File No. 33-56388).
4.2	Form of Certificate for the Company's Common Stock (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997).
4.3	Rights Agreement between the Company and Chemical Mellon Shareholder Services, L.L.C., as Rights Agent, dated as of November 27, 1995. (Incorporated by reference to Exhibit 10.36 to

## Edgar Filing: CRYOLIFE INC - Form S-3

the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000).

- 4.4\* First Amendment to Rights Agreement, effective June 1, 1997, executed by the Company and American Stock Transfer & Trust Company, as successor Rights Agent.
- 5\* Opinion of Arnall Golden & Gregory, LLP regarding legality
- 23.1\* Consent of Arnall Golden & Gregory, LLP (included as part of Exhibit 5 hereto).
- 23.2\* Consent of Deloitte & Touche LLP
- 23.3\* Notice regarding consent of Arthur Andersen LLP

-----

\* Filed with this Form S-3.