

CRYOLIFE INC  
Form 424B5  
March 08, 2005

[QuickLinks](#) -- Click here to rapidly navigate through this document

Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-121406

**The information in this prospectus supplement and the accompanying prospectus is not complete and may be changed. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities and are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, Dated March 8, 2005**

**PROSPECTUS SUPPLEMENT**  
To Prospectus dated January 7, 2005

**400,000 Shares**

**CRYOLIFE, INC.**

**% Convertible Preferred Stock**  
**(Cumulative Dividend, Liquidation Preference \$50 Per Share)**

---

CryoLife, Inc. is offering 400,000 shares of % convertible preferred stock, which is referred to in this prospectus as "convertible preferred stock."

Dividends will be cumulative from the date of original issue at the annual rate of % of the liquidation preference of the convertible preferred stock, payable quarterly on the first day of March, June, September, December, commencing June 1, 2005. Any dividends must be declared by our board of directors and must come from funds that are legally available for dividend payments.

You may convert each share of the convertible preferred stock into approximately shares of our common stock based on the initial conversion price of \$ , subject to certain adjustments.

We may elect to automatically convert the convertible preferred stock into our common stock if the closing price of our common stock has exceeded \$ , which is 150% of the conversion price of the convertible preferred stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

If we elect to automatically convert, or you elect to voluntarily convert, some or all of the convertible preferred stock into our common stock prior to March , 2008, we will make an additional payment on the convertible preferred stock equal to the aggregate amount of dividends that would have been payable on the convertible preferred stock through and including March , 2008, less any dividends already paid on the convertible preferred stock.

We may elect to redeem the convertible preferred stock on or after March , 2008 on the terms described in this prospectus.

Edgar Filing: CRYOLIFE INC - Form 424B5

The convertible preferred stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

Shares of our common stock are listed on the New York Stock Exchange under the symbol "CRY." The last reported sale price of our common shares on March 7, 2005 was \$7.73 per share.

We are authorized to list our convertible preferred stock on the New York Stock Exchange under the symbol "CRY Pr."

**This investment involves risk. See "Risk Factors" beginning on page S-13.**

---

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ 50.00	\$ 20,000,000
Underwriting discounts and commissions	\$ 3.00	\$ 1,200,000
Proceeds, before expenses, to CryoLife, Inc.	\$ 47.00	\$ 18,800,000

---

*The underwriter has a 30-day option to purchase up to 60,000 additional shares of convertible preferred stock from us to cover over-allotments, if any.*

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**Piper Jaffray**

**The date of this prospectus supplement is March , 2005.**

---

## TABLE OF CONTENTS

	<u>Page</u>
<b>Prospectus Supplement</b>	
Summary	S-1
Recent Developments	S-7
Risk Factors	S-13
Special Note Regarding Forward-Looking Statements	S-31
Use of Proceeds	S-33
Dividend Policy	S-33
Ratio of Earnings to Fixed Charges and Preferred Stock Dividends	S-34
Price Range of Common Stock	S-35
Capitalization	S-36
Description of Convertible Preferred Stock	S-37
Material Federal Income Tax Consequences	S-48
Underwriting	S-54
Legal Matters	S-55
Experts	S-56
Where You Can Find More Information	S-56
<b>Prospectus</b>	
Summary	1
About this Prospectus	1
About CryoLife	1
Risk Factors	6
Forward Looking Statements	20
Use of Proceeds	21
Ratio of Earnings to Fixed Charges	21
Description of Capital Stock	22
Description of Depositary Shares	28
Plan of Distribution	30
Where You Can Find More Information	32
Legal Matters	33
Experts	33

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

*CryoLife BioGlue* surgical adhesive and *DynerGraft* are trademarks of CryoLife, Inc. All other trademarks appearing in this prospectus are the property of their respective holders.

## SUMMARY

*The items in the following summary are described in more detail later in this prospectus supplement and the accompanying prospectus. This summary provides an overview of selected information and does not contain all the information you should consider. Therefore, you should also read the more detailed information set out in this prospectus supplement and the accompanying prospectus, the financial statements and the other information incorporated by reference into this prospectus.*

## ABOUT US

CryoLife develops and commercializes implantable medical devices and preserves and distributes human tissues for cardiovascular, vascular, and orthopaedic transplant applications. The implantable devices include BioGlue® Surgical Adhesive ("BioGlue"), porcine heart valves, and grafts of bovine tissue processed using our proprietary SynerGraft® technology.

Our proprietary product BioGlue, designed for cardiovascular, vascular, pulmonary, and general surgical applications, is a polymer based on bovine blood protein and an agent for cross linking proteins. We can distribute BioGlue throughout the United States and more than 50 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. We distribute BioGlue under Conformité Européene ("CE") Mark product certification in the European Economic Area ("EEA") for soft tissue repair procedures (which includes cardiovascular, pulmonary, and additional soft tissue repair procedures). We have also received approval and distribute BioGlue for soft tissue repairs in Canada. Additional marketing approvals have been granted for specified applications in several other countries including countries within Latin America and Asia. The recently available syringe delivery system provides BioGlue without a separate delivery system. This syringe design configuration was approved by the FDA, was added to the CE Mark approval in May 2004, and is currently under review in Canada.

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

Through our continuing research and development activities, we endeavor to use our expertise in protein chemistry, biochemistry, and cell biology, and our understanding of the cardiovascular, vascular, and orthopaedic surgery medical specialties, to acquire and develop useful implantable products and technologies. We generally perform significant research and development work before offering services and products, building on either existing proprietary and non-proprietary knowledge or acquired technology and know-how. Our tissue preservation services were developed based on prior work done by third parties. We developed our BioGlue product from a substance originally developed by a third party and acquired by us. In addition we continue to explore technologies that may further enhance the safety of our tissue processing.

We are developing several new products, including modifications to the BioGlue delivery system. Our Protein Hydrogel Technology, which we refer to as PHT, is the technology underlying BioGlue. We are using PHT as the base for several potential products in development including BioFoam, BioDisc and BioLastic . BioFoam has the potential to be used to rapidly fill and seal internal body cavities, such as aneurysm sacs, and provide hemostasis in penetrating wounds and severe trauma. BioDisc has the potential to be used as a replacement for the soft tissue in spinal discs. BioLastic , a derivative of the

BioGlue technology, might potentially be used for reinforcing or patching vascular tissue and reducing adhesions.

Our business is subject to a number of risks, including the possibility of FDA actions, additional expenses and losses from product recalls, possible losses from ongoing product liability, securities and other litigation, regulatory action, adverse publicity and lower demand for our products resulting from product recalls and other FDA activity, inability to obtain sufficient insurance coverage, possible inability to protect the intellectual property rights in our technology, the possible inability to obtain necessary regulatory approvals, and possible future lack of capital. See "Risk Factors."

In August 2002 the FDA issued an order, which we refer to as the FDA Order, regarding several types of tissue processed by us. Non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife from October 3, 2001 to September 5, 2002 was required to be retained until recalled, destroyed, the safety was confirmed, or an agreement was reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA. In September 2002, we reached an agreement with the FDA permitting us to immediately resume processing and limited distribution of our non-valved cardiac and vascular tissues. We made changes to our procedures, and now process most of the tissues that were subject to the FDA recall.

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

Our proprietary SynerGraft process involves the depopulation of cells in tissue leaving a matrix of protein fibers that has the potential to be repopulated with the recipient's cells. We believe this process increases graft longevity and improves the biocompatibility and functionality of the tissue. During 2003, we received other notices from the FDA stating that the FDA had determined that non-valved human cardiovascular tissue processed using CryoLife's SynerGraft technology would be regulated as medical devices and would require additional premarket approval authorization for continued distribution of these tissues. The FDA also notified us that the application of the SynerGraft technology to human heart valves (CryoValve SG), currently regulated as Class II medical devices, was considered to be a major manufacturing change requiring a 510(k) submission. After receipt of the FDA letter in February 2003, we suspended the use of the SynerGraft technology in the processing of human tissues.

Until the issues surrounding the SynerGraft treated tissues are resolved, we are employing our traditional processing methods on cardiovascular and vascular tissues.

#### **Our Corporate Information**

CryoLife, Inc. was incorporated January 19, 1984 in Florida. All references to "CryoLife," the "Company," "we," "us" or "our" in this prospectus supplement or the accompanying prospectus mean CryoLife, Inc., a Florida corporation, and all consolidated subsidiaries of CryoLife, Inc., except where it is made clear that the term means only the parent company. Our principal executive offices are located at 1655 Roberts Boulevard, NW, Kennesaw, Georgia 30144. Our telephone number is (770) 419-3355 and our Web site is located at [www.cryolife.com](http://www.cryolife.com). Information contained on our Web site is not part of this prospectus supplement or the accompanying prospectus.

**THE OFFERING**

Securities Offered	400,000 shares of % convertible preferred stock, par value \$0.01 per share (460,000 shares of convertible preferred stock if the underwriter exercises its over-allotment option in full). Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of the underwriter's over-allotment option.
Dividends	Dividends will be cumulative from the date of original issue at the annual rate of % of the liquidation preference of the convertible preferred stock, payable quarterly on the first day of March, June, September and December commencing June 1, 2005. Any dividends must be declared by our board of directors and must come from funds that are legally available for dividend payments. Payment of dividends on convertible preferred stock and our common stock are subject to additional restrictions as described under "Risk Factors we may not be able to pay cash dividends on any class of capital stock due to legal and contractual restrictions and lack of liquidity."
Conversion Rights	Unless we redeem the convertible preferred stock, the convertible preferred stock can be converted at your option at any time into shares of our common stock at an initial conversion price of \$ (equivalent to a conversion rate of approximately shares of common stock for each share of convertible preferred stock). The initial conversion price with respect to the convertible preferred stock is subject to adjustment in certain events, including a non-stock fundamental change or a common stock fundamental change, which are explained in more detail under the section entitled "Description of Convertible Preferred Stock Conversion Conversion Price Adjustment Merger, Consolidation or Sale of Assets."
Automatic Conversion	Unless we redeem the convertible preferred stock, we may elect to automatically convert some or all of the convertible preferred stock into shares of our common stock if the closing sale price of our common stock has exceeded 150% of the conversion price for at least 20 out of 30 consecutive trading days ending within five trading days prior to the notice of automatic conversion.
Dividend Make-Whole Payment	If we elect to automatically convert, or you elect to voluntarily convert, some or all of the convertible preferred stock into shares of our common stock prior to March , 2008, we will make an additional payment on the convertible preferred stock equal to the aggregate amount of cumulative dividends that are accrued and unpaid on the convertible preferred stock from the date of original issue through and including March , 2008. This additional payment is payable by us in cash or, at our option, in shares of our common stock, or a combination of cash and shares of our common stock.

Edgar Filing: CRYOLIFE INC - Form 424B5

	<p>In the event of an automatic conversion or any voluntary conversion undertaken after we provide notice of an automatic conversion, the shares of common stock issued in payment of the dividend make-whole payment will be valued at 150% of the conversion price on the effective date of the conversion. In all other circumstances, any shares of our common stock issued in payment of the dividend make-whole payment will be valued at the greater of (i) 95% of the average closing price of our common stock for the five trading days prior to the effective date of conversion or (ii) \$ _____, which was the last reported sale price of our common stock on _____, 2005.</p>
Liquidation Preference	<p>In the event of our voluntary or involuntary dissolution, liquidation or winding up, you will be entitled to be paid a liquidation preference equal to \$50 per share of convertible preferred stock, plus accrued and unpaid dividends before any distribution of assets may be made to holders of capital stock ranking junior to the convertible preferred stock.</p>
Optional Redemption	<p>On or after March _____, 2008, we may redeem the convertible preferred stock, in whole or in part, at our option at the redemption prices set forth in this prospectus supplement, together with accrued but unpaid dividends to, but excluding, the redemption date. See the section entitled "Description of Convertible Preferred Stock - Optional Redemption" below.</p>
Voting Rights	<p>Except as provided by law and in other limited situations described in this prospectus supplement, you will not be entitled to any voting rights. However, you will, among other things, be entitled to vote as a separate class to elect two directors if we have not paid the equivalent of six or more quarterly dividends, whether or not consecutive. These voting rights will continue until we pay the full accrued but unpaid dividends on the convertible preferred stock.</p>
Use of Proceeds	<p>We expect to use the net proceeds of this offering for working capital and general corporate purposes.</p>
New York Stock Exchange Symbol for the Common Stock	<p>Our common stock is traded on the New York Stock Exchange under the symbol "CRY."</p>
Proposed New York Stock Exchange Symbol for the Convertible Preferred Stock	<p>"CRY Pr."</p>
Risk Factors	<p>An investment in the convertible preferred stock involves a high degree of risk. See the section entitled "Risk Factors" beginning on page S-13 for a discussion of certain factors that should be considered in evaluating an investment in the convertible preferred stock.</p>

## SUMMARY CONSOLIDATED FINANCIAL DATA

The following Summary Consolidated Financial Data should be read in conjunction with "Recent Developments Financial Results for the Year Ended December 31, 2004" included herein and our Consolidated Financial Statements and Notes thereto, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information incorporated herein by reference. The selected data presented below for and as of the end of the years ended December 31, 2002, 2003 and 2004 are derived from our Consolidated Financial Statements that were audited by Deloitte and Touche LLP, independent auditors, and are incorporated herein by reference. The selected data presented below as of and for each of the years in the two-year period ended December 31, 2001 are derived from our Consolidated Financial Statements that were audited by Arthur Andersen LLP, independent auditors. The historical results are not necessarily indicative of future results of operations.

	Year Ended December 31,				
	2000	2001	2002	2003	2004
(in thousands, except percentages and per share data)					
<b>Statement of Operations Data</b>					
<b>Revenues</b>					
Products	\$ 9,384	\$ 11,130	\$ 21,597	\$ 28,263	\$ 36,637
Human tissue preservation services	67,096	75,552	55,373	30,777	25,676
Research grants and distribution	616	989	825	492	71
<b>Total Revenues</b>	<b>77,096</b>	<b>87,671</b>	<b>77,795</b>	<b>59,532</b>	<b>62,384</b>
<b>Cost and expenses</b>					
Products	5,847	5,464	10,270	7,506	7,818
Human tissue preservation services (including write-down of \$6,905 in 2004, \$6,861 in 2003, and \$32,715 in 2002)	27,500	31,165	55,363	23,976	29,807
General, administrative, and marketing	28,731	33,844	47,530	53,630	42,640
Research and development	5,207	4,737	4,597	3,644	3,938
Goodwill impairment			1,399		
Interest expense	299	96	692	415	196
Interest income	(1,952)	(1,967)	(895)	(425)	(262)
Other expense, net	(169)	852	273	12	13
<b>Total costs and expenses</b>	<b>65,463</b>	<b>74,191</b>	<b>119,229</b>	<b>88,758</b>	<b>84,150</b>
Income (loss) before income taxes	\$ 11,633	\$ 13,480	\$ (41,434)	\$ (29,226)	\$ (21,766)
Net income/(loss)	\$ 7,817	\$ 9,166	\$ (27,761)	\$ (32,294)	\$ (18,749)
<b>Earnings/(Loss) Per Share<sup>(1)</sup></b>					
Basic	\$ 0.42	\$ 0.49	\$ (1.43)	\$ (1.64)	\$ (0.81)
Diluted	\$ 0.41	\$ 0.47	\$ (1.43)	\$ (1.64)	\$ (0.81)

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



## Edgar Filing: CRYOLIFE INC - Form 424B5

The following table contains a summary of our balance sheet as of December 31, 2004:

on an actual basis; and

on an as adjusted basis to reflect the sale of 400,000 shares of the convertible preferred stock we are offering at the public offering price of \$50 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

	As of December 31, 2004	
	Actual	As adjusted
	(Dollars in Thousands)	
<b>Balance Sheet Data</b>		
Cash, cash equivalents, and marketable securities <sup>(1)</sup>	\$ 9,232	\$ 27,501
Working capital	19,689	37,958
Property, plant and equipment, net	28,729	28,724
Total assets	73,261	91,530
Long-term liabilities, less current portion	5,629	5,629
Total stockholders' equity	49,660	67,929

<sup>(1)</sup> Includes restricted investments of \$563.

## RECENT DEVELOPMENTS

### Financial Results for the Year Ended December 31, 2004

The year ended December 31, 2004 was a period of continued growth of BioGlue, and improvement in the revenues and margins underlying our human tissue preservation business. For the year ended December 31, 2004 BioGlue revenues accounted for 57% of total revenue and for the first time supplanted preservation service revenues as the top component of Company revenue. BioGlue revenues were enhanced by the BioGlue syringe product, which was introduced in 2004, and a list price increase that went into effect on December 1, 2003 domestically and in early 2004 internationally. An additional list price increase on BioGlue was implemented on January 1, 2005.

We continued to experience the ongoing effects of the FDA Order and subsequent FDA activity. Preservation service revenue in 2004 was negatively impacted by a shortage of high demand tissues available for shipment. Tissue scarcity was a direct result of increased tissue processing and release times and lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order, the exhaustion of much of the Company's supply of tissue processed prior to October 3, 2001, and a reduction in procurement levels during 2004. The Company is taking steps intended to improve yields of implantable tissues per donor over the levels experienced in 2003 and 2004 through process changes and process directives and is working to increase procurement of human tissues for processing over the levels experienced in 2004. The Company instituted list fee increases for its cardiovascular and vascular tissues in July 2004 and January 2005, to reflect the higher cost of processing these tissues subsequent to the FDA Order.

We continued to actively monitor our cash flows in an effort to reduce the operating cash shortfall experienced since the FDA Order. We focused our research and development spending on key opportunities, limited our capital expenditures, and targeted spending on regulatory filings to projects with strong market potential. BioGlue margins continued to be in excess of 80%, and BioGlue revenues provided operating cash flows to support the tissue business. Tissue margins are expected to improve as the Company works to increase yields of implantable tissues per donor and to increase service fees to support higher tissue processing costs. The Company is also closely monitoring expenses related to the defense and resolution of lawsuits, in an effort to reduce selling, general and administrative costs from the levels seen in 2003 and 2004.

Below is a summary of the changes in BioGlue revenues and in preservation service revenues, together with changes in costs and expenses and liquidity and capital resources, for the year ended December 31, 2004.

#### *BioGlue Surgical Adhesive*

Revenues from the sale of BioGlue increased 29% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The increase in revenues consisted of an 18% increase due to volume, a 10% increase due to price, and a 1% increase due to foreign exchange. The volume increase was primarily due to demand for the new BioGlue syringe product, which was introduced in mid 2004 and contributed 11% of total sales of BioGlue. Approximately 19% of the 2004 volume increase in BioGlue was due to customers that did not purchase BioGlue in 2003 or 2002. Smaller volume increases were noted in all other BioGlue products. The price increase was primarily due to an increase in average selling prices, due to list price increases that went into effect on December 1, 2003 domestically and in early 2004 internationally. Domestic revenues accounted for 78% of total BioGlue revenues in 2004 and 77% of total BioGlue revenues in 2003.

***Cardiovascular Preservation Services***

Revenues from cardiovascular preservation services decreased 27% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The decrease in revenues consisted of a 35% decrease due to volume, partially offset by an 8% increase due to price and a change in product mix. The volume decrease was primarily due to a decrease in shipments of aortic and pulmonary valves. The decrease in heart valve shipments reflects the continuing impact of the FDA Order and subsequent FDA activity, as reflected in the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2004, the exhaustion of much of the Company's supply of heart valve tissue processed prior to October 3, 2001, increased tissue processing and release times, and lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order. The price increase reflected the fee increase that went into effect in July 2004. The fee increase primarily increased revenues for traditionally processed pulmonary valves and aortic valves. Revenues from cardiovascular preservation services for the twelve months ended December 31, 2003 include \$85,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

Our procurement of cardiac tissues during the twelve months ended December 31, 2004, from which heart valves and non-valved cardiac tissues are processed, decreased 8% as compared to twelve months ended December 31, 2003. Procurement levels of cardiac tissues remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

***Vascular Preservation Services***

Revenues from vascular preservation services decreased 19% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The decrease in revenues consisted of a 26% decrease due to volume, partially offset by a 7% increase due to price. The volume decrease was primarily due to a decrease in shipments of saphenous veins. Decreases were also experienced in SynerGraft processed femoral veins and arteries and traditional processed, and these decreases were partially offset by increases in shipments of femoral arteries. The decrease in vein shipments also reflects the impact of the FDA Order and subsequent FDA activities, as reflected in the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2004, the exhaustion of much of our supply of vascular tissue processed prior to October 3, 2001, the suspension of shipments of SynerGraft processed femoral veins and arteries and increased tissue processing and release times and lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order. The price increase reflects the fee increase that went into effect in July 2004. Revenues from vascular preservation services for the twelve months ended December 31, 2003 include \$752,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

Our procurement of vascular tissues during the twelve months ended December 31, 2004 decreased 21% as compared to twelve months ended December 31, 2003. Procurement levels of vascular tissues remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

***Orthopaedic Preservation Services***

Our orthopaedic preservation services were most affected by the FDA Order and subsequent FDA activity. Revenues from orthopaedic preservation services increased 171% for the twelve months ended December 31, 2004 as compared to the twelve months ended December 31, 2003. The increase in revenues consisted primarily of an increase due to volume, partially offset by a 3% decrease due to price. The volume increase was primarily due to an increase in shipments of boned tendons. Increases were also experienced in non-boned tendons and menisci. The increase in orthopaedic tissue shipments is directly related to the low volumes of shipments in 2003 due to temporary suspensions of

orthopaedic tissue processing and shipments in 2003 and low levels of orthopaedic tissues available for shipment due to the exhaustion of much of our supply of orthopaedic tissue processed prior to October 3, 2001 and increased tissue processing and release times and lower yields of implantable tissue per donor as a result of process changes implemented subsequent to the FDA Order. The increase in average service fees that went into effect in July 2004 for cardiovascular and vascular tissues did not include an increase in orthopaedic tissue processing fees. Revenues from orthopaedic preservation services for the twelve months ended December 31, 2003 include \$63,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

Our procurement of orthopaedic tissues during the twelve months ended December 31, 2004 increased 68% as compared to twelve months ended December 31, 2003. Procurement levels of orthopaedic tissues remain significantly below procurement levels in the second quarter of 2002, prior to the FDA Order.

#### ***Cost of Products***

Cost of products aggregated \$7.8 million in 2004 compared to \$7.5 million in 2003. The increase in cost of products was primarily due to higher BioGlue sales levels during 2004 when compared to 2003.

Cost of products as a percentage of total product revenues was 21% in 2004 compared to 27% in 2003. The decrease is primarily due to a favorable product mix driven by an increase in revenues from BioGlue, which carries higher gross margins than bioprosthetic devices. Gross margins related to BioGlue improved slightly in 2004 as compared to 2003 as a result of increasing manufacturing efficiencies, higher throughput, and an increase in average selling prices.

#### ***Cost of Human Tissue Preservation Services***

Cost of human tissue preservation services increased to \$29.8 million in 2004 as compared to \$24.0 million in 2003. Cost of human tissue preservation services for 2004 and 2003 includes the increases to cost of preservation services of \$6.6 million and \$6.9 million, respectively, reflecting the write-down of deferred tissue preservation costs to market value. The increase in cost of human tissue preservation services is primarily due to increasing tissue processing costs due to process changes implemented subsequent to the FDA Order. The increase is also due to higher overhead cost allocations per unit associated with lower tissue processing volumes, changes in processing methods subsequent to the FDA Order, and a decrease in shipments of tissues treated with the higher margin SynerGraft process as compared to traditional processing.

Cost of human tissue preservation services as a percentage of tissue preservation service revenues was 116% in 2004 as compared to 78% in 2003. Cost of human tissue preservation services as a percentage of tissue preservation service revenues was favorably affected by shipments of tissue with a zero cost basis for which revenues were recognized but costs, estimated to be \$549,000 in 2004 and \$4.3 million in 2003, had already been recorded in previous periods primarily related to write-downs of deferred preservation costs in 2002. The write-downs of deferred preservation costs during 2002 created a new cost basis, which cannot be written back up when these tissues are shipped or become available for shipment.

#### ***General, Administrative and Marketing Expenses***

General, administrative, and marketing expenses decreased 20% to \$42.6 million in 2004, compared to \$53.6 million in 2003, representing 68% and 90%, respectively, of total revenues during such periods. General, administrative, and marketing costs include net expenses related to litigation of \$1.5 million in 2004 and \$12.0 million in 2003. Excluding the effect of litigation expenses, general,

administrative, and marketing expenses in 2004 decreased slightly from 2003. The remaining decrease is primarily due to a reduction in legal and consulting fees related to product liability and regulatory issues of \$2.7 million, partially offset by an increase of approximately \$1.1 million in insurance premiums, separation costs related to the departure of two members of our management of \$557,000 and an increase of approximately \$478,000 in accounting and audit fees related to efforts to comply with the Sarbanes-Oxley Act of 2002. General, administrative, and marketing expenses in both periods were impacted by increased insurance costs, legal costs, and professional fees as compared to pre-FDA Order levels.

### *Liquidity and Capital Resources*

As of December 31, 2004, net working capital (current assets of \$37.7 million less current liabilities of \$18.0 million) was \$19.7 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$14.8 million, with a current ratio of 2 to 1 at December 31, 2003.

In recent periods, our primary requirements for capital have arisen out of working capital needs created by increasing costs of operations and settlements of litigation combined with losses incurred in our tissue preservation services business. Operating results have also been negatively impacted by increases in general, administrative and marketing costs over pre-FDA Order levels, as a result of legal and professional fees and litigation costs. For the 12 months ended December 31, 2004, we funded these requirements primarily through existing cash, cash equivalents, marketable securities and the proceeds from a January 2004 private equity financing.

We expect that the following factors will continue to have an adverse effect on cash flows during 2005:

The anticipated lower preservation services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activity, and related events,

The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,

An expected use of cash related to the defense and resolution of lawsuits and claims, and

The legal and professional costs related to ongoing FDA compliance.

We believe the following factors should have a favorable impact on cash flow from operations during 2005, although there can be no assurance that our efforts will be successful:

Expected increases in revenues due to increases in BioGlue list prices implemented in January 2005,

Expected increases in the service fees for cardiovascular and vascular tissues due to fee increases implemented in July 2004 and January 2005, to reflect the higher cost of processing these tissues,

Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2003 and 2004 through process changes and process directives,

Expected increases in procurement of human tissues for processing over the levels experienced in 2004, and

Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 and 2004.



## Edgar Filing: CRYOLIFE INC - Form 424B5

We believe that our existing cash, cash equivalents, and marketable securities will enable us to meet our liquidity needs at least through December 31, 2005, and that the line of credit we obtained on February 8, 2005 and the proceeds of this offering will supplement our liquidity needs.

Our long term liquidity and capital requirements will depend upon numerous factors, including:

The success of BioGlue and other products using related technology,

Our ability to increase the level of tissue procurement and demand for its tissue preservation services,

Our ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,

Our spending levels on research and development activities, including research studies, to develop and support our service and product pipeline,

The amount and the timing of the resolution of the remaining outstanding product liability lawsuits and other claims,

The outcome of our other litigation; and

To a lesser degree, our success at resolving the issues with the FDA regarding SynerGraft processing of human tissue.

If we are unable to address these issues and continue to experience negative cash flows, we may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond December 31, 2005. Additional funds may not be available when needed or on acceptable terms, which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

### **Recent Events**

#### *Endologix Agreement*

On January 10, 2005, CryoLife and Endologix, Inc. announced the signing of a development and marketing agreement for the percutaneous or endovascular delivery of CryoLife's BioFoam as a self-expanding sealant for endovascular aortic aneurysm grafts. Under the agreement, Endologix will be responsible for preclinical, clinical, and regulatory activities and costs, and we will manufacture BioFoam for clinical use and commercial sale and receive a royalty on future product sales.

#### *AATB Accreditation*

On February 1, 2005, we announced that CryoLife received accreditation from the American Association of Tissue Banks ("AATB"). The AATB is a scientific, not-for-profit peer group organization that facilitates the provision of high-quality transplantable human tissues in quantities sufficient to meet national needs.

#### *New Credit Agreement*

On February 8, 2005, CryoLife and its subsidiaries entered into a new credit agreement with Wells Fargo Foothill, Inc. as lender. The credit agreement provides for a revolving credit facility in an aggregate amount equal to the lesser of \$15.0 million (including a letter of credit subfacility of up to an aggregate of \$2 million) or a borrowing base determined in accordance with the terms of the credit agreement. Generally, the borrowing base is 20% of the appraised value of the business of CryoLife, reduced by specified lender reserves. The credit agreement places limitations on the amount that the Company may borrow, and includes various affirmative and negative covenants, including financial

covenants such as a requirement that CryoLife maintain quarterly (i) a minimum aggregate borrowing capacity plus cash and cash equivalents, as defined, of \$12.5 million or (ii) achieve an increasing level of minimum earnings before interest, taxes, depreciation, and amortization ("EBITDA") and BioGlue gross margins greater than 70% for the preceding twelve months, and cash and cash equivalents, as defined, of \$5.0 million. While the Company expects that its aggregate borrowing availability under the credit agreement will equal \$15.0 million, there can be no assurance that the availability will remain at this level. The credit agreement also includes customary conditions on incurring new indebtedness and limitations on cash dividends. Cash dividends on any class of capital stock are prohibited; provided that cash dividends on preferred stock may be paid so long as the Company maintains \$7.5 million, in the aggregate, of cash, cash equivalents, and borrowing capacity, as defined. There is no restriction on the payment of stock dividends. See "Risk Factors Risks Relating to the Offering we may not be able to pay cash dividends on any class of capital stock due to legal and contractual restrictions and lack of liquidity" and "Dividend Policy." Commitment fees are paid based on the unused portion of the facility. The credit agreement expires on February 7, 2008, at which time the outstanding principal balance will be due. Amounts borrowed under the revolving credit facility bear interest at the bank's prime rate plus 1%. Amounts borrowed under the credit facility are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries, including the stock of our subsidiaries, which we pledged to the lender. On February 8, 2005, CryoLife borrowed approximately \$265,000 against the \$15.0 million then available under its revolving credit facility, and used such borrowings to pay certain expenses of the transaction.



## RISK FACTORS

*Investing in the convertible preferred stock involves a high degree of risk. You should carefully consider the risks described below with all of the other information included in this prospectus before deciding to invest in the convertible preferred stock. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In this event, the market price of the convertible preferred stock and our common stock could decline and you could lose part or all of your investment. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.*

### Risks Related To Our Business

#### *Overview.*

CryoLife has faced extraordinary challenges since it received, on August 13, 2002, an FDA order calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife since October 3, 2001 (the "FDA Order"). The recall resulted in the destruction of much of our tissue, required that we adjust revenue for tissue recall returns, curtailed our processing activities, subjected us to intense FDA scrutiny and additional regulatory requirements that increased cost while we suffered decreased revenues due to lack of processing ability and decreased market demand for our services. During the same year, we were the subject of intense adverse media attention in connection with allegations that tissue processed by us had infected a man in Minnesota and caused his death. We also became the subject of shareholders' class action and derivative shareholder suits, both of which remain pending. Product liability cases and claims increased to unprecedented numbers for us, using all of our related 2002/2003 insurance policy year insurance coverage and taxing our other resources. While many cases and claims have been settled, several remain unresolved. The SEC has initiated and continues to pursue a formal investigation. The combined effect of these challenges has been to reduce our revenues, increase costs to process tissues and operating expenses and strain management resources. Although we have now resumed processing and distribution of the tissues subject to the FDA recall and resolved many of the product liability suits, the foregoing factors will continue to challenge us in our efforts to increase sales and return to profitability. No assurances can be made that we will succeed in those efforts in a timely fashion.

*We have experienced operating losses and negative cash flow, and must address the underlying causes.*

Due principally to factors mentioned above, the Company has suffered net losses and generated negative operating cash flow each year in the three year period ended December 31, 2004 and anticipates net losses and negative cash flow from operations for the year ending December 31, 2005.

We expect that the following factors will continue to have an adverse effect on earnings and cash flows during 2005:

The anticipated lower preservation services revenues as compared to preservation services revenues prior to the FDA Order, subsequent FDA activity, and related events,

The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,

An expected use of cash related to the defense and resolution of lawsuits and claims, and

The legal and professional costs related to ongoing FDA compliance.

## Edgar Filing: CRYOLIFE INC - Form 424B5

Longer term earnings and liquidity and capital requirements will depend upon numerous factors, including:

The success of BioGlue and other products using related technology,

Our ability to increase the level of tissue procurement and demand for our tissue preservation services,

Our ability to reestablish sufficient margins on our tissue preservation services in the face of increased processing costs by improving yields and increasing prices,

Our spending levels on our research and development activities, including research studies, to develop and support our service and product pipeline,

The amount and the timing of the resolution of the remaining outstanding product liability lawsuits and other claims,

The outcome of our other litigation, and

To a lesser degree, our success at resolving the issues with the FDA regarding SynerGraft processing of human tissue.

***If we are unable to address the causes of our operating losses and negative cash flows, we will need to raise additional capital that may not be available or may not be available on terms acceptable to the Company or dilutive to existing shareholders.***

If we are unable to address these issues and continue to experience negative cash flows, we anticipate that we will require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements. Additional funds may not be available when needed or on terms acceptable to us, which could have a material adverse effect on our business, financial condition, results of operations, and cash flows. Issuance of equity capital may be dilutive to existing shareholders.

***Our products and the tissues we process allegedly have caused and may in the future cause injury to patients using our products or tissues and we have been and may be exposed to product liability claims and additional regulatory scrutiny as a result.***

The processing, preservation and distribution of human allograft tissue, bovine tissue products, porcine tissue products and the manufacture and sale of medical devices, entail inherent risks of medical complications for patients and have resulted and may result in product liability claims against us. Plaintiffs have asserted that our tissue or medical devices have caused a variety of injuries including death. When patients are injured, die or have adverse results following procedures using our tissue or medical devices, we have been and may be sued and our insurance coverage has not been and may not be adequate to cover the amounts owed by us under those claims. Adverse judgments and settlements in excess of our available insurance coverage could have a material adverse effect on our financial position, results of operations and cash flows.

As a result of medical complications that are alleged to have been caused by or occur in connection with medical procedures involving our tissue or medical devices, we have been and may be subject to additional FDA and other regulatory scrutiny and inspections. For example, shortly after the FDA Order the FDA posted a notice, now archived, on its website stating its concerns regarding CryoLife's heart valve preservation services. As a result, some surgeons and hospitals decided not to use our heart valves. Cautionary statements from the FDA or other regulators regarding our tissue services or products, or negative reviews from the FDA or regulators of our processing and manufacturing facilities has and may decrease demand for our tissue services or products and could have a material adverse effect on our business, results of operations and financial position.

In addition to the recall resulting from the FDA Order, we have and in the future may have to suspend the distribution of particular types of tissues as a result of reported adverse events in connection with our tissues. For example, during September 2003, in response to a reported infection, the Company halted the shipment of boned orthopaedic tissues in order to conduct an additional review of the systems in place to process and release boned orthopaedic tissues. In March 2002 we stopped shipping SynerGraft-processed porcine valves to Europe after reports of adverse events. Suspension of the sale of, or recall of, our tissue services or medical products could have a material adverse effect on our revenues and profits.

***Our new revolving credit facility imposes restrictions on our ability to borrow, which could make it more difficult to borrow needed funds.***

The credit agreement places limitations on the amount that we may borrow, and includes various affirmative and negative covenants.

Among these financial covenants is a requirement that CryoLife maintain quarterly either

cash, cash equivalents and borrowing capacity in excess of \$12.5 million(the "cash test"); or

an increasing level of earnings before interest, taxes and depreciation, as defined in the credit agreement ("EBITDA"), a BioGlue gross margin greater than 70% for the preceding twelve months as calculated quarterly and cash and cash equivalents (defined as cash and low risk marketable securities that are held in an account in which the lender has a perfected security interest) and borrowing capacity (defined below) in excess of \$5.0 million (the "EBITDA test").

Borrowing capacity is defined as

the lesser of

\$15 million and

20% of the appraised value of the business of CryoLife reduced by the lender's reserves for credit exposure associated with other bank products provided by the lender to us;

*minus* all outstanding obligations under the credit agreement including outstanding letters of credit;

*minus* the aggregate amount of any of our trade payables aged in excess of their historical levels and all of our book overdrafts in excess of our historical practices.

Current forecasts of our EBITDA, coupled with the uncertainties inherent in our operating cash flows, make compliance with the EBITDA test uncertain. Accordingly, we anticipate that compliance with this financial covenant will be dependent on our ability to satisfy the cash test. Giving pro forma effect to the offering, as of March 3, 2005, we would have had \$36.3 million in cash, cash equivalents and borrowing capacity.

Judgments and settlements arising out of product liability or other claims, negative operating cash flow and other factors which adversely affect available cash resources may adversely affect compliance with the cash test. Failure to meet this and other covenants may result in breach of the credit agreement, acceleration of payment of outstanding borrowings and loss of borrowing capacity under the credit agreement.

The credit agreement also includes conditions on incurring new indebtedness and limitations on cash dividends. These restrictions and conditions could make it more difficult or more expensive to borrow money.

***We are increasingly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product.***

BioGlue has become an increasingly important source of our revenues. Revenues from the sale of BioGlue accounted for 57% and 47% of the total revenue for the twelve months ended December 31, 2004 and 2003, respectively. Should this product be the subject of adverse developments with regards to its safety or efficacy, reimbursement practices or if a competitor's product obtains greater acceptance, or our rights to manufacture and market this are challenged, the result could be a material adverse effect on our business, financial condition and results of operations. Furthermore, we have only one supplier for both our syringe and cartridge delivery systems for BioGlue. We do not have a long term contract with this supplier and the supplier could stop supplying syringes and cartridges at any time. The loss of this supplier would have a material adverse impact on our ability to sell BioGlue if we are unable to find a replacement supplier in a timely manner. Any replacement supplier would need to be qualified by regulatory authorities and there can be no assurance that we would be able to find a qualified replacement supplier on a timely basis, if at all. The loss of one or more these suppliers, or their inability to provide us with adequate quantities of their products, could have an adverse impact on our ability to manufacture and sell BioGlue. There can be no assurance that we would be able to replace any such loss on a timely basis, if at all.

***The FDA order and subsequent FDA activity continue to adversely impact our business, including reducing demand for services and increasing processing costs.***

On August 13, 2002, we received the FDA Order calling for the retention, recall and/or destruction of all non-valved cardiac, vascular and orthopaedic tissue processed by us at our headquarters since October 3, 2001 based upon allegations that we violated FDA regulations in our handling of such tissue and alleged contamination through our processing of such tissue that resulted in 14 post-transplant infections, including one death. A significant portion of our 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 our revenues, or approximately \$37.8 million. During 2004, these revenues were approximately \$25.7 million or 41% of 2004 revenues.

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

We have continued to experience a reduced demand for our tissues due to the adverse publicity generated from the recall and from decisions by implanting physicians or risk managers at implanting institutions to use human tissue services provided by our competitors. In addition, as a result of the FDA Order, subsequent FDA activity, and changes in our processing, the costs of such processing have increased and are likely to remain high as compared to cost levels prior to the FDA Order. These high costs had have a material adverse effect on our business, results of operations and financial position and will continue to do so.

The success of our tissue preservation services depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. Any material reduction in the supply of donated human tissue would restrict our growth and adversely affect our business, results of operations and financial conditions. We rely 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 us for processing. As a result, our processing has been constrained in part due to availability

of tissue. If we are unable to improve our relationships with those procurement agencies and we are unable to obtain tissue from procurement agencies that have ceased sending tissue to us for processing, we may continue to be unable to obtain adequate supplies of donated tissues to operate profitably.

***Revenue from orthopaedic tissue preservation services may not return to acceptable levels.***

CryoLife has received much lower revenues from the preservation of orthopaedic tissue since August 14, 2002. For the year ended December 31, 2001, human tissue preservation services revenues for orthopaedic tissue were \$22.5 million, which represented 26% of our revenues. For the six months ended June 30, 2002 (the last period ending prior to the FDA Order), revenues for preservation services for orthopaedic tissue were \$11.5 million, which represented 24% of our revenues. For the year ended December 31, 2004, revenues from preservation services for orthopaedic tissue were \$2.9 million, which represented 5% of our revenues.

The demand for orthopaedic tissue may not return to the levels in existence before the FDA Order, even though we have resumed processing after altering our procedures. Furthermore, there can be no assurance that our anticipated offering of osteochondrial tissue will be successful. As a result, this portion of our business may be discontinued or may only continue at substantially reduced levels. Either of these results would result in a continued significant decrease in our preservation services revenues and have an adverse impact on our ability to return to profitability.

***Physicians have been and may continue to be reluctant to implant our preserved tissues.***

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

***Products and services not included in the FDA recall may come under increased FDA scrutiny.***

Although our heart valve tissues, BioGlue Surgical Adhesive and bioprosthetic devices were not included in the FDA recall, the processing and manufacturing facilities for these products may come under increased scrutiny from the FDA. For example, shortly after the FDA Order the FDA posted a notice, now archived, on its website stating concerns regarding our heart valve preservation services. As a result of the notice, some physicians and hospitals did not use our heart valves. Furthermore, a negative review from the FDA of our processing and manufacturing facilities could have a material adverse effect on our business, results of operations and financial position.

***Adverse publicity may reduce demand for products and services not affected by the FDA recall.***

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

***We may be unable to address the concerns raised by the FDA in its Form 483 notices of observations.***

The FDA issued new Form 483 Notices of Observations in February and October 2003, and another in February 2004. Among the issues raised in the February 2004 483 were the validation and effectiveness of the antimicrobial solution the company uses in processing tissue; the validation of the company's rinse-recovery method; and the company's monitoring and reporting of providers/suppliers' non-compliance with company procedures for obtaining, handling, and transporting tissue. If the responses to the FDA's observations contained in these notices, or any future notices, are deemed unsatisfactory, the FDA could take further action, which could have a material adverse effect on our business, results of operations, financial position or cashflows. Further action by the FDA could include additional recalls of products, requiring us to do additional testing, beginning to require prescriptions for products where they are not currently required, halting the shipping or processing of products, or requiring additional approvals for marketing our products or services.

***The FDA has notified us of its belief that marketing of CryoValve SG and CryoVein SG require additional regulatory submissions and/or approvals.***

During 2003, the FDA notified us that the application of the SynerGraft technology to allograft heart valves (CryoValve SG), currently regulated as Class II medical devices, was considered to be a major manufacturing change requiring a 510(k) submission. CryoLife submitted a 510(k) for CryoValve SG and has received two requests for additional information from FDA. CryoLife submitted a 510(k) for CryoValve SG and has received two requests for additional information from FDA, including a comparison of the SynerGraft-processed porcine valves we stopped shipping to SynerGraft-processed allograft heart valves. While most of the requested information has been provided, we are seeking to resolve certain other requests, involving bench-testing and additional clinical trials, through administrative procedures at the FDA. Resolution of this matter could be time-consuming and expensive, depending in large part on the success of our efforts under the FDA's administrative processes. There can be no assurance that the FDA will agree with us or that the CryoValve SG 510(k) will be cleared in the foreseeable future, if at all. If we are unable to resolve this issue, we may not be able to offer these services.

FDA has also determined that non-valved cardiovascular "CryoVein" tissues processed using SynerGraft technology should be regulated as medical devices and will require additional premarket approval authorization for continued distribution of these tissues. We appealed the designation of SynerGraft-processed cardiovascular tissue as medical devices. Discussions with the FDA to resolve this issue are ongoing. Resolution of this matter could be time-consuming and expensive, depending in large part on the success of our efforts under the FDA's administrative processes. There can be no assurance that the designation of SynerGraft cardiovascular tissue will be resolved favorably. If we are unable to resolve this matter, we may not be able to offer these services.

***Regulatory action outside of the U.S. has affected our business in the past and may also affect our business in the future.***

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 us, although these inquiries are now, to our knowledge, complete. We also offer BioGlue and other products for use in other countries. In the event additional regulatory concerns are raised by other countries, we may be unable to export tissue or other products to those countries.

***Violation of government regulations could result in loss of sales and customers and additional expense to attain compliance.***

The facilities and processes we use are subject to regulation by the FDA and some states. Our facilities are also subject to periodic inspection by the FDA and state regulatory authorities to ensure their compliance with applicable laws and regulations. Failure to comply with these laws and regulations can lead to sanctions, such as written observations of deficiencies made following inspections, warning letters, product recalls, fines, product seizures and consent decrees, which would be made available to the public. Such actions and publicity could affect our ability to sell our products and services. In the past, we have received notifications and warning letters from the FDA relating to deficiencies in our compliances with FDA requirements. We were required to take measures to respond. We also were subject to the FDA Order which had a material adverse effect on our business, results of operations and financial condition. There can be no assurance that the FDA or state regulatory authorities will not request that we take additional steps to correct deficiencies in compliance raised by the FDA or state regulatory authorities in the future. Correction of any such deficiencies could have a material adverse effect on our business.

***CryoLife is the subject of an ongoing SEC investigation.***

As previously disclosed, there is an ongoing SEC investigation. We have cooperated with this investigation both before and after issuance of the formal order of investigation in June 2003, and intend to continue doing so. We voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife shares on August 14, 2002, before trading was halted pending our press release reporting the FDA Order. These individuals were not and are not executive officers of CryoLife. The formal order of investigation indicates that the SEC's scope includes whether, during 2002, among other things, CryoLife or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate controls. The investigation could also encompass matters not specifically identified in the formal order. As of the date hereof, the SEC has had no discussions with our representatives as to whether or against whom it will seek relief, or the nature of any relief that may be sought. At present, we are unable to predict the ultimate focus or outcome of the investigation, or when it will be completed. An unfavorable outcome could have a material adverse effect on our reputation, business, results of operations, financial position and cash flows.

***Our insurance coverage has been and may be either unavailable or insufficient.***

***Product Liability Claims***

Our products and the tissues we process allegedly have caused and may in the future cause injury to patients using our products or tissues and we have been and may be exposed to product liability claims. Following the FDA Order, product liability lawsuits increased to unprecedented numbers for us. These claims have often involved assertions that infections and related morbidity, including death, were the result of inadequacies in our procedures. We maintain claims-made insurance policies to mitigate our financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period.

As of February 21, 2005, we had three outstanding product liability lawsuits against us that are covered by three separate insurance policies, beginning with the policy year 2000/2001. We believe our insurance policies are adequate to defend against the covered lawsuits in each of these time periods.

Additionally, we have six outstanding product liability lawsuits against us that are not covered by insurance policies as either we have used all of our insurance coverage related to that policy year, or the claims were asserted against us in periods after the coverage in the related incident year had lapsed. The most recent product liability lawsuit was filed in March 2005. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against us have not resulted in lawsuits. We are monitoring these claims.

The uninsured lawsuits are not covered by our insurance policies as either these lawsuits relate to the 2002/2003 insurance policy year for which we have used all of our insurance coverage, aggregating \$25 million, or they were asserted in periods after the coverage in the related incident year had lapsed. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against us that have not resulted in lawsuits. We are monitoring these claims.

Our December 31, 2004, consolidated balance sheet reflects a liability in the amount of approximately \$2.8 million for the estimated cost of resolving these claims. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims, and do not reflect actual settlement arrangements or final judgments, the latter of which could include punitive damages, nor do they represent cash set aside for the purpose of making payments. Our December 31, 2004 Consolidated Balance Sheet also reflects an \$8.2 million liability, included as a component of accrued expenses and other current liabilities of \$4.2 million and other long-term liabilities of \$4.0 million on the Consolidated Balance Sheet, for the estimated cost of resolving unreported product liability claims. Our product liability insurance policies do not include coverage for any punitive damages.

If we are 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 we are a defendant, whether now pending or hereafter arising, should be tried with a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve the outstanding or any future product liability claims, it will have a material adverse effect on our financial position, results of operations, and cash flows. Further, if the costs of pending or unreported but incurred product liability claims exceed our current estimates, our business, financial condition and results of operations may be materially adversely affected.

#### *Class Action Lawsuit*

Several putative class action lawsuits were filed in July through September 2002 against CryoLife and certain officers of CryoLife, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that CryoLife made misrepresentations and omissions relating to product safety and CryoLife's alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. CryoLife and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the United States District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003, the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. At present, discovery in the case has closed and the Court has instructed the parties to serve their dispositive motions, if any, by March 11, 2005. Although CryoLife carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment in excess of CryoLife's available insurance coverage could have a material adverse effect on



our financial position, results of operations, and cash flows. At this time, we are unable to predict the outcome of this litigation.

*Shareholder Derivative Action*

On August 30, 2002, a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names CryoLife as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to CryoLife by causing or allowing CryoLife to engage in certain inappropriate practices that caused CryoLife to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that CryoLife's board of directors take certain actions in response to her allegations. On January 16, 2003 another purported derivative suit alleging claims similar to those of the Lichtenberger suit was filed in the Superior Court of Fulton County by complainant Robert F. Frailey. As in the Lichtenberger suit, the filing of the complaint in the Frailey action was preceded by a demand letter sent on Frailey's behalf to CryoLife's board of directors. Both complaints seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of CryoLife. As previously disclosed, CryoLife's board of directors established a committee it determined to be independent to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel evaluated the consolidated amended complaint, and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of CryoLife. Based on the report of the independent committee, CryoLife moved to dismiss the derivative action in May 2004. In an order dated December 1, 2004, the Court denied the motion to dismiss such that the case will proceed into the discovery phase. At this time, CryoLife is unable to predict the outcome of this litigation. Although the derivative suit is brought nominally on behalf of the Company, we expect to continue to incur defense costs and other expenses in connection with the derivative litigation.

***Insurance coverage may be difficult or impossible to obtain in the future and if obtained, the cost of insurance coverage is likely to be much more expensive than in the past.***

Due in part to the current litigation, the FDA Order and subsequent FDA activity, we may be unable to obtain satisfactory insurance coverage in the future, causing us 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 our profitability. For example, we paid a higher fee for our 2003/2004 policy year product liability insurance coverage, which also had a higher retention level and a lower overall limit. Unlike the prior year's policy, the 2003/2004 policy did not cover any claims, which arose prior to the insurance policy year. The 2004/2005 policy is a two-year claims-made policy, covering claims arising since the commencement of the 2003/2004 policy year. Our current insurance policy expires in March 2005. We are currently evaluating with prospective insurers available coverage and cost. We presently expect increases in both cost and retention, although we also expect coverage to be a three-year claims-made policy. There is no assurance we will be successful in obtaining satisfactory coverage upon expiration of our current coverage.

***Intense competition may affect our ability to recover from the FDA Order.***

We face competition from other companies that process human tissue, as well as companies that market mechanical valves and synthetic and animal tissue for implantation and companies that market surgical adhesives and surgical sealants. We believe that at least four domestic tissue banks offer preservation services for allograft heart valves and many companies offer processed porcine heart valves and mechanical heart valves. A few companies dominate portions of the mechanical, porcine and bovine heart valve markets, including St. Jude Medical, Inc., Medtronic, Inc. and Edwards Life Sciences. Our BioGlue product competes with other surgical adhesives and surgical sealants, including Baxter Healthcare's Tisseel, FloSeal and CoSeal products. We are also 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 our competitors have greater financial, technical, manufacturing and marketing resources than CryoLife and are well established in their markets. We increased fees and prices on a number of our services and products effective January 1, 2005. The increase may provide an opportunity for our competitors to gain market share. If we are unable to increase prices as planned and retain or improve our market share, our revenue and return to profitability may be adversely affected.

Our cryopreserved tissues compete with other entities that cryopreserve human tissue on the basis of technology, customer service, and quality assurance. As a result of the decrease in our procurement and processing yields of human tissue since the FDA Order in 2002, the decrease in cardiovascular, vascular, and orthopaedic tissue shipments, and the lack of orthopaedic tissue shipments for a period of time, our competitors have been favorably impacted and we believe we have lost some market share. As compared to mechanical, porcine, and bovine heart valves, we believe that the human heart valves cryopreserved by us compete on the factors set forth above, as well as by providing a tissue that is the preferred replacement alternative with respect to certain medical conditions, such as pediatric cardiac reconstruction, valve replacements for women in their child-bearing years, and valve replacements for patients with endocarditis.

Closure Medical recently updated its plans to launch an absorbable surgical sealant that could compete with BioGlue in certain applications. Competitive surgical adhesive products may also be under development by other large medical device, pharmaceutical, and biopharmaceutical companies. Our BioGlue product competes on the basis of tensile strength and ease of use.

There can be no assurance that our products and services will be able to compete successfully with the products of these or other companies. Any products developed by us 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 our business, financial condition, results of operations and cash flows. The FDA Order and related adverse publicity had an adverse effect on our competitive position, which had a material adverse effect on our results of operations. The FDA Order and subsequent FDA activity may continue to have an adverse effect on our competitive position, which may continue to have a material adverse effect on our results of operations. As a result, our competitors may gain competitive advantages that may be difficult to overcome.

***We may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development or currently under FDA review, and such products and services may not achieve market acceptance.***

CryoLife's growth and profitability will depend, in part, upon its ability to complete development of and successfully introduce new products and services, including new applications of our BioGlue and related technology and applications applying our SynerGraft technology. Developing new products and services to a commercially acceptable form is uncertain, and obtaining required regulatory approval is time consuming and costly. For example, if we are unable to resolve the issues we are addressing with the FDA with regard to tissues processed using SynerGraft, we may incur significant costs over a

lengthy period of time to meet the FDA's requirements, and we may not be successful in meeting them or in offering a commercially successful product.

Although we have conducted pre-clinical studies on our products under development that indicate that such products may be effective in a particular application, there can be no assurance that the results obtained from expanded clinical studies will be consistent with earlier trial results or be sufficient for us to obtain any required regulatory approvals or clearances. There can be no assurance that we 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 our products remains subject to all of the risks associated with the commercialization of new products based on innovative technologies, including unanticipated technical or other problems, manufacturing difficulties and the possible insufficiency of the funds allocated for the completion of such development. Consequently, our products under development may not be successfully developed or manufactured or, if developed and manufactured, such products may not meet price or performance objectives, be developed on a timely basis or prove to be as effective as competing products.

The inability to successfully complete the development of a product, application or service, or a determination by us, for financial, technical or other reasons, not to complete development or obtain regulatory approval of any product, application or service, particularly in instances in which we have made significant capital expenditures, could have a material adverse effect on our business, financial condition, results of operations, and cash flows. 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 products or services, which could include new products based on our Protein Hydrogel Technology such as BioFoam, BioLastic and BioDisc, 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.***

We may invest in new technology licenses or distribution rights that may not succeed in the marketplace. For example, in February 2003 we entered into an arrangement with curasan AG for the distribution of its Cerasorb Ortho, a resorbable bone graft substitute. That arrangement has now been terminated. In such cases, we may be unable to recover our initial investment, which investment could include acquisition of license or distribution rights or the purchase of initial inventory, all of which may adversely impact our 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 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. We have been seeking such funding since 1998 to allow us 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. Even if such financing is obtained, there is no guarantee that the ACT will in fact prove to be effective in the above applications. In addition, any new financing

may cause dilution to the ownership interests of current shareholders, or may include restrictive covenants that could adversely affect our business.

***SynerGraft-treated tissues may not demonstrate expected benefits.***

We process bovine tissues with the SynerGraft technology and market these services outside the U.S. The process involves antigen reduction, which is the depopulation of the cells of the tissue to be implanted, leaving a matrix of protein fibers that has the potential to be repopulated with the recipient's cells. If successful, we believe that such repopulation may increase graft longevity and improve the biocompatibility and functionality of such tissue, resulting in the implanted tissue behaving more like the recipient's own tissue. In animal studies, explanted SynerGraft treated heart valves have been shown to repopulate with the recipient's cells. However, should such tissues implanted in humans not consistently and adequately repopulate with the human host cells, the higher priced SynerGraft-treated tissues may not demonstrate benefits over other alternatives. This could have a material adverse effect on future expansion plans and could limit future growth.

***If we are not successful in expanding our business activities in international markets, we will not be able to pursue one of our strategies for increasing our revenues.***

Our international operations are subject to a number of risks which may vary from the risks we face in the United States, including:

unexpected changes in regulatory requirements and tariffs;

difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships;

longer accounts receivable collection cycles in certain foreign countries;

adverse economic or political changes;

unexpected changes in regulatory requirements;

more limited protection for intellectual property in some countries;

changes in our international distribution network and direct sales force;

changes in currency exchange rates;

potential trade restrictions, exchange controls and import and export licensing requirements; and

potentially adverse tax consequences of overlapping tax structures.

***We are dependent on our key personnel.***

Our business and future operating results depend in significant part upon the continued contributions of our key technical personnel and senior management, many of whom would be difficult to replace. Our business and future operating results also depend in significant part upon our ability to attract and retain qualified management, processing, technical, marketing, sales and support personnel for our operations. Competition for such personnel is intense and there can be no assurance that we will be successful in attracting and retaining such personnel. Our key employees include our management team, consisting of Steven G. Anderson, President, Chief Executive Officer, and Chairman; D. Ashley Lee, CPA, Executive Vice President, Chief Operating Officer and Chief Financial Officer; Sidney B. Ashmore, Vice President, Marketing; David M.

Edgar Filing: CRYOLIFE INC - Form 424B5

Fronk, Vice President, Clinical Research; Albert E. Heacox, PhD, Senior Vice President, Research and Development; and Thomas J. Lynch, JD, PhD, Vice President, Regulatory Affairs and Quality Assurance. CryoLife has employment agreements with these key personnel. Mr. Anderson's employment agreement which expires in September 2005, provides for

S-24

---

payment of \$900,000 if his employment is terminated other than for cause, death, disability or by him for good reason. Mr. Anderson and the Compensation Committee of our Board of Directors are currently negotiating a new agreement. The others expire in August 2005 or September 2005, except for Mr. Lynch's, which expires in August 2006. They provide for payments ranging from \$240,000 to \$360,000 if employment is terminated other than for cause, death, disability or by the employee for good reason. Other than a \$1.5 million life insurance policy on Mr. Anderson, CryoLife does not have key life insurance on these individuals. The loss of key employees, the failure of any key employee to perform adequately or our inability to attract and retain skilled employees as needed could have a material adverse effect on our business, financial condition, results of operations and cash flows.

### **Risks Related To CryoLife And Our Industry**

#### *Extensive government regulation may adversely affect our ability to develop and sell products and services.*

Government regulation in the U.S., the EEA and other jurisdictions can determine the success of our efforts to market and develop our services and products and those of our competitors. Allograft heart valves such as those processed by us 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 us are currently regulated as "human tissue" under rules promulgated by the FDA pursuant to the Public Health Services Act. These rules establish requirements for donor testing and screening of human tissue and record keeping relating to these activities and impose certain registration and product listing requirements on establishments that process or distribute human tissue or cellular-based products. The FDA has finalized a regulation that will implement good tissue practices, akin to good manufacturing practices, followed by tissue banks and processors of human tissue. It is anticipated that these good tissue practices regulations when made effective will increase regulatory oversight of CryoLife and other processors of human tissue. Although CryoLife and its competitors are endeavoring to satisfy the new regulations when they go into effect, there can be no assurance of success.

BioGlue Surgical Adhesive is regulated as a Class III medical device and we believe that 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. We may not obtain the FDA approval required to distribute our porcine heart valve products in the U.S. Distribution of these products within the EC is dependent upon our maintaining the CE Mark for this product and our ISO 13485 certifications, of which there can be no assurance.

Most of our products and services in development, and those of our competitors if successfully developed, will require regulatory approvals from the FDA and perhaps other regulatory authorities before they may be commercially distributed. The process of obtaining required regulatory approvals from the FDA normally involves clinical trials and the preparation of an extensive premarket approval 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 us or our competitors, independently or in collaboration with others, will receive the required approvals for manufacturing and marketing.

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

reduce the period during which a company such as CryoLife has the exclusive right to commercialize patented products.

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

Even if regulatory approval is obtained for any products or services offered by us or one of our competitors, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. Products or services marketed pursuant to FDA or foreign oversight or approvals are subject to continuing regulation. In the U.S., devices and biologics must be manufactured in registered establishments (and, in the case of biologics, licensed establishments) and must be produced in accordance with Quality System Regulations. Manufacturing facilities and processes are subject to periodic FDA inspection. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of devices and biologics is also subject to regulation and may require FDA approval. From time to time, the FDA may modify such regulations, imposing additional or different requirements. Failure to comply with applicable FDA requirements, which may be ambiguous, could result in civil and criminal enforcement actions, warnings, citations, product recalls or detentions and other penalties and could have a material adverse effect on our 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, transplantation, preservation, quality control and storage of human organs. There can be no assurance that restrictive interpretations of NOTA will not be adopted in the future that will challenge one or more aspects of industry methods of charging for preservation services. Our laboratory operations and those of our competitors are subject to the U.S. Department of Labor, Occupational Safety and Health Administration and Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations governing the processing, transportation and storage of human organs and tissue.

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

***Uncertainties related to patents and protection of proprietary technology may adversely affect the value of intellectual property.***

We own several patents, patent applications and licenses relating to our technologies, which we believe provide important competitive advantages. There can be no assurance that our pending patent applications will issue as patents or that challenges will not be instituted concerning the validity or enforceability of any patent owned by us, 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 our technologies or design around the patented aspects of such technologies.

There can be no assurance that our proposed technologies will not infringe patents or other rights owned by others.

In addition, under certain of our license agreements, if we fail 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 our business, financial condition, results of operations, and cash flows. Additionally, we protect our proprietary technologies and processes in part by confidentiality agreements with our collaborative partners, employees and consultants. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach or that our trade secrets will not otherwise become known or independently discovered by competitors, any of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

***Uncertainties regarding future health care reimbursement may affect the amount and timing of revenues.***

Even though we do not receive payments directly from third-party health care payors, their reimbursement methods and policies impact demand for our cryopreserved tissue and other services and products. Third-party healthcare payors provide reimbursement for medical procedures at a specified rate without additional reimbursement for tissue, services and products, such as those distributed or developed by us, used in such procedures. Our preservation services with respect to cardiac, vascular, and orthopaedic tissues may be particularly susceptible to third-party cost containment measures. For example, the initial cost of a cryopreserved allograft heart valve generally exceeds the cost of a mechanical, synthetic or animal-derived valve. In addition, the cost of certain vascular procedures using our vascular tissue exceeds the amount third-party healthcare providers reimburse for such procedures. We are 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 us.

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 us and other our other services and products, could have a material adverse effect on CryoLife. Significant uncertainty exists as to the reimbursement status of newly approved health care products and services and there can be no assurance that adequate third-party coverage will be available for us to maintain price levels sufficient for realization of an appropriate return on our 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 our new products and services, market acceptance of these products would be adversely affected, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

***Rapid technological change could cause services and products to become obsolete.***

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



## **Risks Related To The Offering**

*Securities prices for our shares have been, and may continue to be, volatile, which could make an investment less appealing and lead to costly litigation.*

The trading price of our common stock has been subject to wide fluctuations and may continue to be volatile in the future. Trading price fluctuations can be caused by a variety of factors, including regulatory actions such as the FDA Order, recent product liability claims, variations in operating results, announcement of technological innovations or new products by us or our 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 our control. If our revenues or operating results in future quarters fall below the expectations of securities analysts and investors, the price of our common stock would likely decline further, perhaps substantially. Changes in the trading prices of our capital stock may bear no relation to our actual operational or financial results. If our share prices do not meet the requirements of the New York Stock Exchange, our shares may be delisted. Our closing common stock price in the period January 1, 2002 to March 7, 2005 has ranged from a high of \$31.31 to a low of \$1.89.

The market prices of the securities of biotechnology companies have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class-action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the operating performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management's attention and resources and harm our financial condition and results of operations.

*Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of CryoLife.*

Our 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, we are subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of our capital stock. For example, the Florida Business Corporation Act imposes a requirement that a two-thirds vote of the stockholders is required to approve certain transactions with certain 10% stockholders unless the transaction is approved by disinterested directors. Further, pursuant to the terms of a shareholder rights plan adopted in 1995, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire CryoLife on terms not approved by the board of directors and may have the effect of deterring hostile takeover attempts. These provisions could potentially deprive our stockholders of opportunities to sell shares of our stock at above-market prices.

*Common stock dividends are not likely to be paid in the foreseeable future.*

We have not paid, and do not presently intend to pay, cash dividends on our common stock.

***We may not be able to pay cash dividends on any class of capital stock due to legal and contractual restrictions and lack of liquidity.***

Under Florida law and under the restrictions set forth in our credit agreement, we may not be able to pay cash dividends on our capital stock.

Under Florida law, no distributions may be paid on capital stock, if after giving it effect: (a) the corporation would not be able to pay its debts as they become due in the usual course of business; or (b) the corporation's total assets would be less than the sum of its total liabilities plus (unless the articles of incorporation permit otherwise) the amount that would be needed, if the corporation were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of shareholders whose preferential rights are superior to those receiving the distribution.

Under our new credit agreement, cash dividends on our common stock are prohibited, and cash dividends on our preferred stock may be paid only so long as we maintain at least \$7.5 million, in the aggregate, of borrowing capacity under the credit agreement, cash and cash equivalents, each as more fully described above under "Risks Factors-Risks related to our business-Our new revolving credit facility imposes restrictions on our ability to borrow which could make it more difficult to borrow needed funds." Increased borrowings under the credit agreement and judgments or settlements arising out of product liability or other claims, negative operating cash flow and other factors which adversely affect available cash resources will also adversely affect the Company's ability to make cash dividend payments both generally and under the credit agreement specifically. In addition, the terms of any future financing arrangements entered into by us may also restrict our ability to pay dividends.

Dividends payable on the convertible preferred stock total in the aggregate approximately \$ \_\_\_\_\_ each quarter (\$ \_\_\_\_\_ if the underwriter's over-allotment option is exercised in full). Our earnings have been insufficient to cover our fixed charges in recent years and will be insufficient to cover fixed charges and convertible preferred stock dividend payments immediately following the offering.

If we return to profitability, our ability to pay cash dividends on the convertible stock requires the availability of adequate net assets. Even if adequate net assets are available to pay cash dividends on the convertible preferred stock, we may not have sufficient cash flow to cover fixed charges and the convertible preferred stock dividend payments or to permit the payment of convertible preferred stock dividends. Further, even if we return to profitability and have adequate net assets, we might not have \$7.5 million in borrowing capacity, cash and cash equivalents after paying the cash dividend for the dividend to be permitted under our credit agreement.

***Upon the expiration of a 75-day lock-up agreement, a substantial number of shares of our common stock will become available for sale in the public market, which may cause the market price of our preferred and common stock to decline.***

On June 1, 2005, which is 75 days after the date of this offering, lock-up agreements covering approximately 2.5 million shares of our common stock held by existing stockholders will expire and those shares will become available for sale. If these stockholders sell substantial amounts of our common stock in the public market at concentrated times, the market prices of our capital stock could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price acceptable to us.

***An active, liquid trading market for the convertible preferred stock may never develop.***

Prior to this offering, there was no public market for the convertible preferred stock. An active trading market for the convertible preferred stock may not develop following this offering. You may not be able to sell your shares quickly or at the market price if trading in our stock is not active. The public offering price may not be indicative of prices that will prevail in the trading market. See

"Underwriting" for more information regarding the factors considered in determining the public offering price. Our ability to list and continue to list the convertible preferred stock on the New York Stock Exchange will depend on our ability to meet New York Stock Exchange listing requirements.

***We may allocate the net proceeds from this offering in ways with which you may not agree.***

We expect to use the net proceeds of this offering for working capital and general corporate purposes, including funding our net operating losses. See "Use of Proceeds." Our management, however, has broad discretion in the use of the net proceeds from this offering and could spend the net proceeds in ways that do not necessarily improve our operating results or the value of our common stock.

***If we automatically convert the convertible preferred stock, you should be aware that there is a substantial risk of fluctuation in the price of our common stock from the date we elect to automatically convert to the conversion date.***

We may elect to automatically convert the convertible preferred stock if our common stock price has exceeded 150% of the conversion price for at least 20 trading days during a 30-day trading period ending within five trading days prior to the notice of automatic conversion. You should be aware that there is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

***Automatic conversion will affect your rights and preferences without any action by you.***

We may elect to automatically convert the convertible preferred stock without any action taken by you, and we may do so at a time when you do not think it is prudent to convert your convertible preferred stock. Upon conversion, you will lose all preferences to which the convertible preferred stock is entitled, including your liquidation preference and your dividend preference. Moreover, because you will then own common stock, your ownership interest in CryoLife will be diluted.

***Investors will suffer immediate and substantial dilution.***

The offering price of the convertible preferred stock is substantially higher than the book value per share of our outstanding common stock. Accordingly, investors purchasing shares of convertible preferred stock in this offering will pay a price per share of the common stock into which such preferred stock is convertible that substantially exceeds the book value of our assets after subtracting liabilities.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus supplement and the accompanying prospectus include and incorporate by reference "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements give the current expectations or forecasts of future events. The words "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future" and other similar expressions generally identify forward-looking statements, including, in particular, statements regarding future services, market expansion, revenues, cost savings, regulatory activity, available funds and capital resources, and pending litigation. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates. Such forward-looking statements reflect the views of 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 supplement and the accompanying prospectus.

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

adequacy of product liability insurance to defend against lawsuits;

the outcome of lawsuits filed against CryoLife, and of the SEC investigation;

the impact of the FDA Order and subsequent FDA activity, including the FDA's letters regarding the SynerGraft process and measures taken by us as a result, on future revenues, profits and business operations;

the adequacy of the credit agreement, the net proceeds of this offering, cash and cash flow to meet the Company's liquidity needs at least through December 31, 2005;

the effect of the FDA Order and subsequent FDA activity on sales of BioGlue;

the impact of the FDA's Form 483 Notices of Observation;

the estimates of the amounts accrued for the retention levels under our product liability and directors' and officers' insurance policies, as well as the estimates of the amounts accrued for product loss claims incurred but not reported;

future costs of human tissue preservation services, including our ability to reduce the costs of tissue preservation services and improve yield;

our competitive position, including the impact of price increases;

demand for our products and services and market growth;

the potential of the ACT for use in fibrinolysis (blood clot dissolving), and other drug delivery applications;

the effect of earnings, cash flow and cash on compliance with credit agreement financial covenants and dividend payment restrictions;

Edgar Filing: CRYOLIFE INC - Form 424B5

the impact on CryoLife of adverse results of surgery utilizing tissue processed by it;

our intention to pay dividends on the convertible preferred stock; and

other statements regarding future plans and strategies, anticipated events or trends.

S-31

---

## Edgar Filing: CRYOLIFE INC - Form 424B5

These statements are based on certain assumptions and analyses made by us in light of our experience and our perception of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate in the circumstances. However, whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties that could cause actual results to differ materially from such expectations, including the risk factors discussed in this prospectus supplement and the accompanying prospectus and other factors, many of which are beyond our control. Consequently, all of the forward-looking statements made in this prospectus supplement and the accompanying prospectus are qualified by these cautionary statements and there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to or effects on us or our business or operations. We assume no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

S-32

---

### USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the 400,000 shares of convertible preferred stock we are offering will be approximately \$18.3 million, at the public offering price of \$50 per share, after deducting underwriting discounts and commissions and our estimated offering expenses.

We expect to use the net proceeds of this offering for working capital and general corporate purposes, including working capital needs created by costs of operations combined with losses incurred in our tissue preservation business.

We have and reserve broad discretion to use the proceeds from this offering differently. When and if the opportunity arises, we may use a portion of the proceeds to acquire or invest in complementary businesses, products or technologies. We currently have no commitments or agreements, and are not involved in any negotiations, to acquire any businesses, products or technologies. Pending any ultimate use of any portion of the proceeds from this offering, we intend to invest the proceeds in short-term, investment-grade and interest-bearing instruments.

### DIVIDEND POLICY

Dividends on our capital stock, including the convertible preferred stock, are payable when, as and if declared by our board of directors. Payments of dividends, including dividends on the convertible preferred stock, will be at the discretion of the board of directors and will depend, among other factors, upon our earnings, capital requirements, operations and financial condition.

Under Florida law, no distributions may be paid on capital stock, if after giving it effect: (a) the corporation would not be able to pay its debts as they become due in the usual course of business; or (b) the corporation's total assets would be less than the sum of its total liabilities plus (unless the articles of incorporation permit otherwise) the amount that would be needed, if the corporation were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of shareholders whose preferential rights are superior to those receiving the distribution.

Under our new credit agreement, cash dividends on our common stock are prohibited, and cash dividends on our preferred stock may be paid only so long as we maintain at least \$7.5 million, in the aggregate, of borrowing capacity under the credit agreement, cash and cash equivalents, each as more fully described above under "Risks Factors-Risks related to our business-our new revolving credit facility imposes restrictions on our ability to borrow which could make it more difficult to borrow needed funds." Increased borrowings under the credit agreement and judgments or settlements arising out of product liability or other claims, negative operating cash flow and other factors which adversely affect available cash resources will also adversely affect the Company's ability to make cash dividend payments generally and in compliance with the credit agreement specifically. The terms of any future financing arrangements entered into by us may also restrict our ability to pay dividends.

We currently intend to pay cash dividends on the convertible preferred stock, but we may not be able to under Florida law or under the terms of our credit agreement. If we return to profitability, our ability to pay cash dividends on the convertible stock requires the availability of adequate net assets. Even if adequate net assets are available to pay cash dividends on the convertible preferred stock, we may not have sufficient cash flow to cover fixed charges and the convertible preferred stock dividend payments or to permit the payment of convertible preferred stock dividends. Further, even if we return to profitability and have adequate net assets, we might not have \$7.5 million in borrowing capacity, cash and cash equivalents after paying the cash dividend for the dividend to be permitted under our credit agreement. If we are unable to pay any quarterly dividends on the convertible preferred stock, such dividends will accumulate in preference to payments to holders of our common stock.

We have never declared or paid any cash dividends on our common stock and do not currently anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Except

for dividends payable on the convertible preferred stock, we currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our board of directors may deem relevant.

**RATIO OF EARNINGS TO FIXED CHARGES AND PREFERRED STOCK DIVIDENDS**

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

	Year Ended December 31,				
	2000	2001	2002	2003	2004
	(dollars in thousands)				
Ratio of earnings to fixed charges and preferred stock dividends	16.53X	8.57X	(a)	(a)	(a)
Deficiency of earnings to fixed charges and preferred stock dividends	\$ N/A	\$ N/A	\$ (41,376)	\$ (29,168)	\$ (21,708)

(a) Earnings for this period were insufficient to cover fixed charges and will be insufficient to cover fixed charges and preferred stock dividends immediately following this offering. Dividends on the convertible preferred stock accumulate at the annual aggregate rate of \$ million beginning with the date of their issuance.



**PRICE RANGE OF COMMON STOCK**

Our common stock is traded on the New York Stock Exchange under the symbol "CRY." We have applied to list the convertible preferred stock on the New York Stock Exchange under the symbol "CRY Pr." The following table sets forth, for the calendar periods indicated, the high and low sale prices per share of our common stock as reported on the New York Stock Exchange.

	<u>High</u>	<u>Low</u>
<b>2003</b>		
First Quarter	\$ 9.79	\$ 4.44
Second Quarter	\$ 10.94	\$ 6.25
Third Quarter	\$ 10.98	\$ 4.00
Fourth Quarter	\$ 6.60	\$ 5.00
<b>2004</b>		
First Quarter	\$ 8.25	\$ 5.48
Second Quarter	\$ 6.40	\$ 4.43
Third Quarter	\$ 7.49	\$ 4.43
Fourth Quarter	\$ 8.50	\$ 5.68
<b>2005</b>		
First Quarter (through March 7, 2005)	\$ 8.60	\$ 6.41

S-35

## CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of December 31, 2004:

on an actual basis;

on an as adjusted basis to further reflect sale of 400,000 shares of our convertible preferred stock we are offering at the public offering price of \$50 per share, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

	As of December 31, 2004	
	Actual	As Adjusted
	(unaudited, in thousands)	
Cash, cash equivalents and short-term investments*	\$ 9,232	\$ 27,501
Long-term liabilities, less current portion	5,629	5,629
Stockholders' equity:		
Preferred stock, \$0.01 par value per share; 5,000 shares authorized; Series A junior participating preferred stock, 2,000 shares authorized, no shares issued, actual and as adjusted;		
Convertible Preferred Stock, no shares authorized, no shares issued, actual; 460 shares authorized, 400 issued, as adjusted		4
Common stock, par value \$0.01 per share; 75,000 shares authorized; 24,805 shares issued actual and as adjusted	248	248
Additional paid-in capital	94,846	113,111
Retained deficit	(38,257)	(38,257)
Deferred compensation	(222)	(222)
Accumulated other comprehensive income, net of tax	361	361
Treasury stock, 1,390 shares, at cost	(7,316)	(7,316)
<b>Total stockholders' equity</b>	<b>49,660</b>	<b>67,929</b>
<b>Total capitalization</b>	<b>\$ 55,289</b>	<b>\$ 73,558</b>

\*

Includes restricted investments of \$563

The table above should be read in conjunction with our financial statements and related notes incorporated in this prospectus supplement and the accompanying prospectus. This table is based on 23,415,000 shares of our common stock outstanding as of December 31, 2004 and excludes the following:

Up to            shares of our common stock issuable upon conversion of the convertible preferred stock;

An aggregate of 2,293,000 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2004 under our stock option plans at a weighted average exercise price of \$11.04 per share, including the

Edgar Filing: CRYOLIFE INC - Form 424B5

following stock plans: 1993 Employee Incentive Stock Option Plan, 1998 Long-Term Incentive Plan, 2002 Stock Incentive Plan, Amended and Restated Non-Employee Director's Plan, 2004 Employee Stock Incentive Plan, and 2004 Non-Employee Directors Stock Option Plan; and

An aggregate of 2,367,000 shares of our common stock reserved for future issuance under the above-referenced plans as of December 31, 2004.

S-36

---

## DESCRIPTION OF CONVERTIBLE PREFERRED STOCK

The following is a summary of the material terms of the convertible preferred stock. You should refer to the actual terms of the convertible preferred stock and the articles of amendment to the CryoLife articles of incorporation filed with the Secretary of State of the State of Florida, a form of which is filed as an exhibit to this registration statement. As used in this description, the words "we," "us" or "our" do not include any current or future subsidiary of CryoLife.

### General

Our board of directors has the authority, without stockholder approval, to issue up to 5.0 million shares of preferred stock in one or more series and to determine the rights, privileges and limitations of the preferred stock. The rights, preferences, powers and limitations on different series of preferred stock may differ with respect to dividend rates, amounts payable on liquidation, voting rights, conversion rights, redemption provisions, sinking fund provisions, and purchase funds and other matters.

Pursuant to its authority, our board of directors has designated up to 460,000 shares of the preferred stock that we now have authority to issue as the convertible preferred stock. The shares of convertible preferred stock, when issued and sold in the manner contemplated by this prospectus, will be duly and validly issued, fully paid and nonassessable. You will not have any preemptive rights if we issue other series of preferred stock. The convertible preferred stock is not subject to any sinking fund. We have no obligation to retire the convertible preferred stock. The convertible preferred stock has a perpetual maturity and may remain outstanding indefinitely, subject to your right to convert the convertible preferred stock and our right to cause the conversion of the convertible preferred stock or redeem the convertible preferred stock at our option. Any convertible preferred stock converted or redeemed or acquired by us will, upon cancellation, have the status of authorized but unissued shares of convertible preferred stock. We will be able to reissue these cancelled shares of convertible preferred stock.

### Dividends

When and if declared by our board of directors out of the legally available funds, you will be entitled to receive cash dividends at an annual rate of % of the liquidation preference of the convertible preferred stock. Dividends will be payable quarterly on the first day of March, June, September and December beginning June 1, 2005. If any dividends are not declared, they will accrue and be paid at such later date, if any, as determined by our board of directors. Dividends on the convertible preferred stock will be cumulative from the issue date. Dividends will be payable to holders of record as they appear on our stock books not more than 60 days nor less than 10 days preceding the payment dates, as fixed by our board of directors. If the convertible preferred stock is called for redemption on a redemption date between the dividend record date and the dividend payment date and you do not convert the convertible preferred stock (as described below), you shall receive the dividend payment together with all other accrued and unpaid dividends on the redemption date instead of receiving the dividend on the dividend date. Dividends payable on the convertible preferred stock for any period greater or less than a full dividend period will be computed on the basis of a 360-day year consisting of twelve 30-day months. Accrued but unpaid dividends will not bear interest.

If we do not pay or set aside cumulative dividends in full on the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends, all dividends declared upon shares of the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends will be declared on a pro rata basis until all accrued dividends are paid in full. For these purposes, "pro rata" means that the amount of dividends declared per share on the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends bear to each other will be the same ratio that accrued and unpaid dividends per share on the shares of the convertible preferred

stock and such other preferred stock bear to each other. We will not be able to redeem, purchase or otherwise acquire any of our stock ranking on the same basis as the convertible preferred stock as to dividends or liquidation preferences unless we have paid or set aside full cumulative dividends, if any, accrued on all outstanding shares of convertible preferred stock.

Unless we have paid or set aside cumulative dividends in full on the convertible preferred stock and any other preferred stock ranking on the same basis as to dividends:

we may not declare or pay or set aside dividends on common stock or any other stock ranking junior to the convertible preferred stock as to dividends or liquidation preferences, except that we may declare and pay dividends or distributions of shares, options, warrants or rights to purchase common stock or such other stock ranking junior to the convertible preferred stock as to dividends; and

we will not be able to redeem, purchase or otherwise acquire any of our common stock or other stock ranking junior to the convertible preferred stock as to dividends or liquidation preferences, except in very limited circumstances.

Under Florida law, we may not pay a dividend or distribution to stockholders if after giving it effect:

the corporation would not be able to pay its debts as they become due in the usual course of business, or

the corporation's total assets would be less than the sum of its total liabilities plus the amount needed, if the corporation were to be dissolved at the time of the distribution, to satisfy the preferential rights upon dissolution of shareholders whose preferential rights are superior to those receiving the distribution.

Our ability to pay dividends and make any other distributions in the future will depend upon our financial results, liquidity and financial condition.

Our credit agreement also contains restrictions on the payment of dividends. We will not be able to pay cash dividends on our convertible preferred stock unless following the payment of the dividends we have at least \$7.5 million, in the aggregate, of borrowing capacity under our credit agreement, cash and cash equivalents, each as more fully described above under "Risk Factors Risks related to our business our new revolving credit facility imposes restrictions on our ability to borrow which could make it more difficult to borrow needed funds" and "Risk Factors Risks related to the offering we may not be able to pay cash dividends on any class of capital stock due to legal and contractual restrictions and lack of liquidity." Increased borrowings under the credit agreement and judgments or settlements arising out of product liability or other claims, negative operating cash flow and other factors which adversely affect available cash resources will also adversely affect the Company's ability to make cash dividend payments generally and in compliance with the credit agreement specifically.

## **Conversion**

### ***Conversion Rights***

You may convert the convertible preferred stock at any time into a number of shares of common stock determined by dividing the \$50 liquidation preference by the conversion price of \$ \_\_\_\_\_, subject to adjustment as described below. This conversion price is equivalent to a conversion rate of approximately \_\_\_\_\_ shares of common stock for each share of convertible preferred stock. We will not make any adjustment to the conversion price for accrued or unpaid dividends upon conversion. We will not issue fractional shares of common stock upon conversion. However, we will instead pay cash for each fractional share based upon the market price of the common stock on the last business day prior to the conversion date. If we call the convertible preferred stock for redemption, your right to convert the convertible preferred stock will expire at the close of business on

the business day immediately preceding the date fixed for redemption, unless we fail to pay the redemption price.

In order to convert your shares of convertible preferred stock, you must either:

deliver your convertible preferred stock certificate and a duly signed and completed notice of conversion to the office of the transfer agent, or

if the convertible preferred stock is held in global form, follow procedures established by the depositary as described below under the subsection entitled "Form and Denomination."

The conversion date will be the date all of the applicable conditions have been satisfied. You will not be required to pay any U.S. federal, state or local issuance taxes or duties or costs incurred by us on conversion, but will be required to pay any tax or duty payable as a result of the common stock upon conversion being issued other than in your name. We will not issue common stock certificates unless all taxes and duties, if any, have been paid by the holder. If you convert your convertible preferred stock after a dividend record date and prior to the next dividend payment date, you will have to pay us an amount equal to the dividend payable on such dividend payment date unless the convertible preferred stock has been called for redemption or we have issued a notice of automatic conversion.

***Automatic Conversion***

Unless we redeem the convertible preferred stock, we may elect to convert some or all of the convertible preferred stock into shares of our common stock if the closing price of our common stock has exceeded 150% of the conversion price for at least 20 out of 30 consecutive trading days ending within five trading days prior to the notice of automatic conversion. If we elect to convert less than all of the shares of convertible preferred stock, we shall select the shares to be converted by lot or pro rata or in some other equitable manner in our discretion. If we elect to automatically convert shares of our convertible preferred stock prior to March , 2008, we are required to make the payment discussed under the heading, " Dividend Make-Whole Payment" below. On or after March , 2008, we may not elect to automatically convert the convertible preferred stock if full cumulative dividends on the convertible preferred stock for all past dividend periods have not been paid or set aside for payment.

***Conversion Price Adjustment General***

The conversion price of \$ will be adjusted if:

- (1) we pay a dividend of, or distribute, common stock on shares of our common stock;
- (2) we subdivide or combine our common stock;
- (3) we issue to all holders of common stock certain rights or warrants to purchase our common stock at less than the current market price;
- (4) we pay a dividend or distribute to all holders of our common stock shares of our capital stock or evidences of indebtedness or assets, excluding:
  - those rights, warrants, dividends or distributions referred to in (1) or (3), or
  - dividends and distributions paid in cash;
- (5) we make a dividend or distribution consisting of cash to all holders of common stock;
- (6)

we purchase common stock pursuant to a tender offer made by us or any of our subsidiaries; and

S-39

---

(7)

a person other than us or any of our subsidiaries makes any payment on a tender offer or exchange offer and, as of the closing of the offer, the board of directors is not recommending rejection of the offer. We will only make this adjustment if the tender or exchange offer increases a person's ownership to more than 25% of our outstanding common stock, and only if the payment per share of common stock exceeds the current market price of our common stock. We will not make this adjustment if the offering documents disclose our plan to engage in any consolidation, merger, or transfer of all or substantially all of our properties and if specified conditions are met.

If we implement a new stockholder rights plan or amend our existing rights plan, the new rights plan or the amended rights plan, as the case may be, must provide that upon conversion of the existing convertible preferred stock the holders will receive, in addition to the common stock issuable upon such conversion, the rights under such rights plan regardless of whether the rights have separated from the common stock before the time of conversion. The distribution of rights or warrants pursuant to a stockholder rights plan will not result in an adjustment to the conversion price of the convertible preferred stock until one of the requisite triggering events occurs.

The occurrence and magnitude of certain of the adjustments described above is dependent upon the current market price of our common stock. For these purposes, "current market price" generally means the lesser of:

the closing sale price on the relevant date, or

the average of the closing prices of the common stock for the ten trading day period immediately prior to the relevant date.

We may make a temporary reduction in the conversion price of the convertible preferred stock if our board of directors determines that this decrease would be in the best interests of CryoLife. We may, at our option, reduce the conversion price if our board of directors deems it advisable to avoid or diminish any income tax to holders of common stock resulting from any dividend or distribution of stock or rights to acquire stock or from any event treated as such for income tax purposes. See the section entitled "Material Federal Income Tax Consequences" below for more information.

***Conversion Price Adjustment Merger, Consolidation or Sale of Assets***

If we are involved in a transaction in which shares of our common stock are converted into the right to receive other securities, cash or other property, or in a sale or transfer of all or substantially all of our assets under which the holders of our common stock shall be entitled to receive other securities, cash or other property, then appropriate provision shall be made so that your convertible preferred stock will convert into:

(1)

if the transaction is a common stock fundamental change, as defined below, common stock of the kind received by holders of the common stock as a result of common stock fundamental change in accordance with paragraph (1) below under the subsection entitled " Fundamental Change Conversion Price Adjustments," and

(2)

if the transaction is not a common stock fundamental change, and subject to funds being legally available at conversion, the kind and amount of the securities, cash or other property that would have been receivable upon the recapitalization, reclassification, consolidation, merger, sale, transfer or share exchange by a holder of the number of shares of common stock issuable upon conversion of the convertible preferred stock immediately prior to the recapitalization, reclassification, consolidation, merger, sale, transfer or share exchange, after giving effect to any adjustment in the conversion price in accordance with paragraph (2) below under the subsection entitled " Fundamental Change Conversion Price Adjustments."



## Edgar Filing: CRYOLIFE INC - Form 424B5

The company formed by the consolidation, merger, asset acquisition or share acquisition shall provide for this right in its organizational document. This organizational document shall also provide for adjustments so that the organizational document shall be as nearly equivalent as practicable to adjustments in this section for events occurring after the effective date of the organizational document.

The following types of transactions, among others, would be covered by this adjustment:

- (1) we recapitalize or reclassify our common stock, except for:
  - a change in par value,
  - a change from par value to no par value,
  - a change from no par value to par value, or
  - a subdivision or combination of our common stock,
- (2) we consolidate or merge into any other person, or any merger of another person into us, except for a merger that does not result in a reclassification, conversion, exchange or cancellation of common stock,
- (3) we sell, transfer or lease all or substantially all of our assets and holders of our common stock become entitled to receive other securities, cash or other property, or
- (4) we undertake any compulsory share exchange.

### ***Fundamental Change Conversion Price Adjustments***

If a fundamental change occurs, the conversion price will be adjusted as follows:

- (1) in the case of a common stock fundamental change, the conversion price shall be the conversion price after giving effect to any other prior adjustments effected pursuant to the preceding paragraphs, multiplied by a fraction, the numerator of which is the purchaser stock price, as defined below, and the denominator of which is the applicable price, as defined below. However, in the event of a common stock fundamental change in which:

100% of the value of the consideration received by a holder of our common stock is common stock of the successor, acquiror or other third party, and cash, if any, paid with respect to any fractional interests in such common stock resulting from such common stock fundamental change, and

all of our common stock shall have been exchanged for, converted into or acquired for, common stock of the successor, acquiror or other third party, and any cash with respect to fractional interests,

the conversion price shall be the conversion price in effect immediately prior to such common stock fundamental change multiplied by a fraction, the numerator of which is one (1) and the denominator of which is the number of shares of common stock of the successor, acquiror or other third party received by a holder of one share of our common stock as a result of the common stock fundamental change; and

- (2) in the case of a non-stock fundamental change, the conversion price shall be the lower of:

Edgar Filing: CRYOLIFE INC - Form 424B5

the conversion price after giving effect to any other prior adjustments effected pursuant to the preceding paragraphs, and

the product of:

(A) the applicable price, and

S-41

---

(B)

a fraction, the numerator of which is \$50 and the denominator of which is (x) the amount of the redemption price for one share of convertible preferred stock if the redemption date were the date of the non-stock fundamental change (or if the date of such non-stock fundamental change falls within the period beginning on the first issue date of the convertible preferred stock through \_\_\_\_\_, 2005, the 12-month period commencing \_\_\_\_\_, 2005 and the 12-month period commencing \_\_\_\_\_, 2006, the product of \_\_\_\_\_%, \_\_\_\_\_% or \_\_\_\_\_%, respectively, and \$50 plus (y) any then-accrued and unpaid distributions on one share of convertible preferred stock.

You may receive significantly different consideration upon conversion depending upon whether a fundamental change is a non-stock fundamental change or a common stock fundamental change. In the event of a non-stock fundamental change, your convertible preferred stock will convert into stock and other securities or property or assets, including cash, determined by the number of shares of common stock receivable upon conversion at the conversion price as adjusted in accordance with (2) above. In the event of a common stock fundamental change, under certain circumstances you will receive different consideration depending on whether you convert your convertible preferred stock on or after the common stock fundamental change. For example, you will only receive common stock of the successor, acquiror or other third party if you convert your convertible preferred stock following a common stock fundamental change in which less than 100% of the value of the consideration received by a holder of common stock is common stock of the successor, acquiror or other third party. However, if you had converted your convertible preferred stock prior to the common stock fundamental change, you would have received consideration in the form of such common stock as well as any other securities or assets, including cash, issuable to the holders of our common stock in connection with the common stock fundamental change.

***Definitions for the Fundamental Change Adjustment Provision***

"applicable price" means:

in a non-stock fundamental change in which the holders of common stock receive only cash, the amount of cash received by a holder of one share of common stock, and

in the event of any other fundamental change, the average of the daily closing price for one share of common stock during the 10 trading days immediately prior to the record date for the determination of the holders of common stock entitled to receive cash, securities, property or other assets in connection with the fundamental change or, if there is no such record date, prior to the date upon which the holders of common stock shall have the right to receive such cash, securities, property or other assets.

"common stock fundamental change" means any fundamental change in which more than 50% of the value, as determined in good faith by our board of directors, of the consideration received by holders of our common stock consists of common stock that, for the 10 trading days immediately prior to such fundamental change, has been admitted for listing or admitted for listing subject to notice of issuance on a national securities exchange or quoted on the New York Stock Exchange, except that a fundamental change shall not be a common stock fundamental change unless either:

we continue to exist after the occurrence of the fundamental change and the outstanding convertible preferred stock continues to exist as outstanding convertible preferred stock, or

not later than the occurrence of the fundamental change, the outstanding convertible preferred stock is converted into or exchanged for shares of preferred stock, which preferred stock has rights, preferences and limitations substantially similar, but no less favorable, to those of the convertible preferred stock.

"fundamental change" means the occurrence of any transaction or event or series of transactions or events pursuant to which all or substantially all of our common stock shall be exchanged for, converted into, acquired for or shall constitute solely the right to receive cash, securities, property or other assets, whether by means of an exchange offer, liquidation, tender offer, consolidation, merger, combination, reclassification, recapitalization or otherwise. However, for purposes of adjustment of the conversion price, in the case of any series of transactions or events, the fundamental change shall be deemed to have occurred when substantially all of the common stock shall have been exchanged for, converted into or acquired for, or shall constitute solely the right to receive, such cash, securities, property or other assets, but the adjustment shall be based upon the consideration that the holders of our common stock received in the transaction or event as a result of which more than 50% of our common stock shall have been exchanged for, converted into or acquired for, or shall constitute solely the right to receive, such cash, securities, property or other assets.

"non-stock fundamental change" means any fundamental change other than a common stock fundamental change.

"purchaser stock price" means the average of the daily closing price for one share of the common stock received by holders of the common stock in the common stock fundamental change during the 10 trading days immediately prior to the date fixed for the determination of the holders of the common stock entitled to receive such common stock or, if there is no such date, prior to the date upon which the holders of the common stock shall have the right to receive such common stock.

#### ***Dividend Make-Whole Payment***

If we elect to automatically convert, or you voluntarily convert, some or all of the convertible preferred stock into shares of our common stock prior to March , 2008, we will make an additional payment equal to the total value of the aggregate amount of cumulative dividends that would have accrued and become payable on the convertible preferred stock from the date of original issue through and including March , 2008, less any dividends already paid on the convertible preferred stock. This additional payment is payable by us, in cash, or, at our option, in shares of our common stock or a combination of cash and shares of our common stock. In the event of an automatic conversion or any voluntary conversion undertaken after we provide notice of an automatic conversion, the shares of common stock issued in payment of the dividend make-whole payment will be valued at 150% of the conversion price on the effective date of the conversion. In all other circumstances, any shares of our common stock issued in payment of the dividend make-whole payment will be valued at the greater of (i) 95% of the average closing price of our common stock for the five trading days prior to the effective date of conversion or (ii) \$ , which was the last reported sale price of our common stock on , 2005. In the event of an automatic conversion, the notice of automatic conversion will specify whether we will make the dividend make-whole payment in cash, shares of our common stock or a combination of cash and shares of our common stock. We will not issue fractional shares for any additional payment upon conversion but will instead make a cash adjustment for any fractional share payment.

#### **Liquidation Rights**

In the event of our voluntary or involuntary dissolution, liquidation, or winding up, you shall receive a liquidation preference of \$50 per share and all accrued and unpaid dividends through the distribution date. Holders of any class or series of preferred stock ranking on the same basis as your convertible preferred stock as to liquidation shall also be entitled to receive the full respective liquidation preferences and any accrued and unpaid dividends through the distribution date. Only after the preferred stock holders have received their liquidation preference and any accrued and unpaid dividends will we distribute assets to common stock holders or any of our other stock ranking junior to the shares of convertible preferred stock upon liquidation. If upon such dissolution, liquidation or

winding up, we do not have enough assets to pay in full the amounts due on the convertible preferred stock and any other preferred stock ranking on the same basis with your convertible preferred stock as to liquidation, you and the holders of such other preferred stock will share ratably in any such distributions of our assets:

first in proportion to the liquidation preferences until the preferences are paid in full, and

then in proportion to the amounts of accrued but unpaid dividends.

After we pay any liquidation preference and accrued dividends, you will not be entitled to participate any further in the distribution of our assets. The following events will not be deemed to be a dissolution, liquidation or winding up of CryoLife:

the sale of all or substantially all of the assets;

our merger or consolidation into or with any other corporation; or

our liquidation, dissolution, winding up or reorganization immediately followed by a reincorporation as another corporation.

**Optional Redemption**

On or after March , 2008, we may redeem the convertible preferred stock, out of legally available funds, in whole or in part, at our option, at the redemption prices listed below. The redemption price is as follows for the 12-month period beginning of the following years, beginning , 2008 and ending on , 2009 in the case of the first period:

YEAR	REDEMPTION PRICE
2008	
2009	
2010	
2011	
2012	
2013	
2014	

and \$50.00 at March , 2015 and thereafter. In each case we will pay accrued and unpaid dividends to, but excluding, the redemption date. We are required to give notice of redemption not more than 90 and not less than 30 days before the redemption date.

If we redeem less than all of the shares of convertible preferred stock, we shall select the shares to be redeemed by lot or pro rata or in some other equitable manner in our sole discretion.

**Voting Rights**

You will have no voting rights except as described below or as required by law. Shares held by us or any entity controlled by us will not have any voting rights.

If at any time we have failed to pay dividends on the convertible preferred stock or on any outstanding shares of preferred stock ranking on the same basis as to dividends with the convertible preferred stock in an aggregate amount equal to at least six quarterly dividends whether or not consecutive, we will increase the size of our board of directors by two additional directors. So long as dividends remain due and unpaid, holders of the convertible preferred stock, voting separately as a class with holders of preferred stock ranking on the same basis as to dividends having like voting rights, will be entitled to elect two additional directors at any meeting of stockholders at which directors are to be elected. These directors will be appointed to classes on the board as determined by our board of



directors. These voting rights will terminate when we have declared and either paid or set aside for payment all accrued and unpaid dividends. The terms of office of all directors so elected will terminate immediately upon the termination of these voting rights.

Without the vote or consent of the holders of at least two-thirds of the shares of convertible preferred stock, we may not:

adversely change the rights, preferences and limitations of the convertible preferred stock by modifying our certificate of incorporation or bylaws, or

authorize, issue, reclassify any of our authorized stock into, increase the authorized amount of, or authorize or issue any convertible obligation or security or right to purchase, any class of stock that ranks senior to the convertible preferred stock as to dividends or distributions of assets upon liquidation, dissolution or winding up of the stock.

In addition, without the vote or consent of the holders of at least a majority of the shares of convertible preferred stock we may not:

enter into a share exchange that affects the convertible preferred stock,

consolidate with or merge into another entity, or

permit another entity to consolidate with or merge into us,

unless the convertible preferred stock remains outstanding and its rights, privileges and preferences are unaffected or it is converted into or exchanged for convertible preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to the convertible preferred stock.

No class vote on the part of convertible preferred stock shall be required (except as otherwise required by law or resolution of our board of directors) in connection with the authorization, issuance or increase in the authorized amount of any shares of capital stock ranking junior to or on parity with the convertible preferred stock both as to the payment of dividends and as to distribution of assets upon our liquidation, dissolution or winding up, whether voluntary or involuntary, including our common stock and the convertible preferred stock.

In determining a majority under these voting provisions, holders of convertible preferred stock will vote together with holders of any other preferred stock that rank on parity as to dividends and that have like voting rights.

#### **Form and Denomination**

Except in very limited circumstances, the shares of convertible preferred stock will be evidenced by a global certificate that will be deposited with, or on behalf of, the Depository Trust Company, or DTC, and registered in the name of Cede & Co. as DTC's nominee. Except as set forth below, the global certificate may be transferred, in whole or in part, only to another nominee of DTC or to a successor of DTC or its nominee.

Purchasers may hold their interests in the global certificate directly through DTC or indirectly through organizations that are participants in DTC. Transfers between participants will be effected in the ordinary way in accordance with DTC rules and will be settled in clearing house funds. The laws of some states require that certain persons take physical delivery of securities in definitive form. Consequently, the ability to transfer beneficial interests in the global certificate to such persons may be limited.

Purchasers may beneficially own interests in the global certificate held by DTC only through participants, or certain banks, brokers, dealers, trust companies and other parties that clear through or

maintain a custodial relationship, with a participant, either directly or indirectly through indirect participants. So long as Cede & Co., as the nominee of DTC, is the registered owner of the global certificate, Cede & Co. for all purposes will be considered the sole holder of the global certificate. Except as provided below, owners of beneficial interests in the global certificate will not be entitled to have certificates registered in their names, will not receive or be entitled to receive physical delivery of certificates in definitive form, and will not be considered the holders.

Payment of dividends on and the redemption price of the global certificate will be made to Cede & Co. by wire transfer of immediately available funds. Neither we nor any paying agent will have any responsibility or liability for any aspect of the records relating to or payments made on account of beneficial ownership interests in the global certificate or for maintaining, supervising or reviewing any records relating to such beneficial ownership interests.

We have been informed by DTC that, with respect to any payment of dividends on or the redemption price of the global certificate, DTC's practice is to credit participants' accounts on the payment date with payments in amounts proportionate to their respective beneficial interests in the convertible preferred stock represented by the global certificate as shown on the records of DTC, unless DTC has reason to believe that it will not receive payment on such payment date. Payments by participants to owners of beneficial interests in convertible preferred stock represented by the global certificate held through such participants will be the responsibility of such participants, as is now the case with securities held for the accounts of customers registered in "street name."

If you would like to convert your convertible preferred stock into common stock pursuant to the terms of the convertible preferred stock, you should contact your broker or other direct or indirect DTC participant to obtain information on procedures, including proper forms and cut-off times, for submitting those requests.

Because DTC can only act on behalf of participants, who in turn act on behalf of indirect participants and certain banks, the ability of a person having a beneficial interest in convertible preferred stock represented by the global certificate to pledge such interest to persons or entities that do not participate in the DTC system, or otherwise take actions in respect of such interest, may be affected by the lack of a physical certificate evidencing such interest.

Neither we, the transfer agent, registrar, paying agent nor conversion agent will have any responsibility for the performance by DTC or its participants or indirect participants under the rules and procedures governing their operations. DTC has advised us that it will take any action permitted to be taken by a holder of convertible preferred stock only at the direction of one or more participants to whose account with DTC interests in the global certificate are credited and only in respect of the amount of shares of the convertible preferred stock represented by the global certificate as to which the participant has given this direction.

DTC is a limited purpose trust company organized under the laws of the State of New York, a member of the Federal Reserve System, a "clearing corporation" within the meaning of the Uniform Commercial Code and a "clearing agency" registered pursuant to the provisions of Section 17A of the Exchange Act. DTC was created to hold securities for its participants and to facilitate the clearance and settlement of securities transactions between participants through electronic book-entry changes to accounts of its participants, thereby eliminating the need for physical movement of certificates. Participants include securities brokers and dealers, banks, trust companies and clearing corporations and may include certain other organizations such as the initial purchaser. Certain participants, together with other entities, own DTC. Indirect access to the DTC system is available to others such as banks, brokers, dealers and trust companies that clear through, or maintain a custodial relationship with, a participant, either directly or indirectly.



If DTC is at any time unwilling or unable to continue as depository and a successor depository is not appointed by us within 90 days, we will cause convertible preferred stock to be issued in definitive form in exchange for the global certificate.

**New York Stock Exchange Listing**

We are authorized to list our convertible preferred stock on the New York Stock Exchange under the symbol "CRY Pr."

**Transfer Agent and Registrar**

American Stock Transfer and Trust Company will act as transfer agent and registrar for the convertible preferred stock. Its address is 59 Maiden Lane, Plaza Level, New York, New York, 10038, and its telephone number is (212) 936-5100.

S-47

---

## MATERIAL FEDERAL INCOME TAX CONSEQUENCES

The following summary of the material federal income tax consequences of acquiring, owning and disposing of the convertible preferred stock and the common stock is based on the Internal Revenue Code of 1986, as amended (the "Code"), Treasury regulations, court decisions, and Internal Revenue Service ("IRS") rulings and pronouncements now in effect, all of which are subject to differing interpretations and which are subject to change, possibly on a retroactive basis.

This summary assumes that the convertible preferred stock is acquired at its original offering at its original issue price and that the convertible preferred stock and the common stock are held as capital assets, within the meaning of section 1221 of the Code. This summary does not address all of the tax consequences that may be relevant to particular holders in light of their personal circumstances, or to certain types of holders (such as banks, financial institutions, dealers in securities or commodities, traders in securities that elect to use a mark to market method of accounting for their holdings, insurance companies, regulated investment companies, personal holding companies, corporations subject to the alternative minimum tax, tax-exempt organizations, pension funds, certain U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, certain hybrid entities and their owners, U.S. holders who have a "functional currency" other than the U.S. dollar, persons who own 10% or more of our voting stock, or persons who hold the convertible preferred stock or common stock as positions in a "straddle" or as part of a "hedging," "conversion" or "constructive sale" transaction for United States federal income tax purposes). Also not addressed are the consequences under estate, state, local and foreign tax laws or the tax consequences to subsequent holders of the convertible preferred stock or common stock.

We have not sought and will not seek any rulings from the IRS concerning the tax consequences of the acquisition, ownership or disposition of the convertible preferred stock or the common stock. Accordingly, the IRS may successfully challenge the tax consequences described below. Prospective purchasers are advised to consult their own tax advisors regarding the tax consequences of acquiring, holding, or disposing of the convertible preferred stock or common stock in light of their own investment circumstances.

### **Characterization of Convertible Preferred Stock**

Under section 385(c) of the Code, our characterization of the convertible preferred stock as "stock" is binding upon us and all holders of the convertible preferred stock, other than holders who disclose on their tax returns that they are treating the convertible preferred stock in a manner inconsistent with such characterization. Although our characterization of the convertible preferred stock is not binding upon the IRS or any court, this summary assumes that the convertible preferred stock will be treated in a manner consistent with our characterization. Holders should be aware that if the convertible preferred stock is treated as "debt" for federal income tax purposes, the tax consequences of acquiring, holding and disposing of the convertible preferred stock will differ materially from the tax consequences described in this prospectus.

### **Distributions on Convertible Preferred Stock and Common Stock**

Distributions with respect to the convertible preferred stock and common stock will constitute dividends, to the extent that we have current or accumulated earnings and profits for federal income tax purposes as of the end of the tax year of the distribution. Dividends paid to non-corporate U.S. holders in taxable years beginning prior to January 1, 2009, will be subject to tax as net capital gain at the maximum rate of 15% if the holder has held the shares of stock for more than 60 days during the 120-day period beginning 60 days before the ex-dividend date and other requirements applicable to "qualified dividend income" are satisfied. Dividends paid to corporations will generally be eligible for

the 70% dividends-received deduction under section 243 of the Code, subject to the limitations contained in sections 246 and 246A of the Code.

In general, the dividends-received deduction is available only if the stock in respect of which a dividend is paid has been held for at least 46 days during the 90-day period beginning on the date that is 45 days before the ex-dividend date, or at least 91 days during the 180-day period beginning on the date that is 90 days before the ex-dividend date in the case of a dividend paid with respect to preferred stock and which is attributable to a period or periods aggregating more than 366 days. A taxpayer's holding period for these purposes is reduced by periods during which the taxpayer's risk of loss with respect to the stock is considered diminished by reason of the existence of options, contracts to sell or other similar transactions. The dividends-received deduction will not be available to the extent that the taxpayer is under an obligation to make related payments with respect to positions in substantially similar or related property. The dividends-received deduction is limited to specified percentages of the holder's taxable income and may be reduced or eliminated if the holder has indebtedness "directly attributable to investment" in the stock. Prospective corporate purchasers of convertible preferred stock should consult their own tax advisors to determine whether these limitations might apply to them. No assurance can be given that we will have sufficient earnings and profits for federal income tax purposes to cause all or even any distributions to be taxable as dividends. As a result, no assurance can be given that any distribution on the convertible preferred stock or common stock will be treated as a dividend for which the dividends-received deduction will be available.

If distributions with respect to the convertible preferred stock or common stock exceed our current and accumulated earnings and profits, the excess will be applied against and reduce the holder's basis in the convertible preferred stock or common stock, as applicable. Any amount in excess of the amount of the dividend and the amount applied against basis will be treated as capital gain.

### **Extraordinary Dividends**

If a corporate holder of convertible preferred or common stock receives an "extraordinary dividend" from CryoLife with respect to stock that it has not held for more than two years before the dividend announcement date, the basis of the stock will be reduced (but not below zero) by the portion of the dividend that is not taxable because of the dividends-received deduction. If, because of the limitation on reducing basis below zero, any amount of the non-taxable portion of an extraordinary dividend has not been applied to reduce basis, such amount will be treated as gain from the sale or exchange of stock in the taxable year in which the extraordinary dividend is received. An "extraordinary dividend" on the convertible preferred or common stock would include a dividend that (i) equals or exceeds 5%, in the case of the convertible preferred stock, or 10%, in the case of the common stock, of the holder's adjusted basis in the stock, treating all dividends having ex-dividend dates within an 85-day period as one dividend, or (ii) exceeds 20% of the holder's adjusted basis in the stock, treating all dividends having ex-dividend dates within a 365-day period as one dividend. A holder may elect to use the fair market value of the stock rather than its adjusted basis for purposes of applying the 5%, 10% or 20% limitation if the holder is able to establish such fair market value to the satisfaction of the IRS. An "extraordinary dividend" also includes any amount treated as a dividend in the case of a redemption of the convertible preferred stock or common stock that is not pro rata to all shareholders, irrespective of the holder's holding period of the stock.

Special rules apply with respect to "qualified preferred dividends." A qualified preferred dividend is any fixed dividend payable with respect to stock that (i) provides for fixed preferred dividends payable no less often than annually and (ii) is not in arrears as to dividends when acquired, provided the actual rate of return on such stock does not exceed 15%. For this purpose, the actual rate of return is determined solely by taking into account dividends during such holding period and by using the lesser of the adjusted basis or the liquidation preference in respect of such preferred stock. Where a qualified preferred dividend exceeds the 5% or 20% limitation described above, the extraordinary dividend

rules will not apply if the taxpayer holds the stock for more than five years. If the taxpayer disposes of the stock before it has been held for more than five years, the aggregate reduction in basis will not exceed the excess of the qualified preferred dividends paid on such stock during the period held by the taxpayer over the qualified preferred dividends that would have been paid during such period on the basis of the stated rate of return as determined under section 1059(e)(3) of the Code. The length of time that a taxpayer is deemed to have held stock for this purpose is determined under principles similar to those applicable for purposes of the dividends-received deduction discussed above.

Any loss on the sale or exchange of stock with respect to which an individual holder receives an extraordinary dividend that is also qualified dividend income (see "Distributions on Convertible Preferred Stock and Common Stock" above) will be treated as long-term capital loss to the extent of the dividend. The deductibility of capital losses is limited.

### **Redemption Premium**

If (i) preferred stock is, like the convertible preferred stock, redeemable only at the issuer's option, (ii) the facts and circumstances on the issue date indicate that redemption is more likely than not to occur, and (iii) the redemption price of the preferred stock as of the most likely redemption date exceeds the issue price (so that there is a "redemption premium"), then the redemption premium may be taxable as a constructive dividend to the extent of the issuing corporation's current or accumulated earnings and profits over the period from issuance to the most likely redemption date. If a redemption premium is subject to the foregoing treatment, a holder of the convertible preferred stock would take the amount of the premium into income under an economic accrual method. A holder of a preferred stock would generally be required to include in gross income (irrespective of the holder's method of accounting) a portion of the redemption premium for each year during which it holds the preferred stock even though the cash to which such income is attributable would not be received until maturity or redemption of the preferred stock. The amount of any redemption premium included in income for each year would be calculated under a constant yield to maturity formula that would result in the allocation of less redemption premium to the early years of the holding period of the preferred stock and more redemption premium to later years.

Under applicable Treasury regulations, a redemption premium is not subject to the foregoing treatment if it will be paid "as a result of changes in economic or market conditions over which neither the issuer nor the holder has legal or practical control" and is "solely in the nature of a penalty for premature redemption." The Treasury regulations also provide a "safe harbor," pursuant to which a redemption will not be treated as more likely than not to occur, as to a given holder, if: (x) the issuer and the holder are not "related" under certain tests prescribed by the Code, (y) the issuer is not effectively required or compelled by any plan, arrangement or agreement to redeem the stock, and (z) redemption would not reduce the yield of the stock. Because the foregoing tests are based upon an evaluation of all facts and circumstances surrounding the issuance and redemption of preferred stock, the conclusion cannot be entirely certain; however, it is CryoLife's belief that no part of the premium payable upon redemption of the convertible preferred stock will be treated as a constructive dividend to the holders of the convertible preferred stock. It is also possible that upon an actual redemption, the redemption premium would, together with the other redemption proceeds, be treated as a dividend for federal income tax purposes. See "Redemption of Convertible Preferred Stock for Cash," below.

### **Redemption of Convertible Preferred Stock for Cash**

A redemption of shares of convertible preferred stock by CryoLife for cash will be treated as a distribution taxable as a dividend (and, possibly, an "extraordinary dividend") (see "Distributions on

Convertible Preferred Stock and Common Stock" and "Extraordinary Dividends," above) to redeeming shareholders to the extent of our current or accumulated earnings and profits unless the redemption:

results in a complete termination of the shareholder's interest in CryoLife (within the meaning of section 302(b)(3) of the Code);

is "substantially disproportionate" (within the meaning of section 302(b)(2) of the Code) with respect to the holder; or

is "not essentially equivalent to a dividend" (within the meaning of section 302(b)(1) of the Code).

In determining whether any of these tests has been met, shares considered to be owned by the holder by reason of the constructive ownership rules set forth in section 318 of the Code, as well as shares actually owned, will be taken into account. If any of the foregoing tests is met, the redemption of shares of convertible preferred stock for cash will result in taxable gain or loss equal to the difference between the amount of cash received (except cash attributable to accrued, unpaid, declared dividends, which will be taxable as a dividend described above), and the holder's basis in the redeemed shares. Any such gain or loss will be capital gain or loss and will be long-term capital gain or loss if the holding period exceeds one year. Long-term capital gains are taxable at a maximum rate of 15% in the case of individuals and 35% in the case of corporations. The deductibility of capital losses is subject to limitations.

#### **Conversion of Convertible Preferred Stock into Common Stock**

No gain or loss will generally be recognized upon conversion of shares of convertible preferred stock into shares of common stock, except that (i) gain or loss will be recognized to the extent of the difference between the cash paid in lieu of fractional shares of common stock and the basis of the convertible preferred stock allocable to such fractional shares, (ii) additional payments made as dividend make-whole payments on conversion of convertible preferred stock prior to March 1, 2008, will be treated as distributions taxable as dividends, return of capital or capital gain in the amount of the cash and/or the fair market value of the common stock (measured on the date of distribution) constituting such additional payments (see "Distributions on Convertible Preferred Stock and Common Stock" and "Extraordinary Dividends," above), and (iii), if the conversion of convertible preferred stock takes place when there is a dividend arrearage on the convertible preferred stock and the fair market value of the common stock exceeds the issue price of the convertible preferred stock, a portion of the common stock received might be taxable as a dividend, return of capital or capital gain (see "Distributions on Convertible Preferred Stock and Common Stock" and "Extraordinary Dividends," above). Assuming the conversion is not treated as resulting in the payment of a dividend, the basis of the common stock received upon conversion will be equal to the basis of the shares of convertible preferred stock converted (less the amount of basis allocable to any fractional share of common stock for which cash is received), and the holding period of the common stock will include the holding period of the shares of convertible preferred stock converted. The basis of any common stock treated as a dividend will be equal to its fair market value on the date of the distribution and its holding period will begin on the day after the conversion.

#### **Adjustment of Conversion Price**

Holders of convertible preferred stock or common stock may be deemed to have received constructive distributions where the conversion ratio or conversion price is adjusted to reflect property distributions with respect to common stock into which such convertible preferred stock are convertible. Adjustments to the conversion ratio or conversion price made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing the dilution of the interest of the holders of the convertible preferred stock, however, will generally not be considered to result in a constructive distribution of

stock. Certain of the possible adjustments provided in the convertible preferred stock may not qualify as being pursuant to a bona fide reasonable adjustment formula. If such adjustments were made, the holders of convertible preferred stock might be deemed to have received constructive distributions taxable as a dividend, return of capital or capital gain in accordance with the general rules for the income tax treatment of distributions discussed above in "Distributions on Convertible Preferred Stock and Common Stock" and "Extraordinary Dividends."

### **Backup Withholding**

Under the backup withholding provisions of the Code and applicable Treasury regulations, a holder of convertible preferred stock or common stock may be subject to backup withholding at the rate of 28% with respect to dividends (including original issue discount) paid on, or the proceeds of a sale, exchange or redemption of convertible preferred stock or common stock, unless (i) such holder is a corporation or comes within certain other exempt categories and when required demonstrates this fact or (ii) provides a taxpayer identification number, certifies as to no loss of exemption from backup withholding for interest and dividends and otherwise complies with applicable requirements of the backup withholding rules. The amount of any backup withholding from a payment to a holder will be allowed as a credit against the holder's federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

### **Special Tax Rules Applicable to Foreign Holders**

For purposes of the following discussion, a "Foreign Holder" is any holder who is not (i) a citizen or resident of the United States, (ii) a corporation or partnership (including any entity treated as a corporation or partnership for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state or any political subdivision thereof, (iii) an estate the income of which is subject to United States federal income taxation regardless of source, or (iv) a trust if such trust elects to be treated as a U.S. person for U.S. federal income tax purposes, or a trust (A) over the administration of which a court within the United States is able to exercise primary supervision and (B) all substantial decisions of which one or more United States persons have the authority to control.

Income received by a Foreign Holder in the form of dividends on convertible preferred stock or common stock will be subject to a United States federal withholding tax at a 30% rate upon the actual payment of the dividends except as described below and except where an applicable tax treaty provides for the reduction or elimination of such withholding tax. Dividends paid to Foreign Holders outside the United States that are subject to the withholding tax described above will generally be exempt from United States backup withholding tax but will be subject to United States information reporting requirements. Pursuant to a tax treaty or other agreement, this information may also be made available to the tax authorities in the country in which the Foreign Holder resides. A Foreign Holder generally will be taxable in the same manner as a United States person with respect to dividend income, if such income is effectively connected with the conduct of a trade or business in the United States, and if provided in a tax treaty, attributable to a permanent establishment in the United States. Such effectively connected income received by a Foreign Holder that is a corporation may in certain circumstances be subject to an additional "branch profits tax" at a 30% rate, or if applicable, a lower treaty rate. In order to claim the benefit of a tax treaty or to claim exemption from withholding because the income is effectively connected with the conduct of a trade or business in the U.S., a Foreign Holder must provide a properly executed IRS Form W-8BEN for treaty benefits or W-8ECI for effectively connected income (or such successor form as the IRS designates), prior to the payment of dividends. These forms must be periodically updated. Foreign Holders may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund. If a Foreign Holder holds preferred or common stock through a foreign partnership or a foreign intermediary, the foreign partnership or foreign intermediary will also be required to comply with certain certification

requirements. The rules regarding withholding are complex, are subject to change, and vary depending on your particular situation. We suggest that you consult with your tax advisor regarding the application of such rules to your situation.

Provided that we are not, and have not been, a "United States real property holding corporation" within the meaning of section 897(c) of the Code, a Foreign Holder generally will not be subject to United States federal income or withholding tax on gain realized on the sale or exchange of convertible preferred stock or common stock unless (i) the holder is an individual who is present in the United States for 183 days or more during the taxable year and as to whom such gain is from United States sources or (ii) the gain is effectively connected with a United States trade or business of the holder, and if required by a tax treaty, attributable to a permanent establishment in the United States. Upon a redemption of the convertible preferred stock for cash or an exchange of convertible preferred stock for common stock, we may be required to withhold tax on the entire amount of the proceeds at a 30% rate or lower treaty rate applicable to dividends unless a Foreign Holder is able to demonstrate to our satisfaction that such redemption or exchange satisfies the section 302 tests discussed above with respect to such Foreign Holder (see "Redemption of Convertible Preferred Stock for Cash" above). In the case of an exchange of convertible preferred stock for common stock, this would result in a Foreign Holder receiving fewer shares.

The payment of the proceeds of the sale of convertible preferred stock or common stock to or through the United States office of a broker will be subject to information reporting and possible backup withholding at a rate of 28% unless the owner certifies its non-United States status under penalties of perjury or otherwise establishes an exemption in accordance with applicable Treasury regulations. The payment of the proceeds of the sale of convertible preferred stock or common stock to or through the foreign office of a foreign broker generally will not be subject to information reporting or backup withholding. In the case of the payment of proceeds from the disposition of convertible preferred stock or common stock through a foreign office of a broker that is a United States person or a "United States related person," the applicable Treasury regulations require information reporting, but not backup withholding, on the payment unless the broker has documentary evidence in its files that the owner is a non-United States person and the broker has no actual knowledge to the contrary. For this purpose, a "United States related person" is (i) a "controlled foreign corporation" for United States federal income tax purposes, (ii) a foreign person 50% or more of whose gross income from all sources for a specified period is derived from activities that are effectively connected with the conduct of a United States trade or business or (iii) a foreign partnership that, at any time during its taxable year, is more than 50% owned by United States persons or is engaged in the conduct of a United States trade or business. Any amounts withheld under the backup withholding rules from a payment to a Foreign Holder will be allowed as a refund or a credit against such Foreign Holder's United States federal income tax, provided that the required information is timely furnished to the IRS.

**UNDERWRITING**

The underwriter named below has agreed to buy, subject to the terms of the purchase agreement, the number of shares of convertible preferred stock listed below. The underwriter is committed to purchase and pay for all of the shares if any are purchased.

<b>Underwriter</b>	<b>Number of Shares</b>
Piper Jaffray & Co.	

The underwriter has advised us that it proposes to offer the shares to the public at \$50 per share. The underwriter proposes to offer the shares to certain dealers at the same price less a concession of not more than \$ \_\_\_\_\_ per share. The underwriter may allow and the dealers may reallow a concession of not more than \$ \_\_\_\_\_ per share on sales to certain other brokers and dealers. After the offering, these figures may be changed by the underwriter.

We have granted to the underwriter an option to purchase up to an additional 60,000 shares of convertible preferred stock from us at the same price to the public, and with the same underwriting discount, as the shares set forth in the table above. The underwriters may exercise this option any time during the 30-day period after the date of this prospectus supplement, but only to cover over-allotments, if any.

The following table shows the underwriting fees to be paid to the underwriter in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	<b>No exercise</b>	<b>Full exercise</b>
Per share	\$ 3.00	\$ 3.00
Total	\$ 1,200,000	\$ 1,380,000

**No Sales of Similar Securities**

We, our executive officers and directors have entered into lock-up agreements with the underwriter. Under these agreements, we and each of these persons generally may not, without the prior written approval of the underwriter offer, sell, contract to sell or otherwise dispose of directly or indirectly or hedge our common stock or securities convertible into or exchangeable for or exercisable for our common stock, subject to certain exceptions, including a provision that our Chief Executive Officer may sell up to 50,000 shares during the lock-up period. These restrictions will be in effect for a period of 75 days after the date of this prospectus supplement. At any time and without public notice, the underwriter may, in its sole discretion, release some or all of the securities from these lock-up agreements.

**Indemnification and Contribution**

We have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments the underwriter may be required to make in respect of those liabilities.

**Price Stabilization, Short Positions and Penalty Bids**

In order to facilitate the offering of the convertible preferred stock, the underwriter may engage in transactions that stabilize, maintain or otherwise affect the price of our convertible preferred stock or common stock. Specifically, the underwriter may over-allot in connection with this offering, creating a short position in our preferred stock for its own account. In addition, to cover over-allotments or to stabilize the price of the preferred stock, the underwriter may bid for, and purchase, our convertible



preferred stock or common stock in the open market. The underwriter may close out any short position in our convertible preferred stock or common stock either by exercising their over-allotment option, in whole or in part, or by purchasing our convertible preferred stock or common stock in the open market.

The underwriter may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares of our preferred stock sold by or for the account of that underwriter in stabilizing or short covering transactions. As a result of these activities, the price of our common and convertible preferred stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time. The underwriter may carry out these transactions on the New York Stock Exchange or otherwise.

#### **Determination of Convertible Preferred Stock Terms**

Prior to this offering, there was no public market for the convertible preferred stock. The terms and conditions of the convertible preferred stock, including the dividend rate and the conversion price, will be determined by negotiation by us and the underwriter. The principal factors to be considered in determining these terms and conditions include:

the market price of our common stock;

the information set forth in this prospectus supplement and accompanying prospectus and otherwise available to the underwriters;

our history and prospects and the history of, and prospects for, the industry in which we compete;

our past and present financial performance and an assessment of our management;

our prospects for future earnings and the present state of our development;

the general condition of the securities markets at the time of this offering;

the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and

other factors deemed relevant by the underwriter and us.

#### **Affiliations**

The underwriter and its affiliates have in the past provided and may from time to time provide certain commercial banking, financial advisory, investment banking and other services for us for which they were and will be entitled to receive separate fees. Piper Jaffray acted as our placement agent for our \$21.5 million private placement of 3,444,000 shares of common stock in January 2004. The underwriter and its affiliates may from time to time in the future engage in transactions with us and perform services for us in the ordinary course of their business.

#### **LEGAL MATTERS**

The validity of the convertible preferred stock we are offering will be passed upon for us by Arnall Golden Gregory LLP, Atlanta, Georgia. Faegre & Benson LLP, Minneapolis, Minnesota is counsel for the underwriters in connection with this offering.



### EXPERTS

The consolidated financial statements and the related financial statement schedules as of December 31, 2004, 2003 and 2002 and for the years then ended incorporated in this prospectus by reference from the Annual Report on Form 10-K of CryoLife, Inc. for the year ended December 31, 2004 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm. Their report expresses an unqualified opinion and includes an explanatory paragraph relating to changes in our method of accounting for goodwill and other intangible assets to conform with Statement of Financial Accounting Standards No. 142 and is incorporated herein by reference. The financial statements, financial statement schedules and auditor's report have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing. Management's Report on Internal Controls over Financial Reporting under Sarbanes-Oxley Sec. 404, incorporated in this prospectus by reference from the Annual Report on Form 10-K of CryoLife, Inc. for the year ended December 31, 2004, has been audited by Deloitte & Touche LLP, an independent registered public accounting firm. The auditor's report has been incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC under the Securities Act of 1933 with respect to the shares of convertible preferred stock we are offering by this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus do not include all of the information contained in the registration statement and the exhibits to the registration statement. For further information with respect to us, our common stock and the convertible preferred stock, we refer you to the registration statement and to the exhibits to the registration statement. Statements contained in this prospectus supplement and the accompanying prospectus about the contents of any contract or any other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this 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 supplement and the accompanying prospectus (other than any portions of any such documents that are not deemed "filed" under the Exchange Act in accordance with the Exchange Act and applicable SEC rules):

Our Annual Report on Form 10-K filed with respect to the Registrant's fiscal year ended December 31, 2004.

Our Current Reports on Forms 8-K filed on January 12, February 1, February 11, and February 22, 2005.

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 (other than any portions of any such documents that are not deemed "filed" under the Exchange Act in accordance with the Exchange Act and applicable SEC rules). These documents will be deemed to be incorporated by reference in this prospectus supplement and the accompanying prospectus and to be a part of it from the date they are filed with the SEC. Some information contained in this prospectus supplement updates the information incorporated by reference, and information that we file subsequently with the SEC will automatically update this prospectus supplement and the accompanying prospectus. In other words, in the case of a conflict or inconsistency between information set forth in this prospectus supplement and information incorporated by reference into this prospectus supplement and accompanying prospectus, you should rely on the information contained in the document that was filed later. 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

## Edgar Filing: CRYOLIFE INC - Form 424B5

information on the public reference room. Our SEC filings are also available to the public from commercial document retrieval services and at the Web site maintained by the SEC at <http://www.sec.gov>. This information is also available without charge upon written or oral request to:

CryoLife, Inc.  
Attn: Secretary  
1655 Roberts Boulevard, NW  
Kennesaw, Georgia 30144  
(770) 419-3355

The formation and reporting requirements of the Securities Exchange Act of 1934 currently apply to us and will continue to apply to us following this offering. We intend to furnish holders of our common and convertible preferred stock with annual reports containing, among other information, audited financial statements certified by an independent registered public accounting firm. We intend to furnish other reports as we may determine or as may be required by law.

We maintain an Internet website at [www.cryolife.com](http://www.cryolife.com). We have not incorporated by reference into this prospectus supplement the information on our website, and you should not consider it to be a part of this prospectus supplement.

S-57

---

PROSPECTUS

**\$50,000,000**  
**CRYOLIFE, INC.**

**Common Stock**  
**Preferred Stock**  
**Depository Shares**

---

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

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

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

---

**This investment involves risks. See "RISK FACTORS" beginning on page 6.**

---

**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 January 7, 2005.**

---

## TABLE OF CONTENTS

	<b>Page</b>
Summary	1
About This Prospectus	1
About Cryolife	1
Risk Factors	6
Forward Looking Statements	20
Use of Proceeds	21
Ratio of Earnings to Fixed Charges	21
Description of Capital Stock	22
Description of Depositary Shares	28
Plan of Distribution	30
Where You Can Find More Information	32
Legal Matters	33
Experts	33

---

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

## SUMMARY

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

## ABOUT THIS PROSPECTUS

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

## ABOUT CRYOLIFE

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

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

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

Through its continuing research and development activities, CryoLife endeavors to use its expertise in protein chemistry, biochemistry, cell biology, and immunology and its understanding of the cardiovascular, vascular, and orthopaedic surgery medical specialties, to acquire and develop useful implantable products and technologies. We seek to identify market areas that can benefit from preserved living tissues and other related technologies, to develop innovative techniques and products

within these areas, to secure their commercial protection, to establish their efficacy and then to market these techniques and products. In order to expand CryoLife's service and product offerings, we are in the process of developing or investigating several technologies and products. The products in development have not been subject to completed clinical trials, and have not received FDA or other regulatory approval, so we are not certain if we will derive any revenues from them. CryoLife generally performs significant research and development work before offering its services and products, building on either existing non-proprietary knowledge or acquired technology and know-how. Our tissue preservation services were developed based on work done some years before. Our BioGlue product was developed by us from a substance originally developed by a third party and acquired by us. In addition we continue to explore technologies that may further enhance the safety of our tissue processing.

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

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

CryoLife's business is subject to a number of risks, including the possibility of FDA actions, additional expenses and losses from product recalls, possible losses from ongoing product liability, securities and other litigation, regulatory action, adverse publicity and lower demand for CryoLife products resulting from product recalls and other FDA activity, inability to obtain sufficient insurance coverage, possible inability to protect the intellectual property rights in our technology, the possible inability to obtain necessary regulatory approvals, and possible future lack of capital.

***Food and Drug Administration (FDA) Activity.***

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

The FDA subsequently issued several notices on its Form 483, called Notices of Observation, which set forth its observations at the conclusion of an inspection of our processing facility. The observations



included several as to documentation and procedures. The most recent Notice of Observations was issued in February 2004.

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

CryoLife submitted the required 510(k) for CryoValve SG and has received two requests for additional information from FDA. While most of the requested information has been provided, CryoLife is seeking to resolve certain other requests, involving bench-testing and additional clinical trials, through administrative procedures at the FDA.

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

There can be no assurance that the outstanding issues with respect to the CryoValve SG 510(k) or the designation of SynerGraft cardiovascular tissue will be resolved favorably. In the meantime, CryoLife has voluntarily suspended the use of the SynerGraft technology in the processing of allograft heart valves and other cardiovascular tissue. Additionally, CryoLife discontinued labeling vascular (blood vessel) grafts as suitable for use in arteriovenous access because FDA has determined that this indication is a "non-homologous" use that would require premarket approval as a medical device.

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

***Products Liability Litigation and Insurance Coverage.***

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

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

Of the ten open lawsuits the remaining six are not covered by CryoLife's insurance policies as either these lawsuits relate to the 2002/2003 insurance policy year for which CryoLife has used all of its insurance coverage, aggregating \$25 million, or they were asserted in periods after the coverage in the

related incident year had lapsed. Other product liability claims have been asserted against CryoLife that have not resulted in lawsuits. We are monitoring these claims.

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

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

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

#### **Recent Developments**

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

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

---

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

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

## RISK FACTORS

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

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

### Risks Relating to Our Business

#### Overview

CryoLife has faced extraordinary challenges since it received, on August 13, 2002, an FDA order calling for the retention, recall, and/or destruction of all non-valved cardiac, vascular, and orthopaedic tissue processed by CryoLife since October 3, 2001 (the "FDA Order"). The recall resulted in the destruction of much of CryoLife's tissue, required that it adjust revenue for tissue recall returns, curtailed its processing activities, subjected it to intense FDA scrutiny and additional regulatory requirements that increased cost while CryoLife suffered decreased revenues due to lack of processing ability and decreased market demand for its services. During the same year, CryoLife was the subject of intense adverse media attention in connection with allegations that tissue processed by CryoLife had infected a man in Minnesota and caused his death. CryoLife also became the subject of shareholders' class action and derivative shareholder suits, both of which remain pending. Products liability cases and claims increased to unprecedented numbers for CryoLife, using all of its related 2002/2003 insurance policy year insurance coverage and taxing its other resources. While many cases and claims have been settled, several remain unresolved. Since 2002, a U.S. Senate committee has inquired into safety in the tissue processing industry, making inquiries of CryoLife. The SEC has initiated and continues to pursue a formal investigation of CryoLife. The combined effect of these challenges has been to reduce Company revenues, increase its costs to process tissues and its operating expenses and strain management resources. Although CryoLife has now resumed processing and distribution of the tissues subject to the FDA recall and resolved many of the products liability suits pending against it, the foregoing factors will continue to challenge CryoLife in its efforts to increase sales and return to profitability. No assurances can be made that CryoLife will succeed in those efforts in a timely fashion.

***The Company has experienced operating issues and negative cash flow. The Company must address the underlying causes.***

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

The anticipated lower preservation services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activity, and related events,

The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,

An expected use of cash related to the defense and resolution of lawsuits and claims, and

The legal and professional costs related to ongoing FDA compliance.

## Edgar Filing: CRYOLIFE INC - Form 424B5

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

The success of BioGlue and other products using related technology,

The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,

The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs by improving yields and increasing prices,

The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline, and

The amount and the timing of the resolution of the remaining outstanding product liability claims and other claims against the Company.

***If the Company is unable to address the causes of its operating losses and negative cash flows, it will need to raise additional capital which may not be available.***

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

***The FDA order and subsequent FDA activity continue to adversely impact CryoLife's business, including reducing demand for its services and increasing processing costs.***

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

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

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

could have a material adverse effect on CryoLife's business, results of operations and financial position and may continue to do so.

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

***Revenue from orthopaedic tissue preservation services is minimal and may not return.***

We have received only minimal revenue from the preservation of orthopaedic tissue since August 14, 2002. For the year ended December 31, 2001, human tissue preservation services revenues for orthopaedic tissue were \$22.5 million, which represented 26% of CryoLife's revenues. For the six months ended June 30, 2002, (the last period ending prior to the FDA Order) revenues for preservation services for orthopaedic tissue were \$11.5 million which represented 24% of CryoLife's revenues. For the year ended December 31, 2003, revenues from preservation services for orthopaedic tissue were \$1.1 million, which represented 2% of CryoLife's revenues. For the nine months ended September 30, 2004, they were \$1.7 million, or 4% of revenues.

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

***Physicians may be reluctant to implant CryoLife's preserved tissues.***

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

***Products and services not included in the FDA recall may come under increased FDA scrutiny.***

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

***Adverse publicity may reduce demand for products and services not affected by the FDA recall.***

Even though CryoLife's heart valve tissues, BioGlue Surgical Adhesive and bioprosthetic devices were not included in the FDA Order, there is a possibility that surgeons or risk managers at institutions that

use such products may be reluctant to use such products because of the adverse publicity associated with the FDA Order. Decreased demand for such products, particularly BioGlue, could have a material adverse effect on CryoLife's business, results of operations and financial position.

*We may be unable to address the concerns raised by the FDA in its Form 483 notices of observations.*

The FDA issued new Form 483 Notices of Observations in February and October 2003, and another in February 2004. If CryoLife's responses to the FDA's observations contained in these notices, or any future notices, are deemed unsatisfactory, the FDA could take further action, which could have a material adverse effect on the Company's business, results of operations, financial position or cashflows. Further action by the FDA could include additional recalls of products, requiring us to do additional testing, beginning to require prescriptions for products where they are not currently required, halting the shipping or processing of products, or requiring additional approvals for marketing our products or services.

*The FDA has notified CryoLife of its belief that marketing of CryoValve SG and CryoVein SG require additional regulatory submissions and/or approvals.*

During 2003, FDA notified CryoLife that the application of the SynerGraft technology to allograft heart valves (CryoValve SG), currently regulated as Class II medical devices, was considered to be a major manufacturing change requiring a 510(k) submission. CryoLife submitted a 510(k) for CryoValve SG and has received two requests for additional information from FDA. While most of the requested information has been provided, CryoLife is seeking to resolve certain other requests, involving bench-testing and additional clinical trials, through administrative procedures at the FDA. There can be no assurance that the FDA will agree with CryoLife or that CryoValve SG 510(k) will be cleared in the foreseeable future.

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

*Regulatory action outside of the U.S. may also affect CryoLife's business.*

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

*CryoLife is the subject of an ongoing SEC investigation.*

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

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

***CryoLife's insurance coverage may be insufficient.***

*Product Liability Claims*

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

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

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

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

*Class Action Lawsuit*

Several putative class action lawsuits were filed in July through September 2002 against CryoLife and certain officers of CryoLife, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that CryoLife made misrepresentations and omissions relating to product safety and CryoLife's alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of



purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. CryoLife and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the United States District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003, the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. At present, the case remains in the expert discovery phase. Although CryoLife carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment in excess of CryoLife's available insurance coverage could have a material adverse effect on CryoLife's financial position, results of operations, and cash flows. At this time, CryoLife is unable to predict the outcome of this litigation.

*Shareholder Derivative Action*

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names CryoLife as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to CryoLife by causing or allowing CryoLife to engage in certain inappropriate practices that caused CryoLife to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that CryoLife's Board of Directors take certain actions in response to her allegations. On January 16, 2003 another purported derivative suit alleging claims similar to those of the Lichtenberger suit was filed in the Superior Court of Fulton County by complainant Robert F. Frailey. As in the Lichtenberger suit, the filing of the complaint in the Frailey action was preceded by a demand letter sent on Frailey's behalf to CryoLife's Board of Directors. Both complaints seek undisclosed damages, costs and attorney's fees, punitive damages, and prejudgment interest against the individual defendants derivatively on behalf of CryoLife. As previously disclosed, CryoLife's Board of Directors has established an independent committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel evaluated the consolidated amended complaint, and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. Based on the report of the independent committee, the Company moved to dismiss the derivative action in May 2004. In an order dated December 1, 2004, the Court denied the motion to dismiss. The case will proceed into the discovery phase. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of CryoLife. At this time, CryoLife is unable to predict the outcome of this litigation.

***Insurance coverage may be difficult or impossible to obtain in the future and if obtained, the cost of insurance coverage is likely to be much more expensive than in the past.***

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

claims which arose prior to the insurance policy year. The 2004/2005 policy is a two-year claims-made policy, covering claims arising since the commencement of the 2003/2004 policy year.

***Intense competition may affect CryoLife's ability to recover from the FDA order.***

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

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

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

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

***CryoLife may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and such products and services may not achieve market acceptance.***

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

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

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

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

***Investments in new technologies or distribution rights may not be successful.***

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

***Funding for the ACT technology may not be available.***

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

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

***SynerGraft-treated tissues may not demonstrate expected benefits.***

CryoLife processes bovine tissues with the SynerGraft technology and processed human tissues with that technology until February 2003, following the receipt of the informal FDA letter. The process involves antigen reduction, which is the depopulation of the cells of the tissue to be implanted, leaving a matrix of protein fibers that has the potential to be repopulated with the recipient's cells. If successful, we believe that such repopulation may increase graft longevity and improve the biocompatibility and functionality of such tissue, resulting in the implanted tissue behaving more like the recipient's own tissue. In animal studies, explanted SynerGraft treated allograft heart valves have been shown to repopulate with the hosts' cells. However, should such tissues implanted in humans not consistently and adequately repopulate with the human host cells, the higher priced SynerGraft-treated tissues may not demonstrate benefits over the CryoLife standard processing technology. This could have a material adverse effect on future expansion plans and could limit future growth.

***CryoLife is dependent on its key personnel.***

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

*Our consolidated financial statements as of and for the year ended December 31, 2001 and included in CryoLife's 10-K were audited by Arthur Andersen LLP, which was found guilty of obstruction of justice and the subject of additional litigation.*

Arthur Andersen LLP has been found guilty of obstruction of justice with respect to its activities in connection with Enron Corp. and may be the subject of additional litigation. Arthur Andersen LLP has also ceased practicing before the SEC. Arthur Andersen LLP or any successor in interest may have insufficient assets to satisfy any claims that may be made by investors with respect to the financial statements as of and for the year ending December 31, 2001 included in CryoLife's Form 10-K for the year ending December 31, 2003 and incorporated into this prospectus.

In addition, Arthur Andersen LLP has not consented to the inclusion of their report dated March 27, 2002 in CryoLife's Form 10-K for the year ending December 31, 2003, and as a result, only a copy of such report has been included. Because Arthur Andersen LLP has not consented to the inclusion of their report in our Form 10-K for the year ending December 31, 2003 which is incorporated into this prospectus, claimants may not be able to recover against Arthur Andersen LLP for any untrue statements of a material fact contained in the financial statements audited by Arthur Andersen LLP or any omissions to state a material fact required to be stated therein.

### **Risks Related To CryoLife And Our Industry**

*Extensive government regulation may adversely affect the ability to develop and sell products and services.*

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

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

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

any products developed by CryoLife or its competitors, independently or in collaboration with others, will receive the required approvals for manufacturing and marketing.

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

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

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

In addition, The National Organ Transplant Act ("NOTA") prohibits the acquisition or transfer of human organs for "valuable consideration" for use in human transplantation. NOTA permits the payment of reasonable expenses associated with the removal, transportation, processing, preservation, quality control and storage of human organs. There can be no assurance that restrictive interpretations of NOTA will not be adopted in the future that will challenge one or more aspects of industry methods of charging for preservation services. Laboratory operations of CryoLife and its competitors are subject to the U.S. Department of Labor, Occupational Safety and Health Administration and Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment. Some states have enacted statutes and regulations governing the processing, transportation and storage of human organs and tissue.

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

***Uncertainties related to patents and protection of proprietary technology may adversely affect the value of intellectual property.***

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

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

***Uncertainties regarding future health care reimbursement may affect the amount and timing of revenues.***

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

Changes in the reimbursement methods and policies utilized by third-party health care payors, including Medicare, with respect to cryopreserved tissues provided for implant by CryoLife and other Company services and products, could have a material adverse effect on CryoLife. Significant uncertainty exists as to the reimbursement status of newly approved health care products and services and there can be no assurance that adequate third-party coverage will be available for CryoLife to maintain price levels sufficient for realization of an appropriate return on its investment in developing new products.

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

***Rapid technological change could cause services and products to become obsolete.***

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

**Risks Related To CryoLife's Capital Stock**

***Securities prices for CryoLife shares have been, and may continue to be, volatile.***

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

***Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of CryoLife.***

CryoLife's Articles of Incorporation and Bylaws contain provisions that may discourage or make more difficult any attempt by a person or group to obtain control of CryoLife, including provisions authorizing the issuance of preferred stock without shareholder approval, restricting the persons who may call a special meeting of the shareholders and prohibiting shareholders from taking action by written consent. In addition, CryoLife is subject to certain provisions of Florida law that may discourage or make more difficult takeover attempts or acquisitions of substantial amounts of CryoLife's common stock. Further, pursuant to the terms of a shareholder rights plan adopted in 1995, each outstanding share of common stock has one attached right. The rights will cause substantial dilution of the ownership of a person or group that attempts to acquire CryoLife on terms not approved by the Board of Directors and may have the effect of deterring hostile takeover attempts. These provisions could potentially deprive our stockholders of opportunities to sell shares of our stock at above-market prices. Please read "Description of Capital Stock Anti-Takeover Provisions."

***Common stock dividends are not likely to be paid in the foreseeable future.***

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



***We may not be able to pay cash dividends on our capital stock.***

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

### FORWARD LOOKING STATEMENTS

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

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

adequacy of product liability insurance to defend against lawsuits;

the outcome of lawsuits filed against the Company, and of the SEC investigation;

the impact of the FDA Order and subsequent FDA activity, including the FDA's letters regarding the SynerGraft process and measures taken by the Company as a result, on future revenues, profits and business operations;

the effect of the FDA Order and subsequent FDA activity on sales of BioGlue;

the impact of the FDA's Form 483 Notices of Observation;

the estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies, as well as the estimates of the amounts accrued for product loss claims incurred but not reported;

future costs of human tissue preservation services, including the Company's ability to reduce its costs of tissue preservation services;

the Company's competitive position, including the impact of price increases;

product demand and market growth;

the potential of the ACT for use in cancer therapies, fibrinolysis (blood clot dissolving), and other drug delivery applications;

the impact on the Company of adverse results of surgery utilizing tissue processed by it; and

other statements regarding future plans and strategies, anticipated events or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and

uncertainties which could cause actual results to differ materially from the Company's expectations, including the risk factors discussed in this prospectus and other factors, many of which are beyond the control of CryoLife. Consequently, all of the forward-looking statements

## Edgar Filing: CRYOLIFE INC - Form 424B5

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

### USE OF PROCEEDS

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

### RATIO OF EARNINGS TO FIXED CHARGES

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

	Year Ended December 31,					Nine Months Ended Sept. 30, 2004
	1999	2000	2001	2002	2003	
	(dollars in thousands)					
Ratio of earnings to fixed charges	8.53	16.53	8.81	(a)	(a)	(a)
Deficiency of earnings to fixed charges and preferred stock dividends	\$ N/A	\$ N/A	\$ N/A	\$ (41,376)	\$ (29,168)	\$ (17,714)

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

## DESCRIPTION OF CAPITAL STOCK

### Description Of Capital Stock

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

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

### Common Stock

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

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

### Preferred Stock

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

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

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

the series, the number of shares offered and the liquidation value of the preferred stock;

the price at which the preferred stock will be issued;

the dividend rate, the dates on which the dividends will be payable and other terms relating to the payment of dividends on the preferred stock;

the liquidation preference of the preferred stock;

whether the preferred stock is redeemable or subject to a sinking fund, and the terms of any such redemption or sinking fund;

whether the preferred stock is convertible into or exchangeable for any other securities, and the terms of any such conversion or exchange; and

any additional rights, preferences, qualifications, limitations or restrictions of the preferred stock.

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

### **Stock Options and Restricted Stock Awards**

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

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

### **Articles Of Incorporation And Bylaws**

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

### **Special Meetings**

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

### **Prohibition of Shareholder Action Without Meeting**

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

### **Anti-Takeover Statutes**

The Company is subject to several anti-takeover provisions of the FBCA that apply to a public corporation organized under Florida law unless the corporation has elected to opt out of such provision in its Articles of Incorporation or (depending on the provision in question) its Bylaws. The Company has not elected to opt out of these provisions. The Common Stock of the Company is subject to the "affiliated transaction" and "control-share acquisition" provisions of the FBCA, which are Sections 607.0901 and 607.0902, respectively. These provisions provide that, subject to certain

exceptions, an "affiliated transaction" must be approved by the holders of two-thirds of the voting shares other than those beneficially owned by an "interested shareholder" and that "control shares" acquired in specified shareholders, excluding holders of shares defined as "interested shares." These provisions of the FBCA may have the effect of making it more difficult for any person or group to acquire the Company or substantial amounts of the Company's Common Stock. See "Risk Factors Anti-Takeover Provisions."

#### **Ability To Consider Other Constituencies**

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

#### **Shareholder Rights Plan**

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

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

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

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

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

## Edgar Filing: CRYOLIFE INC - Form 424B5

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

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

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

a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Stock;

the grant to holders of the Preferred Stock of certain rights or warrants to subscribe for or purchase Preferred Stock at a price, or securities convertible into Preferred Stock with a conversion price less than the then-current market price of the Preferred Stock; or

upon the distribution to holders of the Preferred Stock of evidences of indebtedness or assets (excluding regular periodic cash dividends paid out of earnings or retained earnings or dividends payable in Preferred Stock) or of subscription rights or warrants (other than those referred to above).

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

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

a stock split of the Common Stock;

a stock dividend on the Common Stock payable in Common Stock; or

subdivision, consolidation or combination of the Common Stock.

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

Shares of Preferred Stock will not be redeemable. The Preferred Stock will be entitled to a preferential quarterly dividend equal to the greater of \$.10 per share and (after adjustment for the stock splits) approximately 3.33 times the dividend declared per share of Common Stock. In the event of liquidation, any holders of the Preferred Stock will be entitled to a preferential liquidation payment equal to the greater of \$10.00 per share and approximately 3.33 times the payment made per share of Common Stock. Each share of Preferred Stock will be entitled to one vote, voting together with the Common Stock. In the event of any merger, consolidation or other transaction in which Common Stock is exchanged, Preferred Stock will be entitled to receive approximately 3.33 times the amount received per share of Common Stock.



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

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

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

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

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

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

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

#### **Shareholder Action**

Except as otherwise provided by law or in our articles of incorporation or bylaws, the approval by holders of a majority of the shares of common stock present in person or represented by proxy at a meeting and entitled to vote is sufficient to authorize, affirm, ratify or consent to a matter voted on by shareholders. The FBCA General Corporation Act requires the approval of the holders of a majority of

the outstanding stock entitled to vote for certain extraordinary corporate transactions, such as a merger, sale of substantially all assets, dissolution or amendment of the articles of incorporation.

**Transfer Agent And Registrar**

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

## DESCRIPTION OF DEPOSITARY SHARES

### General

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

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

### Dividends and Other Distributions

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

### Redemption of Depositary Shares

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

### Voting the Preferred Stock

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

**Amendment and Termination of the Depositary Agreement**

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

**Charges of Bank Depositary**

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

**Withdrawal of Preferred Stock**

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

**Resignation and Removal of Bank Depositary**

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

**PLAN OF DISTRIBUTION**

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

through agents;

to or through underwriters;

through dealers; or

directly by us.

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

Offers to purchase securities may be solicited by agents designated by us from time to time. Any such agent involved in the offer or sale of the securities in respect of which this prospectus is delivered will be named, and any commissions payable by us to such agent will be set forth, in the applicable prospectus supplement. Unless otherwise indicated in such prospectus supplement, any such agent will be acting on a reasonable best efforts basis for the period of its appointment. Any such agent may be deemed to be an underwriter, as that term is defined in the Securities Act, of the securities so offered and sold. We may periodically engage agents or underwriters in connection with at-the-market offerings or negotiated transactions involving our common stock.

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

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

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

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

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

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

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

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

**WHERE YOU CAN FIND MORE INFORMATION**

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

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

The Registrant's Annual Report on Form 10-K filed with respect to the Registrant's fiscal year ended December 31, 2003.

The Registrant's Current Reports on Forms 8-K filed on January 7, January 26, February 9, February 26, May 10, August 5, October 29, November 4, November 8, November 22, and December 10, 2004.

The Registrant's Quarterly Reports on Form 10-Q filed with respect to the three month periods ended March 31, 2004, June 30, 2004, and September 30, 2004.

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

CryoLife, Inc.  
Attn: Secretary  
1655 Roberts Boulevard, NW  
Kennesaw, Georgia 30144  
(770) 419-3355

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

### **LEGAL MATTERS**

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

### **EXPERTS**

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

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

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



**400,000 Shares**

**CRYOLIFE, INC.**

**% Convertible Preferred Stock**

**(Cumulative Dividend, Liquidation Preferences \$50 Per Share)**

---

**PROSPECTUS SUPPLEMENT**

---

**Piper Jaffray**

March , 2005

---

QuickLinks

[TABLE OF CONTENTS](#)

[SUMMARY](#)

[ABOUT US](#)

[THE OFFERING](#)

[SUMMARY CONSOLIDATED FINANCIAL DATA](#)

[RECENT DEVELOPMENTS](#)

[RISK FACTORS](#)

[SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS](#)

[USE OF PROCEEDS](#)

[DIVIDEND POLICY](#)

[RATIO OF EARNINGS TO FIXED CHARGES AND PREFERRED STOCK DIVIDENDS](#)

[PRICE RANGE OF COMMON STOCK](#)

[CAPITALIZATION](#)

[DESCRIPTION OF CONVERTIBLE PREFERRED STOCK](#)

[MATERIAL FEDERAL INCOME TAX CONSEQUENCES](#)

[UNDERWRITING](#)

[LEGAL MATTERS](#)

[EXPERTS](#)

[WHERE YOU CAN FIND MORE INFORMATION](#)

[TABLE OF CONTENTS](#)

[SUMMARY](#)

[ABOUT THIS PROSPECTUS](#)

[ABOUT CRYOLIFE](#)

[RISK FACTORS](#)

[FORWARD LOOKING STATEMENTS](#)

[USE OF PROCEEDS](#)

[RATIO OF EARNINGS TO FIXED CHARGES](#)

[DESCRIPTION OF CAPITAL STOCK](#)

[DESCRIPTION OF DEPOSITARY SHARES](#)

[PLAN OF DISTRIBUTION](#)

[WHERE YOU CAN FIND MORE INFORMATION](#)

[LEGAL MATTERS](#)

[EXPERTS](#)