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CRYOLIFE INC  
Form 10-Q/A  
November 13, 2003

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q/A

(x) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended June 30, 2003  
Commission File Number 1-13165

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

-----  
Florida 59-2417093  
(State or other jurisdiction (I.R.S. Employer  
of incorporation or organization) Identification No.)

1655 Roberts Boulevard, NW  
Kennesaw, Georgia 30144  
(Address of principal executive offices)  
(zip code)

(770) 419-3355  
(Registrant's telephone number, including area code)

Not Applicable  
(Former name, former address and former fiscal year,  
if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES X NO \_\_\_\_

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

YES X NO \_\_\_\_

The number of shares of common stock, par value \$0.01 per share, outstanding on July 31, 2003 was 19,699,510.

EXPLANATORY NOTE

The Company is filing this amendment to Form 10-Q to amend Items 1 and 2 of Part I to restate its consolidated financial statements for the three and six months ended June 30, 2003 to correct the income tax expense in those periods in accordance with Accounting Principles Board Opinion No. 28, Interim Financial Reporting. As a result, the financial statements as of and for the three and six months ended June 30, 2003 have been restated from the amounts previously reported. The effect of the restatement on the consolidated financial statements

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is detailed in Note 15 to the consolidated financial statements. In addition, we are supplementing Part I, Item 4.

All of the information in this Form 10-Q/A is as of August 5, 2003, the filing date of the original Form 10-Q, and has not been updated for events subsequent to that date other than the restatement of the financial statements discussed in Note 15 to the consolidated financial statements and the reassessment of its disclosure controls pursuant to Part I, Item 4. Although we have amended the forward-looking statements to reflect the amendments referred to above, none of the forward-looking information contained herein has been updated beyond that date. This Form 10-Q/A does not contain Part I Item 3 or Part II Items 1 through 5 as those portions of the previously filed Form 10-Q have not changed.

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### Part I - FINANCIAL INFORMATION

#### Item 1. Financial statements

CRYOLIFE, INC. AND SUBSIDIARIES  
SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended June 30,		Six Mo J
	2003 As Restated See Note 15	2002	2003 As Restate See Note 1
	(Unaudited)		(Un
<b>Revenues:</b>			
Human tissue preservation services, net	\$ 8,615	\$ 17,536	\$ 17,745
Products	6,932	5,473	13,531
Distribution and grant	166	255	357
	15,713	23,264	31,633
<b>Costs and expenses:</b>			
Human tissue preservation services (including write-down of \$10,023 for the three and six months ended June 30, 2002 and \$1,131 for the three months and \$1,428 for the six months ended June 30, 2003)	5,160	17,203	7,603
Products	2,006	1,843	3,647
General, administrative, and marketing	23,539	11,447	35,131
Research and development	1,088	1,196	2,005
Interest expense	147	196	279
Interest income	(116)	(239)	(247)
Other expense (income), net	166	(16)	140
	31,990	31,630	48,558
	-----	-----	-----

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Loss before income taxes	(16,277)	(8,366)	(16,925)
Income tax expense (benefit)	3,644	(2,844)	3,430
Net loss	\$ (19,921)	\$ (5,522)	\$ (20,355)
Net loss per share:			
Basic	\$ (1.01)	\$ (0.28)	\$ (1.04)
Diluted	\$ (1.01)	\$ (0.28)	\$ (1.04)
Weighted average shares outstanding:			
Basic	19,675	19,538	19,654
Diluted	19,675	19,538	19,654

See accompanying notes to summary consolidated financial statements.

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Item 1. Financial Statements

CRYOLIFE, INC.  
SUMMARY CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS)

	June 30, 2003 As Restated See Note 15	December 31, 2002
ASSETS	(Unaudited)	
Current Assets:		
Cash and cash equivalents	\$ 16,147	\$ 10,277
Marketable securities, at market	9,761	14,583
Trade receivables, net	8,260	6,930
Other receivables, net	1,766	11,824
Deferred preservation costs, net	9,559	4,332
Inventories	4,535	4,585
Prepaid expenses and other assets	3,769	2,182
Deferred income taxes	1,275	6,734
Total current assets	55,072	61,447
Property and equipment, net	35,852	38,130
Patents, net	5,313	5,324
Other, net	1,194	1,513
TOTAL ASSETS	\$ 97,431	\$ 106,414
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,174	\$ 3,874
Accrued expenses and other current liabilities	15,071	6,823

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Accrued compensation	1,695	1,627
Accrued procurement fees	3,499	3,769
Note payable	1,616	--
Current maturities of capital lease obligations	1,957	2,169
Current maturities of long-term debt	4,800	5,600
	-----	-----
Total current liabilities	31,812	23,862
	-----	-----
Capital lease obligations, less current maturities	863	971
Deferred income taxes	--	986
Other long-term liabilities	4,881	795
Total liabilities	37,556	26,614
Shareholders' equity:		
Preferred stock	--	--
Common stock (issued 21,045 shares in 2003 and 20,864 shares in 2002)	210	209
Additional paid-in capital	74,063	73,630
Retained (deficit) earnings	(7,569)	12,786
Deferred compensation	(15)	(21)
Accumulated other comprehensive income	362	282
Less: Treasury stock at cost (1,370 shares in 2003 and 1,361 shares in 2002)	(7,176)	(7,086)
	-----	-----
Total shareholder' equity	59,875	79,800
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 97,431	\$ 106,414
	=====	=====

See accompanying notes to summary consolidated financial statements.

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Item 1. Financial Statements

CRYOLIFE, INC.  
SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)

	Six Months Ended June 30,	
	2003 As Restated See Note 15	
	-----	-----
	(Unaudited)	
Net cash from operating activities:		
Net loss	\$ (20,355)	\$
Adjustments to reconcile net loss to net cash provided by operating activities:		
(Gain) loss on sale of marketable equity securities	(19)	

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Depreciation and amortization	2,774	
Provision for doubtful accounts	48	
Write-down of deferred preservation costs	1,428	
Other non-cash adjustments to income	307	
Deferred income taxes	4,410	
Tax effect of nonqualified option exercises	19	
Changes in operating assets and liabilities		
Receivables	9,250	
Deferred preservation costs and inventories	(6,605)	
Prepaid expenses and other assets	856	
Accounts payable, accrued expenses, and other liabilities	10,862	
		-----
Net cash flows provided by operating activities	2,975	-----
Net cash flows from investing activities:		
Capital expenditures	(333)	
Other assets	173	
Purchases of marketable securities	--	
Sales and maturities of marketable securities	4,708	
Proceeds from note receivable	--	
		-----
Net cash flows provided by investing activities	4,548	-----
Net cash flows from financing activities:		
Principal payments of debt	(800)	
Payment of obligations under capital leases	(320)	
Principal payments on short-term note payable	(827)	
Proceeds from exercise of stock options and issuance of common stock	325	
Net cash used in financing activities	(1,622)	
Increase in cash	5,901	
Effect of exchange rate changes on cash	(31)	
Cash and cash equivalents, beginning of period	10,277	
		-----
Cash and cash equivalents, end of period	\$ 16,147	\$
	=====	=====

See accompanying notes to summary consolidated financial statements.

CRYOLIFE, INC. AND SUBSIDIARIES  
NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited summary consolidated financial statements have been prepared in accordance with (i) accounting principles generally accepted in the United States for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the United States Securities and Exchange Commission ("SEC"). Accordingly, the statements do not include all of the information and disclosures required by accounting principles generally accepted in the United States for a complete presentation of financial statements. In the opinion of management, all adjustments (consisting of normal

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recurring accruals) considered necessary for a fair presentation have been included. Certain prior year balances have been reclassified to conform to the 2003 presentation. Operating results for the three and six months ended June 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. For further information, refer to the consolidated financial statements and notes thereto included in the CryoLife Form 10-K for the year ended December 31, 2002, as amended.

The Company expects its liquidity to continue to decrease significantly over the next twelve months due to 1) the anticipated decrease in preservation revenues as compared to preservation revenues prior to the FDA Order as a result of reported tissue infections, the FDA Order, and associated adverse publicity, 2) the increase in cost of human tissue preservation services as a percent of revenue as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and 3) an expected use of cash due to the increased costs relating to the defense and resolution of lawsuits (discussed in Note 13) and legal and professional costs relating to the ongoing FDA compliance and the anticipated required Term Loan pay off during 2003 (discussed in Note 6). The Company believes that anticipated revenue generation, expense management, tax refunds of approximately \$2.4 million resulting from tax loss carrybacks, savings resulting from the reduction in the number of employees in September 2002 necessitated by the reduction in revenues, and the Company's existing cash and marketable securities will enable the Company to meet its liquidity needs through at least June 30, 2004.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including the Company's ability to return to the level of demand and gross margins for its tissue services that existed prior to the FDA Order, the outcome of litigation against the Company (discussed in Note 13), the timing and amount of settlements or other outcomes of the product liability claims (discussed in Note 13), the resolution of the dispute with its upper layer excess product liability insurance carrier (discussed in Note 13), the ability to arrange and fund a global settlement of outstanding claims for an amount substantially below the amount accrued (discussed in Note 13), and the Company's ability to find suitable funding sources to replace the Term Loan (discussed in Note 6). The Company 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 June 30, 2004. 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. In addition, if one or more of the product liability lawsuits in which the Company 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 the Company's available insurance coverage and liquid assets. The items described above are factors that indicate that the Company may be unable to continue operations beyond June 30, 2004.

### NOTE 2 - FDA ORDER ON HUMAN TISSUE PRESERVATION AND OTHER FDA CORRESPONDENCE

#### FDA ORDER

On August 13, 2002 the Company received an order from the Atlanta district office of the U.S. Food and Drug Administration ("FDA") regarding the non-valved cardiac, vascular, and orthopaedic tissue processed by the Company since October 3, 2001 (the "FDA Order"). The FDA Order followed an April 2002 FDA Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter dated June 17, 2002, ("Warning Letter"). Revenue from human tissue preservation services

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accounted for 78% of the Company's revenues for the six months ended June 30, 2002, (the last period ended prior to the issuance of the FDA Order) and of those revenues 67%, or \$26.9 million, were derived from preservation of tissues subject to the FDA Order. The FDA Order contained the following principal provisions:

- o The FDA alleged that, based on its inspection of the Company's facility on March 25 through April 12, 2002, certain human tissue processed and distributed by the Company may be in violation of 21 Code of Federal Regulations ("CFR") Part 1270. (Part 1270 requires persons or entities engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue to perform certain medical screening and testing on human tissue intended for transplantation. The rule also imposes requirements regarding procedures for the prevention of contamination or cross-contamination of tissues during processing and the maintenance of certain records related to these activities.)
- o The FDA alleged that the Company had not validated procedures for the prevention of infectious disease contamination or cross-contamination of tissue during processing at least since October 3, 2001.
- o Non-valved cardiac, vascular, and orthopaedic tissue processed by the Company from October 3, 2001 to September 5, 2002 must be retained until it is recalled, destroyed, the safety is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.
- o The FDA strongly recommended that the Company perform a retrospective review of all tissue in inventory (i.e. currently in storage at the Company) that was not referenced in the FDA Order to assure that it was recovered, processed, stored, and distributed in conformance with 21 CFR 1270.
- o The Center for Devices and Radiological Health ("CDRH"), a division of the FDA, would evaluate whether there are similar risks that may be posed by the Company's allograft heart valves, and would take further regulatory action if appropriate.

Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order on quality assurance quarantine and recalled the non-valved cardiac, vascular, and orthopaedic tissues subject to the FDA Order (i.e. processed since October 3, 2001) that had been distributed but not implanted. In addition, the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues. On September 5, 2002 the Company reached an agreement with the FDA (the "Agreement") that supplements the FDA Order and allows non-valved cardiac and vascular tissues subject to recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company completes steps to assure that the tissue is used for approved purposes and that patients are notified of risks associated with tissue use. Specifically, the Company must obtain physician prescriptions, and tissue packaging must contain specified warning labels. The Agreement calls for the Company to undertake to identify third-party records of donor tissue testing and to destroy tissue from donors in whom microorganisms associated with an infection are found. The Agreement had a 45-business day term and was renewed on November 8, 2002, January 8, 2003, March 17, 2003, and June 13, 2003. This most recent renewal expires on September 5, 2003. The Company is unable to predict whether or not the FDA will grant further renewals of the Agreement. In addition, pursuant to the Agreement, the Company agreed to perform additional

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procedures in the processing of non-valved cardiac and vascular tissues and subsequently resumed processing these tissues. The Agreement contained the requirement that tissues subject to the FDA Order be replaced with tissues processed under validated methods. The Company also agreed to establish a corrective action plan within 30 days from September 5, 2002 with steps to validate processing procedures. The corrective action plan was submitted on October 5, 2002.

On December 31, 2002 the FDA clarified the Agreement noting that non-valved cardiac and vascular tissues processed since September 5, 2002 are not subject to the FDA Order. Specifically, for non-valved cardiac and vascular tissue processed since September 5, 2002, the Company is not required to obtain physician prescriptions, label the tissue as subject to a recall, or require special steps regarding procurement agency records of donor screening and testing beyond those required for all processors of human tissue. These restrictions also do not apply to orthopaedic tissue processed by the Company since September 5, 2002. A renewal of the Agreement that expires on September 5, 2003 is therefore not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed since September 5, 2002.

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A new FDA 483 Notice of Observations ("February 2003 483") was issued in connection with the FDA inspection in February 2003, but corrective action was implemented on most of its observations during the inspection. The Company believes the observations, most of which focus on the Company's systems for handling complaints, will not materially affect the Company's operations. The Company responded to the February 2003 483 in March 2003. The Company has met with the FDA to review its response to the February 2003 483. No additional comments regarding the adequacy of its response were issued at that time. The Company continues to work with the FDA to review process improvements.

After receiving the FDA Order, the Company met with representatives of the FDA's CDRH division regarding CDRH's review of the Company's processed allograft heart valves, which are not subject to the FDA Order. On August 21, 2002 the FDA publicly stated that allograft heart valves have not been included in the FDA Order as these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. However, the FDA published a public health web notification stating that it had serious concerns regarding the Company's processing and handling of allograft heart valves. On June 27, 2003 the FDA modified the notification by labeling it "archived document - no longer current information - not for official use." There have been no further conversations with the FDA's CDRH division on this matter.

### PROCUREMENT

As a result of the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, the Company's procurement of cardiac tissues during the three and six months ended June 30, 2003, from which heart valves and non-valved cardiac tissues are processed, decreased 20% and 24%, respectively, as compared to the three and six months ended June 30, 2002. The Company's second quarter 2003 procurement of cardiac tissues increased 12% from the first quarter of 2003. The Company has continued to process and distribute heart valves since the receipt of the FDA Order, as these tissues are not subject to the FDA Order.

During the first quarter of 2003 the Company limited its vascular procurement until it addressed the observations detailed in the April 2002 483, most of



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which were addressed in the first quarter of 2003, and due to resource constraints as a result of the September 2002 employee force reduction. The Company continued to limit its vascular procurement in the second quarter of 2003 and will continue to limit its vascular procurement until it can fully evaluate the demand for its vascular tissues. The Company's procurement of vascular tissue for the three and six months ended June 30, 2003 decreased 50% and 57%, respectively, as compared to the three and six months ended June 30, 2002. The Company's second quarter 2003 procurement of vascular tissues increased 53% from first quarter of 2003. The Company expects that vascular procurement will continue to increase during 2003.

The Company resumed limited processing of orthopaedic tissues in late February 2003 following the FDA inspection of the Company's processing operations. The Company's procurement of whole and partial knees during the three and six months ended June 30, 2003 was approximately 43% and 26%, respectively, of whole and partial knee procurement levels for the three and six months ended June 30, 2002. The Company's procurement of orthopaedic tendons during the three and six months ended June 30, 2003 was approximately 14% and 8%, respectively, of orthopaedic tendon procurement levels for the three and six months ended June 30, 2002. The Company resumed limited distribution of recently processed orthopaedic tissues in the second quarter of 2003.

### ACCOUNTING TREATMENT

As a result of the FDA Order the Company recorded a reduction to pretax income of \$12.6 million in the quarter ended June 30, 2002. The reduction was comprised of a net \$8.9 million increase to cost of human tissue preservation services, a \$2.4 million reduction to revenues (and accounts receivable) for the estimated return of the tissues subject to recall by the FDA Order, and a \$1.3 million accrual recorded in general, administrative, and marketing expenses for retention levels under the Company's product liability and directors' and officers' insurance policies of \$1.2 million (see Note 13), and for estimated expenses of \$75,000 for packaging and handling for the return of affected tissues under the FDA Order. The net increase of \$8.9 million to cost of preservation services was comprised of a \$10.0 million write-down of deferred preservation costs for tissues subject to the FDA Order, offset by a \$1.1 million decrease in cost of preservation services due to the estimated tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the \$10.0 million write-down). The Company evaluated many factors in determining the magnitude of impairment to deferred preservation costs as of June 30, 2002, including the impact of the FDA Order, the possibility of continuing action by the FDA or other United States and foreign government agencies, and the possibility of unfavorable actions by physicians, customers, procurement organizations, and others. As a result of this evaluation,

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management believed that since all non-valved cardiac, vascular, and orthopaedic allograft tissues processed since October 3, 2001 were under recall pursuant to the FDA Order, and since the Company did not know if it would obtain a favorable resolution of its appeal and request for modification of the FDA Order, the deferred preservation costs for tissues subject to the FDA Order had been significantly impaired. The Company estimated that this impairment approximated the full balance of the deferred preservation costs of the tissues subject to the FDA Order, which included the tissues stored by the Company and the tissues to be returned to the Company, and therefore recorded a write-down of \$10.0 million for these assets.

In the quarter ended September 30, 2002 the Company recorded a reduction to pretax income of \$24.6 million as a result of the FDA Order. The reduction was comprised of a net \$22.2 million increase to cost of human tissue preservation

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services, a \$1.4 million write-down of goodwill, and a \$1.0 million reduction to revenues (and accounts receivable) for the estimated return of the tissues shipped during the third quarter subject to recall by the FDA Order. The net \$22.2 million increase to cost of preservation services was comprised of a \$22.7 million write-down of deferred preservation costs, offset by a \$0.5 million decrease in cost of preservation services due to the estimated and actual tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the \$22.7 million write-down).

The Company evaluated multiple factors in determining the magnitude of impairment to deferred preservation costs at September 30, 2002, including the impact of the FDA Order, the possibility of continuing action by the FDA or other United States and foreign government agencies, the possibility of unfavorable actions by physicians, customers, procurement organizations, and others, the progress made to date on the corrective action plan, and the requirement in the Agreement that tissues subject to the FDA Order be replaced with tissues processed under validated methods. As a result of this evaluation, management believed that all tissues subject to the FDA Order, as well as the majority of tissues processed prior to October 3, 2001, including heart valves, which were not subject to the FDA Order, were fully impaired. Management believed that most of the Company's customers would only order tissues processed after the September 5, 2002 Agreement or tissues processed under future procedures approved by the FDA once those tissues were available. The Company anticipated that the tissues processed under the Agreement would be available early to mid-November. Thus, the Company recorded a write-down of deferred preservation costs for processed tissues in excess of the supply required to meet demand prior to the release of these interim processed tissues.

As a result of the write-down of deferred preservation costs, the Company recorded \$6.3 million in income tax receivables and \$4.5 million in deferred tax assets as of December 31, 2002. Upon destruction or shipment of the remaining tissues associated with the deferred preservation costs write-down, the deferred tax asset will become deductible in the Company's related tax return assuming there is future income to offset the tax asset. A refund of approximately \$8.9 million related to 2002 federal income taxes was generated through a carry back of operating losses and write-downs of deferred preservation costs. The Company filed its 2002 federal income tax returns in April of 2003 and received its tax refund during the second quarter of 2003. In addition, the Company recorded \$2.5 million in income tax receivables as of December 31, 2002 related to estimated tax payments for 2002. The Company received payment of the \$2.5 million in January of 2003.

On September 3, 2002 the Company announced a reduction in employee force of approximately 105 employees. In the third quarter of 2002 the Company recorded accrued restructuring costs of approximately \$690,000, for severance and related costs of the employee force reduction. The expense was recorded in general, administrative, and marketing expenses and was included as a component of accrued expenses and other current liabilities on the Summary Consolidated Balance Sheet. During the year ended December 31, 2002 the Company utilized \$580,000 of the accrued restructuring costs, including \$505,000 for salary and severance payments, \$64,000 for placement services for affected employees, and \$11,000 in other related costs. During the quarter ended March 31, 2003 the Company utilized \$64,000 of the accrued restructuring costs, including \$57,000 for salary and severance payments and \$7,000 in other related costs. In March 2003 the Company reversed the remaining accrual of \$46,000 in unused restructuring costs, which was primarily due to lower than anticipated medical claims costs for affected employees. The Company has not incurred and does not expect to incur any additional restructuring costs associated with the employee force reduction subsequent to March 31, 2003.

In the quarter ended March 31, 2003 the Company recorded a favorable adjustment of \$848,000 to the estimated tissue recall returns due to lower actual tissue

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returns under the FDA Order than were originally estimated in the second and

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third quarters of 2002. The adjustment increased cardiac tissue revenues by \$92,000, vascular tissue revenues by \$711,000, and orthopaedic tissue revenues by \$45,000 in the first quarter of 2003. As of June 30, 2003 approximately \$60,000 remains in the accrual for estimated return of tissues subject to recall by the FDA Order.

During the three and six months ended June 30, 2003 the Company recorded \$1.1 million and \$1.4 million, respectively, as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs from tissues processed in the three and six months ended June 30, 2003 that exceeded market value. As of June 30, 2003 the balance of deferred preservation costs was \$4.3 million for allograft heart valve tissues, \$452,000 for non-valved cardiac tissues, \$4.0 million for vascular tissues, and \$738,000 for orthopaedic tissues.

### OTHER FDA CORRESPONDENCE

On February 20, 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company's CryoValve(R) SG and that premarket approval marketing authorization should be obtained for the Company's CryoVein(R) SG when marketed or labeled as an arteriovenous ("A-V") access graft. The agency's position is that use of the SynerGraft(R) technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft, and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

The Company is in discussions with the FDA about the type of submissions necessary for these products. The Company advised the FDA that it has voluntarily suspended use of the SynerGraft technology in the processing of allograft heart valves and vascular tissue until the regulatory status of the CryoValve SG and CryoVein SG is resolved. Additionally, the Company has discontinued labeling its vascular grafts for use as A-V access grafts. The FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SynerGraft tissue are resolved, the Company will employ its traditional processing methods on these tissues. Distribution of allograft heart valves and vascular tissue processed using the Company's traditional processing protocols will continue. The outcome of the discussions with the FDA regarding the use of the SynerGraft process on human tissue could result in an inability to process tissues with the SynerGraft technology until further submissions and FDA approvals are granted. The Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue.

### NOTE 3 - CASH EQUIVALENTS AND MARKETABLE SECURITIES

The Company maintains cash equivalents, which consist primarily of highly liquid investments with maturity dates of 90 days or less at the time of acquisition, and marketable securities in several large, well-capitalized financial institutions, and the Company's policy disallows investment in any securities rated less than "investment-grade" by national rating services.

Management determines the appropriate classification of debt securities at the time of purchase and reevaluates such designations as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. Debt securities not

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classified as held-to-maturity or trading and marketable equity securities not classified as trading are classified as available-for-sale. At June 30, 2003 and December 31, 2002 all marketable equity securities and debt securities were designated as available-for-sale.

Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of tax, reported in a separate component of shareholders' equity. Interest income, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in investment income. The cost of securities sold is based on the specific identification method.

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The following is a summary of cash equivalents and marketable securities (in thousands):

	Cost Basis	Unrealized Holding Gains/ (Losses)	Estimated Market Value
June 30, 2003			
-----			
Cash equivalents:			
Money market funds	\$ 9,601	\$ --	\$ 9,601
Municipal obligations	5,000	--	5,000
	-----	-----	-----
	\$ 14,601	\$ --	\$ 14,601
	=====	=====	=====
Marketable securities:			
Municipal obligations	\$ 9,549	\$ 212	\$ 9,761
	=====	=====	=====
December 31, 2002			
-----			
Cash equivalents:			
Money market funds	\$ 52	\$ --	\$ 52
Municipal obligations	7,175	--	7,175
	-----	-----	-----
	\$ 7,227	\$ --	\$ 7,227
	=====	=====	=====
Marketable securities:			
Municipal obligations	\$ 14,276	\$ 307	\$ 14,583
	=====	=====	=====

Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of \$70,000 at June 30, 2003 and \$104,000 as of December 31, 2002, are included in the accumulated other comprehensive income account of shareholders' equity.

The marketable securities of \$9.8 million on June 30, 2003 and \$14.6 million on December 31, 2002 had maturity dates as follows: approximately zero and \$1.2 million, respectively, of marketable securities had a maturity date of less than 90 days, approximately \$6.5 million and \$8.0 million, respectively, had a maturity date between 90 days and 1 year, and approximately \$3.3 million and \$5.4 million, respectively, had a maturity date between 1 and 5 years.

NOTE 4 - INVENTORIES

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Inventories are comprised of the following (in thousands):

	June 30, 2003	December 31, 2002	
	-----		
	(Unaudited)		
Raw materials	\$ 2,621	\$ 2,341	
Work-in-process	286	306	
Finished goods	1,628	1,938	
	-----		
	\$ 4,535	\$ 4,585	
	=====		

### NOTE 5 -INCOME TAXES

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets primarily as a result of net operating losses in 2002 and 2003, primarily due to reductions in revenues, write-downs of deferred preservation costs, additional professional fees, and accruals for product liability claims, as a result of the FDA Order, FDA Warning Letter, and reported tissue infections. The Company periodically assesses the recoverability of deferred tax assets and provides a

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valuation allowance when management believes it is more likely than not that its deferred tax assets will not be realized.

During the first quarter of 2003 the Company recorded a valuation allowance of \$658,000 for deferred tax assets generated by capital losses when management determined that it was more likely than not that these deferred tax assets would not be realized in future periods. During the second quarter of 2003, the Company evaluated several factors to determine if a valuation allowance relative to its deferred tax assets was necessary. The Company reviewed its historic operating results, including the reasons for its operating losses in 2002 and 2003, uncertainties regarding projected future operating results due to the effects of the adverse publicity resulting from the FDA Order, FDA Warning Letter, and reported tissue infections and the changes in processing methods resulting from the FDA Order, and the uncertainty of the outcome of product liability claims (see Note 13). Based on the results of this analysis, the Company has determined that it is more likely than not that \$9.7 million of the Company's \$11.0 million in deferred tax assets will not be realized. Therefore, the Company recorded an additional valuation allowance of \$9.0 million against its net deferred tax assets during the second quarter of 2003. As of June 30, 2003 the Company had a total of \$9.7 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of \$1.3 million. This remaining \$1.3 million of deferred tax assets was not subject to valuation as it is expected to become recoverable by the end of the year. This amount along with \$1.1 million in income tax receivable, totaling \$2.4 million, represents expected tax refunds resulting from 2003 tax losses which can be carried back to offset taxes paid in prior years.

As a result of recording a valuation allowance, the Company has reported an income tax expense of \$3.6 million and \$3.4 million for the three and six months ended June 30, 2003, respectively.

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### NOTE 6 - DEBT

On April 25, 2000 the Company entered into a loan agreement permitting the Company to borrow up to \$8 million under a line of credit during the expansion of the Company's corporate headquarters and manufacturing facilities. Borrowings under the line of credit accrued interest equal to Adjusted LIBOR plus 2% adjusted monthly. On June 1, 2001 the line of credit was converted to a term loan (the "Term Loan") to be paid in 60 equal monthly installments of principal plus interest computed at Adjusted LIBOR plus 1.5% (2.82% at June 30, 2003). At June 30, 2003 the principal balance of the Term Loan was \$4.8 million. The Term Loan is secured by substantially all of the Company's assets. The Term Loan contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios, a minimum tangible net worth requirement, and the requirement that no materially adverse event has occurred. The lender has notified the Company that the FDA Order, as described in Note 2, and the inquiries of the SEC, as described in Note 13, have had a material adverse effect on the Company that constitutes an event of default. Additionally, as of June 30, 2003, the Company is in violation of the debt coverage ratio and net worth financial covenants. Therefore, all amounts due under the Term Loan as of June 30, 2003 are reflected as a current liability on the Summary Consolidated Balance Sheets. The Company and the lender are currently in the process of negotiating specific terms of a forbearance agreement, which if entered into would increase the interest rate charged on the Term Loan effective August 1, 2003 to Adjusted LIBOR plus 4% (5.32% at June 30, 2003), accelerate the principal payments on the Term Loan by requiring a balloon payment to pay off the outstanding balance by October 31, 2003, and cause the Company to pay a \$12,000 modification fee and the lender's attorneys costs, which have yet to be determined. As of August 4, 2003 the Company has sufficient cash and cash equivalents to pay the remaining outstanding balance of the Term Loan.

In the quarter ended June 30, 2003 the Company entered into two agreements to finance \$2.9 million in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. The amount financed accrues interest at a 3.75% rate and is payable in equal monthly payments through January 2004. As of June 30, 2003 the outstanding balance of the agreements was \$1.6 million.

### NOTE 7 - DERIVATIVES

The Company's Term Loan, which accrues interest computed at Adjusted LIBOR plus 1.5%, exposes the Company to changes in interest rates going forward. On March 16, 2000 the Company entered into a \$4.0 million notional amount

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forward-starting interest swap agreement, which took effect on June 1, 2001 and expires in 2006. This swap agreement was designated as a cash flow hedge to effectively convert a portion of the Term Loan balance to a fixed rate basis, thus reducing the impact of interest rate changes on future income. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement, without an exchange of the underlying principal amounts. The differential to be paid or received is recognized in the period in which it accrues as an adjustment to interest expense on the Term Loan.

On January 1, 2001 the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") as amended. SFAS 133 requires the Company to recognize all derivative instruments on the balance sheet at fair

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value, and changes in the derivative's fair value must be recognized currently in earnings or other comprehensive income, as applicable. The adoption of SFAS 133 impacts the accounting for the Company's forward-starting interest rate swap agreement. Upon adoption of SFAS 133, the Company recorded an unrealized loss of approximately \$175,000 related to the interest rate swap, which was recorded as part of long-term liabilities and accumulated other comprehensive income as the cumulative effect of adopting SFAS 133 within the Statement of Shareholders' Equity.

In August 2002 the Company determined that changes in the derivative's fair value could no longer be recorded in other comprehensive income, as a result of the uncertainty of future cash payments on the Term Loan caused by the lender's ability to declare an event of default as discussed in Note 6. Beginning in August 2002 the Company started recording all changes in the fair value of the derivative currently in other expense/income on the Summary Consolidated Statements of Operations, and amortizing the amounts previously recorded in other comprehensive income into other expense/income over the remaining life of the agreement.

During the quarter ended June 30, 2003 the Company became aware of the lender's intention to accelerate the payment of the Term Loan, as discussed in Note 6 above. Therefore, the Company recorded an expense of \$222,000, to reclass the unamortized portion of the other comprehensive loss to other expense/income on the Summary Consolidated Statements of Operations. The Company and the lender are currently in the process of negotiating the specific terms of a forbearance agreement, which, if entered into, is expected to require the Company to pay the lender by October 31, 2003 an amount equal the fair value of the swap agreement. For the three and six months ended June 30, 2003 the Company recorded a total expense of \$216,000 and \$207,000, respectively, on the interest rate swap.

As of June 30, 2003 the notional amount of this swap agreement was \$2.4 million, and the fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$227,000. The fair value of the swap agreement is recorded as part of short-term liabilities. The unamortized value of the swap agreement, recorded in the accumulated other comprehensive income account of shareholders' equity, was zero at June 30, 2003.

### NOTE 8 - COMPREHENSIVE LOSS

Components of comprehensive loss consist of the following, net of tax (in thousands):

	Three Months Ended June 30,		Six Month Ju
	2003	2002	2003
	(Unaudited)		(U
Net loss	\$ (19,921)	\$ (5,522)	\$ (20,355)
Unrealized (loss)/gain on investments	(27)	128	(61)
Change in fair value of interest rate swap (including cumulative effect of adopting SFAS 133 in 2001)	159	15	172
Translation adjustment	127	250	(31)
Comprehensive loss	\$ (19,662)	\$ (5,129)	\$ (20,275)

The tax effect on the change in unrealized gain/loss on investments is a benefit of \$17,000 and an expense of \$66,000 for the three months ended June 30, 2003 and 2002, respectively. The tax effect on the change in unrealized gain/loss on investments is a benefit of \$34,000 and an expense of \$27,000 for the six months ended June 30, 2003 and 2002, respectively. The tax effect on the change in fair value of the interest rate swap is \$82,000 and \$7,000 for the three months ended June 30, 2003 and 2002, respectively. The tax effect on the change in fair value of the interest rate swap is \$88,000 and \$2,000 for the six months ended June 30, 2003 and 2002, respectively. The tax effect on the translation adjustment is zero for the three months ended June 30, 2003 and 2002, respectively. The tax effect on the translation adjustment is \$110,000 and zero for the six months ended June 30, 2003 and 2002, respectively.

NOTE 9 - LOSS PER SHARE

The following table sets forth the computation of basic and diluted earnings per share (in thousands, except per share data):

	Three Months Ended June 30,		Six
	2003	2002	2003
	----- (Unaudited) -----		-----
Numerator for basic and diluted earnings per share - loss available to common shareholders	\$ (19,921)	\$ (5,522)	\$ (20,
Denominator for basic earnings per share - weighted-average basis	19,675	19,538	19,
Effect of dilutive stock options	--	--	
Denominator for diluted earnings per share - adjusted weighted-average shares	19,675	19,538	19,
Net loss per share:			
Basic	\$ (1.01)	\$ (0.28)	\$ (1
Diluted	\$ (1.01)	\$ (0.28)	\$ (1

The effect of stock options of 529,000 and 674,000 shares for the three months ended June 30, 2003 and 2002, respectively, was excluded from the calculation because these amounts are antidilutive for the periods presented. The effect of stock options of 446,000 and 692,000 shares for the six months ended June 30, 2003 and 2002, respectively, was excluded from the calculation because these amounts are antidilutive for the periods presented.



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On July 23, 2002 the Company's Board of Directors authorized the purchase of up to \$10 million of its common stock. As of August 13, 2002 the Company had repurchased 68,000 shares of its common stock for \$663,000. No further purchases are anticipated in the near term.

### NOTE 10 - STOCK-BASED COMPENSATION

On December 31, 2002 the Company was required to adopt SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" ("SFAS 148"). SFAS 148 amends SFAS No. 123, "Accounting for Stock-Based Compensation" to provide alternative methods of transition for companies that voluntarily elect to adopt the fair value recognition and measurement methodology prescribed by SFAS 123. In addition, regardless of the method a company elects to account for stock-based compensation arrangements, SFAS 148 requires additional disclosures in the footnotes of both interim and annual financial statements regarding the method the Company uses to account for stock-based compensation and the effect of such method on the Company's reported results. The adoption of SFAS 148 did not have a material effect on the financial position, results of operations, and cash flows of the Company.

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The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations ("APB 25") in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under SFAS 123 requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of the grant, no compensation expense is recognized.

Pro forma information regarding net income and earnings per share is required by SFAS 123, which requires that the information be determined as if the Company has accounted for its employee stock options granted under the fair value method of that statement. The fair values for these options were estimated at the dates of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months June
	2003	2002	2003
	(Unaudited)		(Unaudited)
Expected dividend yield	0%	0%	0%
Expected stock price volatility	.605	.630	.615
Risk-free interest rate	2.13%	3.67%	2.41%
Expected life of options	3.3 Years	5.3 Years	3.9 Years

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because

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the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair values of the options are amortized to expense over the options' vesting periods. The Company's pro forma information follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months June
	2003	2002	2003
	(Unaudited)		(Unaudited)
Net loss--as reported	\$ (19,921)	\$ (5,522)	\$ (20,355)
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of tax	544	572	672
Net loss--pro forma	\$ (20,465)	\$ (6,094)	\$ (21,027)
Net loss per share--as reported:			
Basic	\$ (1.01)	\$ (0.28)	\$ (1.04)
Diluted	\$ (1.01)	\$ (0.28)	\$ (1.04)
Net loss per share--proforma:			
Basic	\$ (1.04)	\$ (0.31)	\$ (1.07)
Diluted	\$ (1.04)	\$ (0.31)	\$ (1.07)

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### NOTE 11 - ACCOUNTING PRONOUNCEMENTS

The Company was required to adopt SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143") on January 1, 2003. SFAS 143 addresses accounting and reporting for retirement costs of long-lived assets resulting from legal obligations associated with acquisition, construction, or development transactions. The adoption of SFAS 143 did not have a material effect on the results of operations or financial position of the Company.

The Company was required to adopt SFAS No. 145, "Rescission of FASB Statements 4, 44 and 64, Amendment to FASB Statement 13, and Technical Corrections" ("SFAS 145"), on January 1, 2003. SFAS 145 rescinds SFAS No.s 4, 44 and 64, which required gains and losses from extinguishments of debt to be classified as extraordinary items. SFAS 145 also amends SFAS No. 13 eliminating

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inconsistencies in certain sale-leaseback transactions. The provisions of SFAS 145 are effective for fiscal years beginning after May 15, 2002. The adoption of SFAS 145 did not have a material effect on the results of operations or financial position of the Company.

The Company was required to adopt SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") on January 1, 2003. SFAS 146 requires that costs associated with exit or disposal activities be recorded at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The adoption of SFAS 146 did not have a material effect on the results of operations or financial position of the Company.

### NOTE 12 - SEGMENT INFORMATION

The Company has two reportable segments: Human Tissue Preservation Services and Implantable Medical Devices. The Company's segments are organized according to services and products.

The Human Tissue Preservation Services segment includes external revenue from cryopreservation services of cardiac, vascular, and orthopaedic allograft tissues. The Implantable Medical Devices segment includes external revenue from product sales of BioGlue(R) Surgical Adhesive, bioprosthetic devices, including stentless porcine heart valves, SynerGraft treated porcine heart valves, and SynerGraft treated bovine vascular grafts, and Cerasorb(R) Ortho bone graft substitute. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company's management, is segment gross margin, or net external revenues less cost of preservation services and products. The Company does not segregate assets by segment, therefore, asset information is excluded from the segment disclosures below.

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The following table summarizes revenues, cost of preservation services and products, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended June 30,		Six Months June
	2003	2002	2003
	(Unaudited)		(Unaudited)
<b>Revenue:</b>			
Human tissue preservation services, net	8,615	17,536	17,745
Implantable medical devices	6,932	5,473	13,531
All other a	166	255	357
	<b>\$ 15,713</b>	<b>\$ 23,264</b>	<b>\$ 31,633</b>
<b>Cost of Preservation Services and Products:</b>			
Human tissue preservation services	5,160	17,203	7,603

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Implantable medical devices	2,006	1,843	3,647
All other a	--	--	--
	-----	-----	-----
	7,166	19,046	11,250
	-----	-----	-----
Gross Margin (Loss):			
Human tissue preservation services	3,455	333	10,142
Implantable medical devices	4,926	3,630	9,884
All other a	166	255	357
	-----	-----	-----
	\$ 8,547	\$ 4,218	\$ 20,383
	-----	-----	-----

(a) The "All other" designation includes 1) grant revenue and 2) distribution revenue.

The following table summarizes net revenues by product (in thousands):

	Three Months Ended June 30,		Six Months June
	2003	2002	2003
	-----		-----
	(Unaudited)		(U
Revenue:			
Human tissue preservation services, net			
Cardiovascular tissue	\$ 5,036	\$ 7,336	\$ 9,761
Vascular tissue	3,299	4,641	7,554
Orthopaedic tissue	280	5,559	430
	-----	-----	-----
Total preservation services	8,615	17,536	17,745
	-----	-----	-----
BioGlue surgical adhesive	6,839	5,251	13,333
Other implantable medical devices	93	222	198
Distribution and grant	166	255	357
	-----	-----	-----
	\$ 15,713	\$ 23,264	\$ 31,633
	=====	=====	=====

NOTE 13 - COMMITMENTS AND CONTINGENCIES

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. Following the FDA Order, a greater number of lawsuits than has historically been the case have been filed. As of August 1, 2003 approximately 21 lawsuits were open that were filed against the Company between May 18, 2000 and May 23, 2003. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, 15 allege product liability claims arising out of the Company's orthopaedic tissue services, five allege product liability claims arising out of the Company's allograft heart valve tissue services, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, when it was a subsidiary of the Company.

Of the 21 open lawsuits, two lawsuits were filed in the 2000/2001 insurance policy year, four were filed in the 2001/2002 insurance policy year, 14 were filed in the 2002/2003 insurance policy year and one was filed in the 2003/2004 policy year. For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. Two of the three insurance companies who issued policies for the 2002/2003 year have confirmed coverage for the first two layers of coverage totaling \$15 million; however, most of this coverage has already been used in the settlement of other lawsuits. A third insurance company, covering the \$10 million of remaining insurance, has indicated that it intends to exclude eleven matters under its policy, which is expected to have the effect of substantially decreasing the total coverage available. The Company is currently evaluating all of its alternatives in connection with resolving the dispute with its upper layer excess carrier concerning the restrictions on the matters it has excluded from coverage. Additionally, the Company has called a meeting with the plaintiffs' attorneys to determine the feasibility of obtaining a global settlement of the outstanding claims. However, based on the analysis of the product liability lawsuits now pending against the Company, settlement negotiations to date, the position taken by the upper layer excess carrier and advice from counsel, during the second quarter of 2003 the Company has recorded a liability of \$9.0 million in the accrued expenses and other current liabilities line of the Summary Consolidated Balance Sheet and a related expense of \$9.0 million in general, administrative, and marketing expenses for the potential expense of resolving these lawsuits and reflecting the uninsured portion of the estimated liability. The amounts recorded are reflective of potential legal fees and settlement costs related to these lawsuits, and do not reflect actual settlement arrangements or final judgments, which could include punitive damages. The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. If the Company is unsuccessful in arranging settlements of product liability claims for an amount substantially below the amount accrued, there may not be sufficient insurance coverage and liquid assets to meet these obligations, even if the Company satisfactorily resolves the restrictions on the upper layer excess insurance coverage. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay and one or more of the product liability lawsuits in which the Company is a defendant should be tried and a substantial verdict rendered in favor of the plaintiffs(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. If the Company 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 the Company.

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. As of December 31, 2002 the Company had accrued \$3.6 million for estimated costs for unreported product claims. On May 2, 2003 the insurance carrier for the 2003/2004 policy altered the policy effective April 1, 2003 to be a first year claims made policy, i.e. only claims incurred and reported during the policy period April 1, 2003 through March 31, 2004 are covered by this policy. During the second quarter of 2003 the Company engaged an

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independent actuarial firm to update the analysis of the unreported product claims as of June 30, 2003. As a result the Company accrued an additional \$3.9 million during the second quarter of 2003 to increase the total accrual to \$7.5 million for estimated costs for unreported product liability claims related to services performed and products sold prior to June 30, 2003. The \$3.9 million expense was recorded in the second quarter of 2003 in general, administrative, and marketing expenses. The \$7.5 million balance is included as a component of accrued expenses and other current liabilities of \$3.5 million and other long-term liabilities of \$4.0 million on the Summary Consolidated Balance Sheets.

At June 30, 2003 there was \$150,000 accrued for required insurance retention payments for the Company's product liability insurance policies claims related to the 2000/2001 and 2001/2002 policy year. There were no amounts accrued for required insurance retention payments for the Company's product liability and directors' and officers' insurance policies claims related to the 2002/2003 policy year as the Company had met its retention levels under these insurance policies.

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Several putative class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company, 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 the Company failed to disclose its alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. The Company 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. The Company carries directors' and officers' liability insurance policies, which the Company presently believes to be adequate to defend against this action. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

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 the Company as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in certain inappropriate practices that caused the Company to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that the Company'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 purported demand letter sent on Frailey's behalf to the Company'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 the Company. The Company's Board of Directors has established an independent

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committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation and has concluded its investigation. The committee's report concludes that no officer or director breached any fiduciary duty and recommends that the Board of Directors seek to have the lawsuits dismissed. The Company anticipates responding to the complaint in August of 2003.

On August 19, 2002 the Company issued a press release announcing that on August 17, 2002, the Company received a letter from the Atlanta District Office of the SEC inquiring into certain matters relating to the Company's August 14, 2002 announcement of the recall order issued by the FDA. Since that time, the Company has been cooperating with the SEC in its inquiry, which as the SEC notified the Company in July 2003, became a formal investigation in June 2003. The Company plans to continue to cooperate with the SEC in its investigation.

NOTE 14 - SUBSEQUENT EVENTS

On August 4, 2003 the Company approved a buyback of employee stock options with an exercise price of \$23 or greater. The option buyback was approved for an aggregate of up to \$350,000 using a Black Scholes valuation model. The Company anticipates making the offer to employees in third quarter of 2003.

NEITHER THE ABOVE STATEMENT NOR THIS QUARTERLY REPORT ON FORM 10-Q IS AN OFFER TO PURCHASE, OR A SOLICITATION OF AN OFFER TO SELL, OPTIONS TO PURCHASE SHARES OF COMMON STOCK OF CRYOLIFE, INC. SUCH AN OFFER WILL BE MADE ONLY BY AN "OFFER TO PURCHASE OPTIONS" AND RELATED "LETTER OF TRANSMITTAL" TO BE DISSEMINATED TO OPTIONHOLDERS AT A LATER DATE. OPTIONHOLDERS INVITED TO PARTICIPATE IN THE BUYBACK DESCRIBED IN THE ABOVE STATEMENT SHOULD READ THESE DOCUMENTS, AS WELL AS CRYOLIFE'S TENDER OFFER STATEMENT ON SCHEDULE TO, WHEN THEY ARE AVAILABLE BECAUSE THEY CONTAIN IMPORTANT INFORMATION. THESE AND OTHER FILED DOCUMENTS WILL BE AVAILABLE FOR FREE FROM THE SEC'S WEBSITE AT WWW.SEC.GOV AND CRYOLIFE. THE OFFER WILL NOT BE MADE TO, NOR WILL TENDERS BE ACCEPTED FROM OR ON BEHALF OF, OPTIONHOLDERS IN ANY JURISDICTION IN WHICH MAKING OR ACCEPTING THE OFFER WOULD VIOLATE THAT JURISDICTION'S LAWS.

NOTE 15 - RESTATEMENT

Subsequent to the issuance of the Company's consolidated financial statements for the three and six month periods ended June 30, 2003, the Company determined that there were \$2.4 million in tax loss carrybacks available to the Company at June 30, 2003. Therefore, the entire deferred tax asset balance need not have a valuation allowance. As a result, the consolidated financial statements as of and for the three and six months ended June 30, 2003 have been restated from the amounts previously reported as follows (in thousands, except per share data):

Three Months Ended June 30, 2003		Six Months Ended June 30, 2003	
-----	-----	-----	-----
As Previously Reported	As Restated	As Previously Reported	Re
-----	-----	-----	-----

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	(Unaudited)		(Unaudited)				
Income tax expense	\$	6,069	\$	3,644	\$	5,855	\$
Net loss	\$	(22,346)	\$	(19,921)	\$	(22,780)	\$
Net loss per share:							
Basic	\$	(1.14)	\$	(1.01)	\$	(1.16)	\$
Diluted	\$	(1.14)	\$	(1.01)	\$	(1.16)	\$

	June 30, 2003	
	As Previously Reported	As Restated
	(Unaudited)	
Other receivables, net	\$ 616	\$ 1,766
Deferred income taxes	--	1,275
Total current assets	52,647	55,072
TOTAL ASSETS	95,006	97,431
Retained deficit	(9,994)	(7,569)
Total shareholders' equity	57,450	59,875
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 95,006	\$ 97,431

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PART I - FINANCIAL INFORMATION

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

RECENT EVENTS

A new FDA 483 Notice of Observations ("February 2003 483") was issued in connection with the FDA inspection in February 2003, but corrective action was implemented on most of its observations during the inspection. The Company believes the observations, most of which focus on the Company's systems for handling complaints, will not materially affect the Company's operations. The Company responded to the February 2003 483 in March 2003. The Company has met with the FDA to review its response to the February 2003 483. No additional comments regarding the adequacy of its response were issued at that time. The Company continues to work with the FDA to review process improvements.

On February 20, 2003 the Company received a letter from the FDA stating that a



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510(k) premarket notification should be filed for the Company's CryoValve SG and that premarket approval marketing authorization should be obtained for the Company's CryoVein SG when used for arteriovenous ("A-V") access. The agency's position is that use of the SynerGraft technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft, and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

The Company is in discussions with the FDA about the type of submissions necessary for these products. The Company advised the FDA that it has voluntarily suspended use of the SynerGraft technology in the processing of allograft heart valves and vascular tissue until the regulatory status of the CryoValve SG and CryoVein SG is resolved. Additionally, the Company has discontinued labeling its vascular grafts for use as A-V access grafts. The FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SynerGraft tissue are resolved, the Company will employ its traditional processing methods on these tissues. Distribution of allograft heart valves and vascular tissue processed using the Company's traditional processing protocols will continue. The outcome of the discussions with the FDA regarding the use of the SynerGraft process on human tissue could result in an inability to process tissues with the SynerGraft technology until further submissions and FDA approvals are granted. The Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue, and as such, revenues and gross margins will be adversely affected in the third and fourth quarters of 2003.

During the second quarter of 2003, the Company's upper layer excess product liability insurance carrier, which covers \$10 million of insurance, indicated that it intends to exclude eleven matters under its policy, which is expected to have the effect of substantially decreasing the total coverage available. The Company is currently evaluating all of its alternatives in connection with resolving the dispute with its upper layer excess carrier concerning the restrictions on the matters it has excluded from coverage. See further discussion regarding product liability claims in Part II. Item 1. Legal Proceedings.

The Company and the lender are currently in the process of negotiating specific terms of a forbearance agreement, which, if entered into, would increase the interest rate charged on the Term Loan effective August 1, 2003 to Adjusted LIBOR plus 4% (5.32% at June 30, 2003), accelerate the principal payments on the Term Loan by requiring a balloon payment to pay off the outstanding balance by October 31, 2003, and cause the Company to pay a \$12,000 modification fee and the lender's attorneys costs, which have yet to be determined. As of August 4, 2003 the Company has sufficient cash and cash equivalents to pay the remaining outstanding balance of the Term Loan.

### CRITICAL ACCOUNTING POLICIES

A summary of the Company's significant accounting policies is included in Note 1 to the consolidated financial statements, as filed in the Form 10-K for the fiscal year ended December 31, 2002, as amended. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company's operating results and financial condition. The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States, which require the Company to make estimates and assumptions. The following are accounting policies that management believes are

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most important to the portrayal of the Company's financial condition and results and may involve a higher degree of judgment and complexity.

**DEFERRED PRESERVATION COSTS:** Tissue is procured from deceased human donors by organ and tissue procurement agencies, which consign the tissue to the Company for processing and preservation. Preservation costs related to tissue held by the Company are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities. Deferred preservation costs consist primarily of laboratory and personnel expenses, tissue procurement fees, fringe benefits, facility allocations, and freight-in charges, and are stated at the lower of cost or market, net of reserve, on a first-in, first-out basis.

During 2002 the Company recorded a write-down of deferred preservation costs of \$8.7 million for valved cardiac tissues, \$2.9 million for non-valved cardiac tissues, \$11.9 million for vascular tissues, and \$9.2 million for orthopaedic tissue, totaling \$32.7 million. These write-downs were recorded as a result of the adverse publicity surrounding the FDA Order as discussed at Note 2 to the Summary Consolidated Financial Statements in this Form 10-Q. The amount of these write-downs reflected managements' estimates based on information available to it at the time the estimates were made. These estimates may prove inaccurate, as the ultimate impact of the FDA Order is determined. Management continues to evaluate the recoverability of these deferred preservation costs based on the factors discussed in Note 2 to Summary Consolidated Financial Statements and will record additional write-downs if it becomes clear that additional impairments have occurred. The write-down created a new cost basis, which cannot be written back up if these tissues become shippable. The cost of human tissue preservation services may be favorably affected depending on the future level of tissue shipments related to previously written-down deferred preservation costs. The shipment levels of these written-down tissues will be affected by the amount and timing of the release of tissues processed after September 5, 2002, as a result of the Agreement with the FDA, since, under the Agreement, written-down tissues may be shipped if tissues processed after September 5, 2002 are not available for shipment.

The Company regularly evaluates its deferred preservation costs to determine if the carrying value is appropriately recorded at the lower of cost or market value. During the three and six months ended June 30, 2003 the Company recorded \$1.1 million and \$1.4 million, respectively, as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs from tissues processed in the three and six months ended June 30, 2003 that exceeded market value. The amount of these write-downs reflects managements' estimates of market value based on information available to it at the time the estimates were made and actual results may differ from these estimates.

As of June 30, 2003 the balance of deferred preservation costs was \$4.3 million for allograft heart valve tissues, \$452,000 for non-valved cardiac tissues, \$4.0 million for vascular tissues, and \$738,000 for orthopaedic tissues.

**DEFERRED INCOME TAXES:** Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets primarily as a result of net operating losses in 2002 and 2003, primarily due to reductions in revenues, write-downs of deferred preservation costs, additional professional fees, and accruals for product liability claims, as a result of the FDA Order, FDA Warning Letter, and reported tissue infections. The Company periodically assesses the recoverability of deferred tax assets and provides a valuation allowance when management believes it is more likely than not that its deferred tax assets will not be realized.

During the first quarter of 2003 the Company recorded a valuation allowance of \$658,000 for deferred tax assets generated by capital losses when management

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determined that it was more likely than not that these deferred tax assets would not be realized in future periods. During the second quarter of 2003, the Company evaluated several factors to determine if a valuation allowance relative to its deferred tax assets was necessary. The Company reviewed its historic operating results, including the reasons for its operating losses in 2002 and 2003, uncertainties regarding projected future operating results due to the effects of the adverse publicity resulting from the FDA Order, FDA Warning Letter, and reported tissue infections and the changes in processing methods resulting from the FDA Order, and the uncertainty of the outcome of product liability claims (see Note 13). Based on the results of this analysis, the Company has determined that it is more likely than not that \$9.7 million of the Company's \$11.0 million in deferred tax assets will not be realized. Therefore, the Company recorded an additional valuation allowance of \$9.0 million against its net deferred tax assets during the second quarter of 2003. As of June 30, 2003 the Company had a total of \$9.7 million in valuation allowances against

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deferred tax assets and a net deferred tax asset balance of \$1.3 million. This remaining \$1.3 million of deferred tax assets was not subject to valuation as it is expected to become recoverable by the end of the year. This amount along with \$1.1 million in income tax receivable, totaling \$2.4 million, represents expected tax refunds resulting from 2003 tax losses which can be carried back to offset taxes paid in prior years.

Management will continue to evaluate the recoverability of the deferred tax assets and may remove the valuation allowance if it determines that it is more likely than not that the deferred tax assets will be realized in future periods.

**VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS AND GOODWILL:** The Company assesses the impairment of its long-lived, identifiable intangible assets and related goodwill annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that management considers important that could trigger an impairment review include the following:

- o Significant underperformance relative to expected historical or projected future operating results;
- o Significant negative industry or economic trends;
- o Significant decline in the Company's stock price for a sustained period; and
- o Significant decline in the Company's market capitalization relative to net book value.

Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), requires the write-down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. In applying SFAS 144, the Company defined the specific asset groups used to perform the cash flow analysis. The Company defined the asset groups at the lowest level possible, by identifying the cash flows from groups of assets that could be segregated from the cash flows of other assets and liabilities. Using this methodology, the Company determined that its asset groups consisted of the long-lived assets related to the Company's two reporting segments. As the Company does not segregate assets by segment, the Company allocated assets to the two reporting

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segments based on factors including facility space and revenues. The Company used a fourteen-year period for the undiscounted future cash flows. This period of time was selected based upon the remaining life of the primary assets of the asset groups, which are leasehold improvements. The undiscounted future cash flows related to these asset groups exceeded their carrying values as of June 30, 2003 and, therefore, management has concluded that there is not an impairment of the Company's long-lived intangible assets and tangible assets related to the tissue preservation business or medical device business. However, depending on the Company's ability to rebuild demand for its tissue preservation services, the outcome of discussions with the FDA regarding the shipping of orthopaedic tissues, and the future effects of adverse publicity surrounding the FDA Order and reported infections on preservation revenues, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

Beginning with the Company's adoption of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142") on January 1, 2002 the goodwill resulting from business acquisitions is not amortized, but is instead subject to periodic impairment testing in accordance with SFAS 142. Patent costs are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method. Other intangibles, which consist primarily of manufacturing rights and agreements, are amortized over the expected useful lives of the related assets (primarily five years). As a result of the FDA Order, the Company determined that an evaluation of the possible impairment of intangible assets under SFAS 142 was necessary. The Company engaged an independent valuation expert to perform the valuation using a discounted cash flow methodology, and as a result of this analysis, the Company determined that goodwill related to its tissue processing reporting unit was fully impaired as of September 30, 2002. Therefore, the Company recorded a write-down of \$1.4 million in goodwill during the quarter ended September 30, 2002. Management does not believe an impairment exists related to the other intangible assets that were assessed in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144").

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PRODUCT LIABILITY CLAIMS: In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. Following the FDA Order, a greater number of lawsuits than has historically been the case have been filed. 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. As of December 31, 2002 the Company had accrued \$3.6 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2002. The Company retained an independent actuarial firm to estimate the unreported claims. During the second quarter of 2003 the independent actuarial firm updated the analysis of the unreported product claims as of June 30, 2003. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby, projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim

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experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. As a result of the actuarial valuation the Company accrued an additional \$3.9 million to increase the total accrual to \$7.5 million for unreported product liability claims related to services performed and products sold prior to June 30, 2003. The \$3.9 million expense was recorded in the second quarter of 2003 in general, administrative, and marketing expenses. The \$7.5 million balance is included as a component of accrued expenses and other current liabilities of \$3.5 million and other long-term liabilities of \$4.0 million on the Summary Consolidated Balance Sheets.

For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. Two of the three insurance companies who issued policies for the 2002/2003 year have confirmed coverage for the first two layers of coverage totaling \$15 million; however, most of this coverage has already been used in the settlement of other lawsuits. A third insurance company, covering the last \$10 million of the remaining insurance, has indicated that it intends to exclude eleven matters under its policy, which is expected to have the effect of substantially decreasing the total coverage available. The Company is currently evaluating all of its alternatives in connection with resolving the dispute with its upper layer excess carrier concerning the restrictions on the matters it has excluded from coverage. Additionally, the Company has called a meeting with the plaintiffs' attorneys to determine the feasibility of obtaining a global settlement of the outstanding claims. However, based on the analysis of the product liability lawsuits now pending against the Company, settlement negotiations to date, the position taken by the upper layer excess carrier and advice from counsel, during the second quarter of 2003 the Company has recorded a liability of \$9.0 million in the accrued expenses and other current liabilities line of the Summary Consolidated Balance Sheet and a corresponding expense in general, administrative, and marketing expenses for the estimated expense of resolving these lawsuits and reflecting the uninsured portion of the estimated liability. The amounts recorded are reflective of potential legal fees and settlement costs related to these lawsuits, and do not reflect actual settlement arrangements or final judgments, which could include punitive damages. The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. If the Company is unsuccessful in arranging settlements of product liability claims for an amount substantially below the amount accrued, there may not be sufficient insurance coverage and liquid assets to meet these obligations, even if the Company satisfactorily resolves the restrictions on the upper layer excess insurance coverage. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay and one or more of the product liability lawsuits in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiffs(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. If the Company 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 the Company.

### NEW ACCOUNTING PRONOUNCEMENTS

The Company was required to adopt SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS 143") on January 1, 2003. SFAS 143 addresses accounting and

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reporting for retirement costs of long-lived assets resulting from legal obligations associated with acquisition, construction, or development transactions. The adoption of SFAS 143 did not have a material effect on the results of operations or financial position of the Company.

The Company was required to adopt SFAS No. 145, "Rescission of FASB Statements 4, 44 and 64, Amendment to FASB Statement 13, and Technical Corrections" ("SFAS 145"), on January 1, 2003. SFAS 145 rescinds SFAS No.s 4, 44 and 64, which required gains and losses from extinguishments of debt to be classified as extraordinary items. SFAS 145 also amends SFAS No. 13, eliminating inconsistencies in certain sale-leaseback transactions. The provisions of SFAS 145 are effective for fiscal years beginning after May 15, 2002. The adoption of SFAS 145 did not have a material effect on the results of operations or financial position of the Company.

The Company was required to adopt SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") on January 1, 2003. SFAS 146 requires that costs associated with exit or disposal activities be recorded at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The adoption of SFAS 146 did not have a material effect on the results of operations or financial position of the Company.

### RESULTS OF OPERATIONS (IN THOUSANDS)

#### REVENUES

	Three Months Ended June 30,		Six Months June
	2003	2002	2003
Revenues as reported	\$ 15,713	\$ 23,264	\$ 31,633
Estimated tissue recall returns	--	2,433	--
Adjustment to estimated tissue recall returns	--	--	(848)
Adjusted revenues (a)	\$ 15,713	\$ 25,697	\$ 30,785

Revenues as reported decreased 32% and 35% for the three and six months ended June 30, 2003, respectively, as compared to the three and six months ended June 30, 2002. Revenues as reported for the six months ended June 30, 2003 include

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(a) The measurement "adjusted revenues" is defined as revenues prior to estimated tissue recall returns and adjustment to estimated tissue recall returns. This measurement may be deemed to be a "non-GAAP" financial measure as that term is defined in Regulation G and Item 10(e) of Regulation S-K and is included for informational purposes to provide comparable disclosure in the current and prior periods of revenues derived from services provided with respect to tissues and products shipped in the normal course of business. The estimated tissue recall returns have been excluded from revenues in the prior

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year periods to exclude the effect of an estimated amount of tissues to be returned subsequent to the period presented due to the FDA recall. Excluding this unfavorable item from the prior periods was necessary to show a clearer comparison to current year periods and to illustrate the magnitude of the decrease in current year revenues. The adjustment to estimated tissue recall returns has been excluded from revenues in the 2003 six month period to exclude the effect of an adjustment to the estimated amount of tissues to be returned due to the FDA recall. Excluding this favorable item from the current year periods was necessary to show a clearer comparison to prior year periods and to illustrate the magnitude of the decrease in current year revenues. The presentation of revenue as reported without the presentation of adjusted revenues might mislead investors with respect to the magnitude of the decrease in the Company's current year revenues relative to the prior year.

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\$848,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated. Revenues as reported for the three and six months ended June 30, 2002 were adversely affected by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of \$2.4 million in preservation service revenues. As of June 30, 2003 approximately \$60,000 remains in the accrual for estimated return of tissues subject to recall by the FDA Order.

Adjusted revenues decreased 39% and 40% for the three and six months ended June 30, 2003, respectively, as compared to the three and six months ended June 30, 2002. This decrease in adjusted revenues for the three and six months ended June 30, 2003 was primarily due to a 57% and 58% decrease, respectively, of human tissue preservation service revenues as a result of the FDA Order's restriction on shipments of certain tissues, the Company's cessation of orthopaedic processing until late February 2003, a decrease in 2003 processing levels relative to processing levels prior to the issuance of the FDA Order in August of 2002, and decreased demand as a result of the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections. These decreases were partially offset by an increase in BioGlue Surgical Adhesive revenues for the three and six months ended June 30, 2003 of 30% and 32%, respectively, due to increased demand.

Management believes that revenues will exceed third quarter 2002 levels in the third quarter of 2003, but will still show a significant decrease for the full year 2003 compared to 2002. The ongoing corrective actions taken by the Company regarding the FDA issues and the anticipated resolution of the FDA issues should assist the Company in rebuilding demand for its preservation services. In the event the Company is not successful in rebuilding demand for its preservation services, future revenues can be expected to remain significantly below historical levels prior to the issuance of the FDA Order. As discussed in Note 2 to the Summary Consolidated Financial Statements, the outcome of the discussions with the FDA regarding the use of the SynerGraft process on human tissue could result in a reduction in SynerGraft processed cardiovascular and vascular tissue which would reduce revenue and the gross margins with respect to cardiovascular and vascular tissues.

BIOGLUE SURGICAL ADHESIVE

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	Three Months Ended June 30,		Six Months June
	2003	2002	2003
Revenues as reported	\$ 6,839	\$ 5,251	\$ 13,333
BioGlue revenues as reported as a percentage of total revenue as reported	44%	23%	42%
BioGlue revenues as reported as a percentage of total adjusted revenues(a)	44%	20%	43%

Revenues as reported from the sale of BioGlue Surgical Adhesive increased 30% and 32%, respectively, for the three and six months ended June 30, 2003 as compared to the three and six months ended June 30, 2002. The 30% increase in revenues as reported for the three months ended June 30, 2003 was primarily due to an increase in BioGlue sales volume due to an increase in demand in both foreign and domestic markets which increased revenues by 28%, and by an increase in average selling prices which increased revenues by 2%. The 32% increase in revenues as reported for the six months ended June 30, 2003 was due to an increase in BioGlue sales volume due to an increase in demand in both foreign and domestic markets which increased revenues by 26%, and by an increase in average selling prices which increased revenues by 6%. Volume increases in both the three and six months ended June 30, 2003 were lead by increases in the BioGlue 2ml and 5ml product sizes. Domestic revenues accounted for 77% and 78% of total BioGlue revenues for the three and six months ended June 30, 2003, respectively, and 77% and 79% of total BioGlue revenues for the three and six months ended June 30, 2002, respectively.

There is a possibility that the Company's BioGlue manufacturing operations could come under increased scrutiny from the FDA as a result of their review of the Company's tissue processing laboratories.

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CARDIOVASCULAR PRESERVATION SERVICES

	Three Months Ended June 30,		Six Months June
	2003	2002	2003
Revenues as reported	\$ 5,036	\$ 7,336	\$ 9,761
Estimated tissue recall returns	--	340	--
Adjustment to estimated tissue recall returns	--	--	(92)
Adjusted revenues(a)	\$ 5,036	\$ 7,676	\$ 9,669
Cardiovascular revenues as reported as a percentage of total revenue as reported	32%	32%	31%



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Cardiovascular adjusted revenues as a percentage of total adjusted revenues(a)	32%	30%	31%
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Revenues as reported from cardiovascular preservation services decreased 31% and 33%, respectively, for the three and six months ended June 30, 2003 as compared to the three and six months ended June 30, 2002. Cardiovascular revenues as reported for the six months ended June 30, 2003 include \$92,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated. Cardiovascular revenues as reported for the three and six months ended June 30, 2002 were adversely affected by the estimated effect of the tissues returned subject to the FDA Order on service revenues for non-valved cardiac tissues, which resulted in an estimated decrease of \$340,000 in service revenues during the three and six months ended June 30, 2002.

Adjusted revenues from cardiovascular preservation services decreased 34% and 35%, respectively, for the three and six months ended June 30, 2003 as compared to the three and six months ended June 30, 2002. The 34% decrease in adjusted revenues for the three months ended June 30, 2003 was due to a decrease in cardiovascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, the FDA public health web notification, and reported tissue infections, and the restrictions on shipments of certain non-valved cardiac tissues subject to the FDA Order which reduced revenues by 42%, partially offset by an increase in average service fees which increased revenues by 8%. The 35% decrease in adjusted revenues for the six months ended June 30, 2003 was due to a decrease in cardiovascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, the FDA public health web notification, and reported tissue infections, and the restrictions on shipments of certain non-valved cardiac tissues subject to the FDA Order which reduced revenues by 42%, partially offset by an increase in average service fees which increased revenues by 7%. The increase in average service fees for the three and six months ended June 30, 2003 was due to a higher percentage of heart valve shipments, which were not subject to the FDA Order, than non-valved cardiac tissue shipments and due to a higher percentage of tissue shipments of valves treated with the SynerGraft process than traditional processing when compared to the corresponding prior year periods.

As a result of the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, the Company's procurement of cardiac tissues during the three and six months ended June 30, 2003, from which heart valves and non-valved cardiac tissues are processed, decreased 20% and 24%, respectively, as compared to the three and six months ended June 30, 2002. The Company's second quarter 2003 procurement of cardiac tissues increased 12% from the first quarter of 2003.

The Company believes that cardiovascular revenues in the third quarter of 2003 will approach third quarter 2002 levels, but will still show a decrease for the full year 2003 compared to 2002, as a result of the adverse publicity surrounding the FDA Order, FDA Warning Letter, the FDA public health web notification, and certain reported tissue infections. On June 27, 2003 the FDA modified its public health web notification on the Company by labeling it "archived document - no longer current information - not for official use." This action may assist the Company in rebuilding demand for its cardiovascular tissues. If the Company is unable to rebuild demand for its preservation services for these tissues, future cardiac preservation revenue could continue to decrease. The Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue, and as such, revenues and gross margins will be adversely affected in the third and fourth quarters of 2003 until FDA approval can be obtained to begin using the SynerGraft process again.

## VASCULAR PRESERVATION SERVICES

	Three Months Ended June 30,		Six Months June
	2003	2002	2003
Revenues as reported	\$ 3,299	\$ 4,641	\$ 7,554
Estimated tissue recall returns	--	1,713	--
Adjustment to estimated tissue recall returns	--	--	(711)
Adjusted revenues (a)	\$ 3,299	\$ 6,354	\$ 6,843
Vascular revenues as reported as a percentage of total revenue as reported	21%	20%	24%
Vascular adjusted revenues as a percentage of total adjusted revenues (a)	21%	25%	22%

Revenues as reported from vascular preservation services decreased 29% and 35%, respectively, for the three and six months ended June 30, 2003 as compared to the three and six months ended June 30, 2002. Vascular revenues as reported for the six months ended June 30, 2003 include \$711,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated. Vascular revenues as reported for the three and six months ended June 30, 2002 were adversely affected by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of \$1.7 million in service revenues.

Adjusted revenues from vascular preservation services decreased 48% and 49%, respectively, for the three and six months ended June 30, 2003 as compared to the three and six months ended June 30, 2002. The 48% decrease in adjusted revenues for the three months ended June 30, 2003 was due to a decrease in vascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, and the restrictions on shipments of certain vascular tissues subject to the FDA Order which reduced revenues by 49%, partially offset by an increase in average service fees, which increased revenues by 1%. The 49% decrease in adjusted revenues for the six months ended June 30, 2003 was due to a decrease in vascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, and the restrictions on shipments of certain vascular tissues subject to the FDA Order which reduced revenues by 46% and by a decrease in average service fees which reduced revenues by 3%.

During the first quarter of 2003 the Company limited its vascular procurement until it addressed the observations detailed in the April 2002 483, most of which were addressed in the first quarter of 2003, and due to resource constraints as a result of the September 2002 employee force reduction. The

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Company continued to limit its vascular procurement in the second quarter of 2003 and will continue to limit its vascular procurement until it can fully evaluate the demand for its vascular tissues. The Company's procurement of vascular tissue for the three and six months ended June 30, 2003 decreased 50% and 57%, respectively, as compared to the three and six months ended June 30, 2002. The Company's second quarter 2003 procurement of vascular tissues increased 53% from first quarter of 2003. The Company expects that vascular procurement will continue to increase during 2003.

The Company believes that vascular revenues in the third quarter of 2003 will exceed third quarter 2002 levels, but will still show a decrease for the full year 2003 compared to 2002, as a result of the adverse publicity surrounding the FDA Order, FDA Warning Letter, and certain reported tissue infections. If the Company is unable to rebuild demand for its preservation services for these tissues, future vascular preservation revenue could continue to decrease.

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### ORTHOPAEDIC PRESERVATION SERVICES

	Three Months Ended June 30,		Six Mont June
	2003	2002	2003
Revenues as reported	\$ 280	\$ 5,559	\$ 430
Estimated tissue recall returns	--	380	--
Adjustment to estimated tissue recall returns	--	--	(45)
Adjusted revenues(a)	\$ 280	\$ 5,939	\$ 385
Orthopaedic revenues as reported as a percentage of total revenue as reported	2%	24%	1%
Orthopaedic adjusted revenues as a percentage of total adjusted revenues(a)	2%	23%	1%

Revenues as reported from orthopaedic preservation services decreased 95% and 96%, respectively, for the three and six months ended June 30, 2003 as compared to the three and six months ended June 30, 2002. Orthopaedic revenues as reported for the six months ended June 30, 2003 include \$45,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated. Orthopaedic revenues as reported for the three and six months ended June 30, 2002 were adversely affected by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of \$380,000 in service revenues.

Adjusted revenues from orthopaedic preservation services decreased 95% and 97%, respectively, for the three and six months ended June 30, 2003 as compared to

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the three and six months ended June 30, 2002. The 95% decrease in adjusted revenues for the three months ended June 30, 2003 was due to a decrease in orthopaedic volume primarily resulting from the restrictions on shipments of certain orthopaedic tissues subject to the FDA Order, cessation of processing of orthopaedic tissue until late February 2003, and a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, which reduced revenues by 94% and a decrease in orthopaedic average service fees which reduced revenues by 1%. The 97% decrease in adjusted revenues for the six months ended June 30, 2003 was due to a decrease in orthopaedic volume primarily due to the restrictions on shipments of certain orthopaedic tissues subject to the FDA Order, cessation of processing of orthopaedic tissue until late February 2003, and a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, which reduced revenues by 96% and a decrease in orthopaedic average service fees which reduced revenues by 1%.

The Company resumed limited processing of orthopaedic tissues in late February 2003 following the FDA inspection of the Company's operations as discussed in Note 2 to the Summary Consolidated Financial Statements, and during the quarter ended June 30, 2003 the Company began shipments of the non-boned orthopaedic tissues processed. The Company resumed shipment of boned orthopaedic tissues processed since February 2003 in early August 2003. The majority of orthopaedic revenues for the three months ended June 30, 2003 have been from shipments of orthopaedic tissues that were processed since February 2003. The Company's procurement of whole and partial knees during the three and six months ended June 30, 2003 was approximately 43% and 26%, respectively, of whole and partial knee procurement levels for the three and six months ended June 30, 2002. The Company's procurement of orthopaedic tendons during the three and six months ended June 30, 2003 was approximately 14% and 8%, respectively, of orthopaedic tendon procurement levels for the three and six months ended June 30, 2002. The Company resumed limited distribution of recently processed orthopaedic tissues in the first quarter of 2003.

The Company believes that orthopaedic revenues will continue to increase slowly during the third and fourth quarters of 2003, but will still show a significant decrease for the third quarter of 2003 as compared to the third quarter of 2002 as well as for the full year 2003 compared to 2002, due to the Company's inability to ship orthopaedic grafts processed between October 3, 2001 and September 5, 2002 pursuant to the FDA Order, the adverse publicity resulting

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from the FDA Order, FDA Warning Letter, and the reported infections in some orthopaedic allograft recipients. If the Company is unable to rebuild demand for its preservation services for orthopaedic tissues, future orthopaedic preservation revenue may be minimal.

### IMPLANTABLE MEDICAL DEVICES

Revenues from implantable medical devices decreased 58% to \$93,000 for the three months ended June 30, 2003 from \$222,000 for the three months ended June 30, 2002, representing 1% of total revenues as reported during such periods. Revenues from implantable medical devices decreased 52% to \$198,000 for the six months ended June 30, 2003 from \$414,000 for the six months ended June 30, 2002, representing 1% of total revenues as reported during such periods.

### DISTRIBUTION AND GRANT REVENUES

Grant revenues increased to \$166,000 and \$357,000, respectively, for the three and six months ended June 30, 2003 from \$104,000 and \$131,000 for the three and

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six months ended June 30, 2002. Grant revenues in 2003 and 2002 were attributable to the Activation Control Technology ("ACT") research and development programs through AuraZyme Pharmaceuticals, Inc. ("AuraZyme") and the SynerGraft research and development programs. In February 2001 the Company formed the wholly owned subsidiary AuraZyme to foster the commercial development of ACT, a reversible linker technology that has potential uses in the areas of cancer therapy, fibrinolysis (blood clot dissolving), and other drug delivery applications.

Distribution revenues decreased to zero for the three and six months ended June 30, 2003 from \$151,000 and \$292,000, respectively, for the three and six months ended June 30, 2002. Distribution revenues consisted of commissions received for the distribution of orthopaedic tissues for another processor. The Company does not currently anticipate receiving distribution revenues from any third party processors in 2003.

### COST OF HUMAN TISSUE PRESERVATION SERVICES

Cost of human tissue preservation services decreased to \$5.2 million and \$7.6 million, respectively, for the three and six months ended June 30, 2003 as compared to \$17.2 million and \$25.3 million, respectively, for the three and six months ended June 30, 2002. Cost of human tissue preservation services as a percentage of revenues as reported is 60% and 43%, respectively, for the three and six months ended June 30, 2003 as compared to 98% and 67%, respectively, for the three and six months ended June 30, 2002. Cost of human tissue preservation services for the three and six months ended June 30, 2003 includes an increase to cost of preservation services to adjust the value of certain deferred tissue preservation costs that exceeded market value of \$1.1 million and \$1.4 million, respectively, and the favorable effect of shipments of tissue with a zero cost basis due to write-downs of deferred preservation costs in the second and third quarter of 2002 of \$1.0 million and \$3.4 million, respectively. Cost of human tissue preservation services for the three and six months ended June 30, 2002 includes a \$10.0 million write-down of deferred preservation costs for tissues subject to the FDA Order, offset by a \$1.1 million decrease in cost of preservation services due to the estimated tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the \$10.0 million write-down). Factors that negatively impacted cost of human tissue preservation services were higher overhead cost allocations associated with the decreased volume of tissues processed and changes in processing methods resulting from the FDA Order.

The Company anticipates cost of human tissue preservation services will increase quarter over quarter during the third and fourth quarters of 2003 as compared to 2002, but will still show a significant decrease for the full year 2003 compared to 2002, due to the deferred preservation cost write-downs in the second and third quarters of 2002 as discussed in Note 2 to the Summary Consolidated Financial Statements. The cost of human tissue preservation services as a percent of revenue will continue to be high compared to pre-FDA Order levels as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue. The cost of human tissue preservation services may be minimally favorably affected, depending on the future level of tissue shipments related to previously written-down deferred preservation costs, because the write-down creates a new cost basis, which cannot be written back up if these tissues are shipped or become available for shipment. The shipment levels of these written-down tissues will be affected by the amount and timing of the release of tissues processed after September 5, 2002, pursuant to the Agreement with the FDA, since written-down tissues may

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only be shipped if tissues processed after the Agreement are not available for shipment. Additionally, the Company believes that once the issues with the FDA are resolved, cost of human tissue preservation as a percentage of revenues will decrease as compared to current levels.

### COST OF PRODUCTS

Cost of products aggregated \$2.0 million for the three months ended June 30, 2003 compared to \$1.8 million for the three months ended June 30, 2002, representing 29% and 34%, respectively, of total product revenues as reported during such periods. The increase in cost of products for the three months ended June 30, 2003 is primarily due to an increase in shipments of BioGlue, partially offset by a decrease in the costs related to bioprosthetic products. Cost of products aggregated \$3.6 million for the six months ended June 30, 2003 compared to \$4.1 million for the six months ended June 30, 2002, representing 27% and 39%, respectively, of total product revenues as reported during such periods. The decrease in cost of products for the six months ended June 30, 2003 is primarily due to a large decrease in the costs related to bioprosthetic products in the first quarter of 2003 as compared to 2002 due to lower sales and production levels for these products, partially offset by an increase in BioGlue shipments. The decrease in cost of products as a percentage of total product revenues as reported for the three and six months ended June 30, 2003 is primarily due to a favorable product mix that was affected by the increase in revenues from BioGlue Surgical Adhesive, which carries higher gross margins than bioprosthetic devices.

### GENERAL, ADMINISTRATIVE, AND MARKETING EXPENSES

General, administrative, and marketing expenses increased 106% to \$23.5 million for the three months ended June 30, 2003, compared to \$11.4 million for the three months ended June 30, 2002, representing 150% and 49%, respectively, of total revenues during such periods. General, administrative, and marketing expenses increased 68% to \$35.1 million for the six months ended June 30, 2003, compared to \$20.9 million for the six months ended June 30, 2002, representing 111% and 43%, respectively, of total revenues during such periods. The increase in expenditures for the three and six months ended June 30, 2003 was primarily due to an accrual of \$9.0 million for the estimated expense to resolve ongoing product liability claims in excess of insurance coverage, \$3.9 million for estimated unreported product liability claims related to services performed and products sold prior to June 30, 2003, and \$150,000 for required insurance retention payments for the Company's product liability insurance policies related to prior policy years, partially offset by a \$575,000 reversal of previous retention accruals for which the Company has already fulfilled its payment obligations. (See Legal Proceedings at Part II Item 1 for further discussion of these items.) Additional increases in costs for the three and six month periods ending June 30, 2003 were due to an increase of approximately \$1.3 million and \$3.3 million, respectively, in professional fees (legal, consulting, and accounting) due to increased litigation, litigation settlement costs, and issues surrounding the FDA Order, and an increase of approximately \$179,000 and \$488,000, respectively, in insurance premiums.

The Company expects to continue to incur significant legal costs and professional fees to defend and resolve the lawsuits filed against the Company and to address FDA compliance requirements.

### RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses decreased 9% to \$1.1 million for the three months ended June 30, 2003, compared to \$1.2 million for the six months ended June 30, 2002, representing 7% and 5%, respectively, of total revenues during such periods. Research and development expenses decreased 15% to \$2.0 million for the six months ended June 30, 2003, compared to \$2.3 million for the six

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months ended June 30, 2002, representing 6% and 5%, respectively, of total revenues as reported during such periods. Research and development spending in 2003 was primarily focused on the Company's core tissue cryopreservation, SynerGraft, and Protein Hydrogel Technologies. Research and development spending in 2002 was primarily focused on the Company's SynerGraft and Protein Hydrogel Technologies.

### OTHER COSTS AND EXPENSES

Interest expense, net of interest income, was \$31,000 and \$32,000 for the three and six months ended June 30, 2003, as compared to \$43,000 and \$149,000, respectively, of interest income, net of interest expense, for the three and six months ended June 30, 2002. The decrease in net interest income for the three and six months ended June 30, 2003 was due to reduced investments earning

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interest in 2003 as compared to 2002, lower investment interest rates in 2003, and additional interest payments due to the financing of 2003 insurance premiums, partially offset by a reduction in the principal debt amount outstanding due to scheduled principal payments. Interest expense for the six months ended June 30, 2002 was unfavorably affected by interest from the convertible debenture early in 2002 before its conversion into common stock in March of 2002.

Other expense was \$166,000 and \$140,000 for the three and six months ended June 30, 2003 as compared to other income of \$16,000 and \$72,000 for the three and six months ended June 30, 2002. The increase in other expense was primarily due to an expense of \$222,000 to reclass the unamortized portion of the other comprehensive loss on the Company's interest rate swap to other expense/income (discussed in the Interest Rate Swap Agreements section below).

The Company's income tax expense of \$3.6 million for the three months ended June 30, 2003 was primarily due to the establishment of an additional valuation allowance against the Company's deferred tax assets of \$9.0 million, partially offset by the current quarter income tax benefit of \$5.4 million, recorded at an effective income tax rate of 33%. The Company's income tax expense of \$3.4 million for the six months ended June 30, 2003 was primarily due to the expense related to the establishment of a valuation allowance against the Company's deferred tax assets of \$9.0 million, partially offset by an income tax benefit of \$5.6 million, recorded at an effective income tax rate of 33%. The effective income tax rate was 34% for the three and six months ended June 30, 2002.

### SEASONALITY

The demand for the Company's cardiovascular tissue preservation services is seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiovascular tissue preservation services is primarily due to the high number of surgeries scheduled during the summer months. However, the demand for the Company's human vascular and orthopaedic tissue preservation services, BioGlue Surgical Adhesive, and bioprosthetic cardiovascular and vascular devices does not appear to experience seasonal trends.

### LIQUIDITY AND CAPITAL RESOURCES

#### OVERALL TREND IN LIQUIDITY AND CAPITAL RESOURCES

The Company expects its liquidity to continue to decrease significantly over the

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next twelve months due to 1) the anticipated decrease in preservation revenues as compared to preservation revenues prior to the FDA Order as a result of reported tissue infections, the FDA Order, and associated adverse publicity, 2) the increase in cost of human tissue preservation services as a percent of revenue as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and 3) an expected use of cash due to the increased costs relating to the defense and resolution of lawsuits (discussed in Note 13 to the Summary Consolidated Financial Statements) and legal and professional costs relating to the ongoing FDA compliance and the anticipated required Term Loan pay off during 2003 (discussed in Note 6 to the Summary Consolidated Financial Statements). The Company believes that anticipated revenue generation, expense management, tax refunds of approximately \$2.4 million resulting from tax loss carrybacks, savings resulting from the reduction in the number of employees in September 2002 necessitated by the reduction in revenues, and the Company's existing cash and marketable securities will enable the Company to meet its liquidity needs through at least June 30, 2004. In addition, as discussed in Note 13, the Company has recorded \$9.0 million related to the potential expense of resolving current product liability claims in excess of insurance coverage. The \$9.0 million accrual is reflective of settlement costs related to outstanding lawsuits, and does not reflect actual settlement arrangements or judgments, including punitive damages, which may be assessed by the courts. The \$9.0 million accrual is not a cash reserve. Should expenses related to the accrual be incurred, the expenses would have to be paid from insurance proceeds and liquid assets, if available. The Company has called a meeting with the plaintiffs' attorneys to determine the feasibility of obtaining a global settlement on outstanding claims in order to substantially reduce the potential cash payout related to these accruals and is currently evaluating all of its alternatives in connection with resolving the dispute with its upper layer excess carrier concerning the restrictions on the matters it has excluded from coverage. If the Company is unsuccessful in arranging settlements of product liability claims for an amount substantially below the amount accrued, there may not be sufficient insurance coverage and liquid assets to meet these obligations, even if the

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Company satisfactorily resolves the restrictions on the upper layer excess insurance coverage. However, if the Company is unable to settle the outstanding claims for amounts within its ability to pay and one or more of the product liability lawsuits in which the Company is a defendant should be tried during this period with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. The Company's product liability insurance policies do not include coverage for any punitive damages that may be assessed at trial. There is a possibility that significant punitive damages could be assessed in one or more lawsuits which would have to be paid out of the liquid assets of the Company, if available.

In addition, as discussed in Note 13, the Company has recorded \$7.5 million for estimated costs of unreported product liability claims related to services performed and products sold prior to June 30, 2003. The \$7.5 million accrual is not a cash reserve. The timing of the actual payment of the expense related to the accrual is dependent on when and if claims are asserted. Should expenses related to the accrual be incurred, the expenses would have to be paid from insurance proceeds and liquid assets, if available. Since amounts expensed are estimates, the actual amounts required could vary significantly.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including the Company's ability to return to the level of demand for its tissue services that existed prior to the FDA Order, the outcome



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of litigation against the Company (discussed in Note 13), the timing of and amount required to resolve the product liability claims (discussed in Note 13), the resolution of the dispute with its upper excess product liability insurance carrier (discussed in Note 13), the ability to arrange and fund a global settlement of outstanding claims for an amount substantially below the amount of the accrual (discussed in Note 13), and the Company's ability to find suitable funding sources to replace the Term Loan (discussed in Note 6). The Company 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 June 30, 2004. 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 are factors that indicate that the Company may be unable to continue operations.

On August 4, 2003 the Company approved a buyback of employee stock options with an exercise price of \$23 or greater. The option buyback was approved for an aggregate of up to \$350,000 using a Black Scholes valuation model. The Company anticipates making the offer to employees in third quarter of 2003.

NEITHER THE ABOVE STATEMENT NOR THIS QUARTERLY REPORT ON FORM 10-Q IS AN OFFER TO PURCHASE, OR A SOLICITATION OF AN OFFER TO SELL, OPTIONS TO PURCHASE SHARES OF COMMON STOCK OF CRYOLIFE, INC. SUCH AN OFFER WILL BE MADE ONLY BY AN "OFFER TO PURCHASE OPTIONS" AND RELATED "LETTER OF TRANSMITTAL" TO BE DISSEMINATED TO OPTIONHOLDERS AT A LATER DATE. OPTIONHOLDERS INVITED TO PARTICIPATE IN THE BUYBACK DESCRIBED IN THE ABOVE STATEMENT SHOULD READ THESE DOCUMENTS, AS WELL AS CRYOLIFE'S TENDER OFFER STATEMENT ON SCHEDULE TO, WHEN THEY ARE AVAILABLE BECAUSE THEY CONTAIN IMPORTANT INFORMATION. THESE AND OTHER FILED DOCUMENTS WILL BE AVAILABLE FOR FREE FROM THE SEC'S WEBSITE AT WWW.SEC.GOV AND CRYOLIFE. THE OFFER WILL NOT BE MADE TO, NOR WILL TENDERS BE ACCEPTED FROM OR ON BEHALF OF, OPTIONHOLDERS IN ANY JURISDICTION IN WHICH MAKING OR ACCEPTING THE OFFER WOULD VIOLATE THAT JURISDICTION'S LAWS.

### NET WORKING CAPITAL

At June 30, 2003 net working capital (current assets of \$55.1 million less current liabilities of \$31.8 million) was \$23.3 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$37.6 million, with a current ratio of 3 to 1 at December 31, 2002. The Company's primary capital requirements historically arose from general working capital needs, capital expenditures for facilities and equipment, and funding of research and development projects. The Company has historically funded these requirements through bank credit facilities, cash generated by operations, and equity offerings. Based on the decrease in revenues resulting from the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, and the anticipated costs to be paid by the Company in resolving pending litigation, the Company expects that its cash used in operating activities will continue to be high and will increase to the extent

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funds are needed to defend and resolve litigation, and that net working capital will significantly decrease.

### NET CASH FROM OPERATING ACTIVITIES

Net cash provided by operating activities was \$3.0 million and \$750,000 for the six months ended June 30, 2003 and 2002, respectively. Current year net cash provided of \$3.0 million is primarily due to the receipt of \$11.4 million in federal income tax returns through a carry back of operating losses and

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write-downs of deferred preservation costs and estimated tax payments for 2002, partially offset by the year to date net loss excluding the effect of non-cash items. The non-cash items which favorably affect the net loss for the six months ended June 30, 2003 include an increase in accounts payable, accrued expenses, and current liabilities of \$10.9 million, largely due to accruals of legal fees and settlement costs expected to be paid out in future periods as discussed in the Results of Operations section above, valuation on deferred tax assets net of current year deferred tax benefit of \$4.4 million, depreciation and amortization of \$2.8 million, write-down of deferred preservation costs of \$1.4 million and provision for doubtful accounts of \$48,000. These favorable non-cash items are partially offset by a \$6.6 million increase in deferred preservation costs.

### NET CASH FROM INVESTING ACTIVITIES

Net cash provided by investing activities was \$4.5 million and \$4.1 million in the six months ended June 30, 2003, and June 30, 2002, respectively. The \$4.5 million in current year net cash provided was primarily due to \$4.7 million in cash from sales and maturities of marketable debt securities, partially offset by \$333,000 in capital expenditures.

### NET CASH FROM FINANCING ACTIVITIES

Net cash used in financing activities was \$1.6 million and \$1,000 in the six months ended June 30, 2003 and 2002, respectively. The \$1.6 million in current year net cash used was primarily due to \$827,000 in principal payments on short term notes payable for the financing of insurance premiums, \$800,000 in principal payments on the Term Loan and \$320,000 in payments on capital leases, partially offset by a \$325,000 increase in cash due to proceeds from the issuance of stock in connection with the exercise of stock options and the Company's employee stock purchase plan.

### SCHEDULED CONTRACTUAL OBLIGATIONS AND FUTURE PAYMENTS

Scheduled contractual obligations and the related future payments subsequent to June 30, 2003 are as follows (in thousands):

	Total	Remainder of 2003	2004	2005
	-----	-----	-----	-----
Debt	\$ 4,800	\$ 4,800	\$ --	\$ --
Note Payable	1,634	1,362	272	--
Capital Lease Obligations	3,215	421	843	843
Operating Leases	26,096	1,111	2,115	2,091
Purchase Commitments	635	235	400	--
	-----	-----	-----	-----
Total Contractual Obligations	\$ 36,380	\$ 7,929	\$ 3,630	\$ 2,934
	=====	=====	=====	=====

The Company's Term Loan, of which the principal balance was \$4.5 million as of August 4, 2003, contains certain restrictive covenants including, but not limited to, maintenance of certain financial ratios and a minimum tangible net worth requirement, and the requirement that no materially adverse event has occurred. The lender has notified the Company that the FDA Order, as described in Note 2 to the Summary Consolidated Financial Statements, and the SEC's investigation of the Company, as described in Note 13, have had a material adverse effect on the Company that constitutes an event of default. Additionally, as of June 30, 2003, the Company is in violation of the debt

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coverage ratio and net worth financial covenants. Therefore, all amounts due under the Term Loan as of June 30, 2003 are reflected as a current liability on the Summary Consolidated Balance Sheets. The Company and the lender are currently in the process of negotiating specific terms of a forbearance agreement, which, if entered into, would increase the interest rate charged on the Term Loan effective August 1, 2003 to LIBOR plus 4% (5.32% at June 30,

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2003), accelerate the principal payments on the Term Loan by requiring a balloon payment to pay off the outstanding balance by October 31, 2003, and cause the Company to pay a \$12,000 modification fee and the lender's attorneys costs, which have yet to be determined. As of August 4, 2003 the Company has sufficient cash and cash equivalents to pay the remaining outstanding balance of the Term Loan. Since the lender is in the process of accelerating the payment of the debt, the above chart shows payment of the outstanding balance of the Term Loan during 2003.

In the quarter ended June 30, 2003 the Company entered into two agreements to finance \$2.9 million in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. The amount financed accrues interest at a 3.75% rate and is payable in equal monthly payments through January 2004. As of August 4, 2003 the outstanding balance of the agreements was \$1.3 million.

Due to cross default provisions included in the Company's debt agreements, as of June 30, 2003 the Company was in default of certain capital lease agreements maintained with the lender of the Term Loan. Therefore, all amounts due under these capital leases are reflected as a current liability on the Summary Consolidated Balance Sheets as of June 30, 2003.

### INTEREST RATE SWAP AGREEMENT

The Company's Term Loan, which currently accrues interest computed at Adjusted LIBOR plus 1.5%, exposes the Company to changes in interest rates going forward. On March 16, 2000, the Company entered into a \$4 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and expires in 2006. This swap agreement was designated as a cash flow hedge to effectively convert a portion of the Term Loan balance to a fixed rate basis, thus reducing the impact of interest rate changes on future income. This agreement involves the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement, without an exchange of the underlying principal amounts. The differential to be paid or received is recognized in the period in which it accrues as an adjustment to interest expense on the Term Loan.

On January 1, 2001 the Company adopted SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") as amended. SFAS 133 requires the Company to recognize all derivative instruments on the balance sheet at fair value, and changes in the derivative's fair value must be recognized currently in earnings or other comprehensive income, as applicable. The adoption of SFAS 133 impacts the accounting for the Company's forward-starting interest rate swap agreement. Upon adoption of SFAS 133, the Company recorded an unrealized loss of approximately \$175,000 related to the interest rate swap, which was recorded as part of long-term liabilities and accumulated other comprehensive income as the cumulative effect of adopting SFAS 133 within the Statement of Shareholders' Equity.

In August 2002 the Company determined that changes in the derivative's fair value could no longer be recorded in other comprehensive income, as a result of

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the uncertainty of future cash payments on the Term Loan caused by the lender's ability to declare an event of default as discussed in Note 6 to the Summary Consolidated Financial Statements. Beginning in August 2002 the Company started recording all changes in the fair value of the derivative currently in other expense/income on the Summary Consolidated Statements of Operations, and amortizing the amounts previously recorded in other comprehensive income into other expense/income over the remaining life of the agreement.

During the quarter ended June 30, 2003 the Company became aware of the lender's intention to accelerate the payment of the Term Loan, as discussed in Note 6. Therefore, the Company recorded an expense of \$222,000, to reclass the unamortized portion of the other comprehensive loss to other expense/income on the Summary Consolidated Statements of Operations. The Company and the lender are currently in the process of negotiating the specific terms of a forbearance agreement, which, if entered into, is expected to require the Company to pay the lender by October 31, 2003 an amount equal to the fair value of the swap agreement. For the three and six months ended June 30, 2003 the Company recorded a total expense of \$216,000 and \$207,000, respectively, on the interest rate swap.

As of June 30, 2003 the notional amount of this swap agreement was \$2.4 million, and the fair value of the interest rate swap agreement, as estimated by the bank based on its internal valuation models, was a liability of \$227,000. The fair

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value of the swap agreement is recorded as part of short-term liabilities. The unamortized value of the swap agreement, recorded in the accumulated other comprehensive income account of shareholders' equity, was zero at June 30, 2003.

### STOCK REPURCHASE

On July 23, 2002 the Company's Board of Directors authorized the purchase of up to \$10 million of its common stock. As of August 13, 2002 the Company had repurchased 68,000 shares of its common stock for \$663,000. No further purchases are anticipated in the near term.

### CAPITAL EXPENDITURES

The Company expects that its full year capital expenditures in 2003, which were \$333,000 through June 30, 2003, will be less than its expenditures in 2002, which were approximately \$4.1 million. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to resume normal operating levels once it has fully evaluated the demand for its tissues and resumed distribution of orthopaedic tissues. The Company does not currently anticipate any major purchase of equipment as a result of the April 2002 and February 2003 FDA inspections.

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### FORWARD-LOOKING STATEMENTS

This Form 10-Q/A contains forward-looking statements and information made or provided by the Company that are based on the beliefs of its management as well

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as estimates and assumptions made by and information currently available to management. The words "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future" and other similar expressions generally identify forward-looking statements, including, in particular, statements regarding anticipated revenues, cost savings, insurance coverage, 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. Readers are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates.

Some of the forward-looking statements contained in this Form 10-Q/A include those regarding:

- o Expected increases in tissue processing revenues;
- o The impact of recent accounting pronouncements;
- o The adequacy of insurance coverage;
- o The outcome of lawsuits filed against the Company;
- o The impact of the FDA Order, related Agreements, reported tissue infections, and the related adverse publicity on future revenues, profits and business operations, future tissue procurement levels, and the estimates underlying the related charges recorded in the second and third quarter;
- o Future costs of human tissue preservation services;
- o The impact of the February 2003 FDA 483 and of the FDA letter regarding SynerGraft processed cardiovascular and vascular tissues;
- o The estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies;
- o The estimates of the amounts accrued for product liability claims;
- o The amount and timing of tax refunds the Company expects to receive;
- o The adequacy of current financing arrangements through June 30, 2004, product demand, and market growth; and
- o Expectations regarding an offer to repurchase certain options from employees.

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 without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risks set forth under "Risk Factors" in Part I, Item 1 of the Company's Form 10-K for the year ended December 31, 2002 and other factors, many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q/A 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.

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### RISKS AND UNCERTAINTIES

The risks and uncertainties which might impact the forward-looking statements and the Company include concerns that:

- o The impact of the FDA Order, the FDA Warning Letter, reported tissue infections, and the resulting adverse publicity on CryoLife's business, liquidity, and capital resources has been and may continue to be material;
- o The Company may not have sufficient borrowing or other capital available to fund its business over the long-term;
- o Present and future litigation is expected to be resolved only by substantial payments by the Company in excess of available insurance coverage;
- o The outcomes of product liability, securities class action, and derivative cases are inherently uncertain, which makes predicting liability difficult;
- o Pending litigation may not be settled on terms acceptable to the Company;
- o The Company may not have sufficient resources to pay damage awards in lawsuits against it to the extent that they exceed or are not covered by insurance;
- o Damage awards may include punitive damages, which are not covered by insurance;
- o Due to the possibility of severe decreases in the Company's revenues and working capital, and to the extent the Company does not have sufficient resources to pay the existing and future claims against it, it may be forced to cease operations or to obtain protection under applicable bankruptcy or insolvency laws;
- o The Company may not be able to obtain sufficient cardiovascular, vascular, and orthopaedic tissue to operate profitably;
- o Shipments of orthopaedic tissues are now minimal and demand may not return;
- o Physicians may be reluctant to implant the Company's preserved tissues;
- o Heart valves processed by the Company may also be recalled;
- o Products not included in the FDA Order may come under increased scrutiny;
- o Demand for heart valves processed by the Company has decreased and may decrease further in the future;
- o Adverse publicity may reduce demand for products not affected by the FDA Order;
- o The Company may be unable to address the concerns raised by the FDA in its February 2003 Form 483 Notice of Observations, or the February 2003 letter regarding the use of SynerGraft technology to process human tissue;
- o Regulatory action outside of the U.S. may also affect the Company's business;
- o The Company may not receive all or a portion of the expected income tax refunds when expected;
- o The Company is the subject of a formal SEC investigation;
- o As a result of the FDA Order and resulting financial impact, CryoLife's lender has notified it that it is in default of certain provisions of the Company's credit facility, resulting in cross defaults under CryoLife's leases on various equipment;
- o The Company's insurance coverage is expected to be insufficient to cover judgments under existing or future claims;
- o 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;

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- o Intense competition may affect the Company's ability to recover from the FDA Order and develop its surgical adhesive business;
- o Extensive government regulation may delay the Company's ability to develop and sell products and services;
- o Uncertainties regarding future health care reimbursement may affect the amount and timing of the Company's revenues; and
- o Depending upon market and other conditions, the Company may not make an offer to repurchase employee options during the third quarter as currently anticipated, or ever.

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### Item 4. Controls and Procedures.

The Company's management, including the Company's President and Chief Executive Officer ("CEO") along with the Company's Vice President of Finance, Treasurer, and Chief Financial Officer ("CFO"), does not expect that its Disclosure Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake.

In October of 2003 the Company in consultation with its audit firm determined that there were tax loss carrybacks available to the Company that had not previously been identified that should have been accounted for in the quarter ended June 30, 2003. This amendment to the Company's Form 10-Q corrects that error. The Company's audit firm also provides tax return preparation, tax advice and tax planning services.

Based upon the Company's most recent Disclosure Controls evaluation, including an analysis of the reasons underlying the error regarding the tax refund available to the Company in the second quarter, the CEO and CFO have concluded that, as of June 30, 2003, the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized and reported within the time periods specified in the United States Securities and Exchange Commission's rules and forms. The CEO and CFO have determined that no changes in the Company's Disclosure Controls or internal control over financial reporting were required as a result of the error regarding the tax refund available to the Company in the second quarter.

During the quarter ended June 30, 2003, there were no changes in the Company's internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company's internal control over financial reporting.

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Part II - OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K.

(a) The exhibit index can be found below.

Exhibit Number -----	Description -----
3.1	Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to Form 10-Q for the quarter ended March 31, 2003.)
3.2	ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to Form 10-Q for the quarter ended March 31, 2003.)
3.3	Articles of Amendment to the Certificate of Incorporation of the Company. (Incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).

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12.1*	Letter Agreement between the Company and FDA, dated June 13, 2003.
31.1**	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Current Reports on Form 8-K.

The Registrant filed a Current Report on Form 8-K with the Commission on May 1, 2003 with respect to the Press Release dated May 1, 2003 announcing the registrant's results of operations for the first quarter 2003.

The Registrant filed a Current Report on Form 8-K with the Commission on April 3, 2003 with respect to the Press Release regarding the settlement of the Lykins lawsuit.

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\* Previously filed.

\*\* Filed herewith.



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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CRYOLIFE, INC.  
(Registrant)

/s/ STEVEN G. ANDERSON

/s/ DAVID ASHLEY LEE

-----  
STEVEN G. ANDERSON  
Chairman, President, and  
Chief Executive Officer  
(Principal Executive Officer)

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DAVID ASHLEY LEE  
Vice President, Treasurer, and  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)

November 13, 2003

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DATE

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