

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

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2004
Commission File Number 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida
(State or other jurisdiction
of incorporation or organization)

59-2417093
(I.R.S. Employer
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 NO

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

YES NO

The number of shares of common stock, par value \$0.01 per share, outstanding on May 10, 2004 was 23,251,881.

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 March 31,	
	2004	2003
	(Unaudited)	
Revenues:		
Human tissue preservation services	\$ 6,225	\$ 9,130
Products	8,859	6,599
Research grants	2	191
Total revenues	15,086	15,920
Costs and expenses:		
Human tissue preservation services (Including write-down of \$3,650 in 2004 and \$297 in 2003)	9,103	2,443
Products	1,947	1,641
General, administrative, and marketing	10,148	11,592
Research and development	921	917
Interest expense	43	132
Interest income	(66)	(131)
Other expense (income), net	16	(26)
Total costs and expenses	22,112	16,568

Loss before income taxes	(7,026)	(648)
Income tax benefit	--	(214)
Net loss	\$ (7,026)	\$ (434)
Loss per share:		
Basic	\$ (0.32)	\$ (0.02)
Diluted	\$ (0.32)	\$ (0.02)
Weighted average shares outstanding:		
Basic	22,241	19,634
Diluted	22,241	19,634

See accompanying notes to summary consolidated financial statements.

Item 1. Financial Statements

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

	March 31, 2004	December 31, 2003
ASSETS	(Unaudited)	
Current Assets:		
Cash and cash equivalents	\$ 22,149	\$ 5,672
Cash held in escrow	--	972
Marketable securities, at market	3,262	5,272
Trade receivables, net	7,797	6,377
Other receivables, net	3,562	1,865
Deferred preservation costs, net	7,434	8,811
Inventories	4,163	4,450
Prepaid expenses and other assets	1,305	2,344
Total current assets	49,672	35,763
Property and equipment, net	31,733	32,886
Patents, net	4,992	5,244
Other, net	1,120	1,134
TOTAL ASSETS	\$ 87,517	\$ 75,027
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,768	\$ 2,171
Accrued expenses and other current liabilities	11,489	11,570
Accrued compensation	1,403	1,136
Accrued procurement fees	3,298	4,358
Current maturities of capital lease obligations	1,626	1,738
Total current liabilities	20,584	20,973
Capital lease obligations, less current maturities	693	751
Other long-term liabilities	4,999	4,965
Total liabilities	26,276	26,689
Shareholders' Equity:		
Preferred stock	--	--
Common stock (24,600 issued shares in 2004 and 21,130 shares in 2003)	246	211
Additional paid-in capital	94,425	74,460
Retained deficit	(26,534)	(19,508)
Deferred compensation	(6)	(9)
Accumulated other comprehensive income	300	365

Less: Treasury stock at cost (1,372 shares in 2004 and
1,371 shares in 2003)

	(7,190)	(7,181)
Total shareholders' equity	61,241	48,338
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 87,517	\$ 75,027

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)

	Three Months Ended March 31,	
	2004	2003
	(Unaudited)	
Net cash from operating activities:		
Net loss	\$ (7,026)	\$ (434)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,349	1,401
Provision for doubtful accounts	24	24
Write-down of deferred preservation costs	3,650	297
Other non-cash adjustments to income	4	19
Deferred income taxes	--	(342)
Changes in operating assets and liabilities:		
Receivables	(3,180)	1,871
Income taxes	41	--
Deferred preservation costs and inventories	(1,986)	(3,647)
Prepaid expenses and other assets	1,054	725
Accounts payable, accrued expenses, and other liabilities	729	(3,847)
Net cash used in operating activities	(5,341)	(3,933)
Net cash from investing activities:		
Capital expenditures	(119)	(79)
Other assets	182	(2)
Sales and maturities of marketable securities	2,000	1,205
Net cash provided by investing activities	2,063	1,124
Net cash from financing activities:		
Principal payments of debt	--	(400)
Payment of obligations under capital leases	(170)	(159)
Proceeds from private equity offering	19,891	--
Proceeds from exercise of stock options and issuance of common stock	100	136
Net cash provided by (used in) financing activities	19,821	(423)
Increase (decrease) in cash and cash equivalents	16,543	(3,232)
Effect of exchange rate changes on cash	(66)	(147)
Cash and cash equivalents, beginning of period	5,672	10,277
Cash and cash equivalents, end of period	\$ 22,149	\$ 6,898

See accompanying notes to summary consolidated financial statements.

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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 recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. 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, 2003.

The Company expects that its operations will continue to generate negative cash flows throughout the remainder of 2004 due to:

- o The anticipated lower preservation revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activity, and related events (discussed in Note 2),
- o 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, and
- o An expected use of cash related to the defense and resolution of lawsuits (discussed in Note 13).

The Company believes anticipated revenue generation, expense management, tax refunds expected to be approximately \$2.4 million, and the Company’s existing cash, cash equivalents, and marketable securities will enable the Company to meet its liquidity needs through at least March 31, 2005.

The Company’s long term liquidity and capital requirements will depend upon numerous factors, including:

- o The Company’s ability to return to the level of demand for its tissue services that existed prior to the FDA Order,
- o The Company’s ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs,
- o The Company’s spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- o The amount and the timing of the resolution of the remaining outstanding product liability claims (discussed in Note 13), and
- o The outcome of other litigation against the Company (discussed in Note 13).

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 March 31, 2005. 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.

Note 2 – FDA Order on Human Tissue Preservation and Other FDA Correspondence and Notices

FDA Order

On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues 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”). Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order (i.e. processed since October 3, 2001) on quality assurance quarantine and recalled the portion of those tissues that had been distributed but not implanted. In addition, the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues.

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On September 5, 2002 the Company entered into an agreement with the FDA (the “Agreement”) that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to the recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company had completed steps to ensure that the tissue was used for approved purposes and that patients were notified of risks associated with tissue use. The Agreement had a renewable 45-business day term, and the final renewal expired on September 5, 2003. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). A renewal of the Agreement that expired on September 5, 2003 was not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

In addition, pursuant to the Agreement, the Company agreed to perform additional procedures in the processing of non-valved cardiac and vascular tissues and subsequently resumed processing these tissues. 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.

Accounting Treatment

As a result of the FDA Order the Company evaluated multiple factors in determining the magnitude of impairment to deferred preservation costs, including the impact of the FDA Order, the possibility of continuing action by the FDA or other U.S. and foreign government agencies, and the possibility of unfavorable actions by physicians, customers, procurement organizations, and others. As a result of its evaluation in the quarter ended June 30, 2002 the Company recorded a reduction to pretax income of \$12.6 million 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), and a \$1.3 million accrual recorded in general, administrative, and marketing expenses. In the quarter ended September 30, 2002 the Company recorded a reduction to pretax income of \$24.6 million comprised of a net \$22.2 million increase to cost of human tissue preservation services, a \$1.4 million write-down of goodwill, and a \$1.0 million reduction to revenues (and accounts receivable).

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. 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, estimated tax payments for 2002 of \$2.5 million were recorded as a receivable by the Company as of

December 31, 2002 and were received in January 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 accrued restructuring costs of approximately \$690,000, for severance and related costs of the employee force reduction. During the quarter ended March 31, 2003 the Company utilized \$64,000 of the accrued restructuring costs and reversed the remaining accrual of \$46,000 in unused restructuring costs. 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 returns under the FDA Order than were originally estimated in 2002. The adjustment increased cardiac tissue revenues by \$92,000, vascular tissue revenues by \$711,000, and orthopaedic tissue revenues by \$45,000 in the first quarter of 2003. In the quarter ended September 30, 2003 the Company recorded a favorable adjustment of \$52,000 to reverse the remaining unused portion of the estimated tissue recall returns due to lower overall actual tissue returns under the FDA Order than were estimated. Although vascular and orthopaedic returns were lower than expected, cardiac returns were higher than expected. Therefore, the \$52,000 adjustment decreased cardiac tissue revenues by \$7,000 and increased vascular tissue revenues by \$41,000 and orthopaedic tissue revenues by \$18,000 in the third quarter of 2003. Management determined that no additional accruals were necessary for tissue returns under the FDA Order. Therefore, as of September 30, 2003 and in subsequent periods there was no accrual for estimated return of tissues subject to recall by the FDA Order.

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Other FDA Correspondence and Notices

FDA 483 Notices of Observations were issued in connection with the FDA inspections of the Company's facilities in February 2003, October 2003, and February 2004. The Company responded to the February 2003 483 in March 2003, responded to the October 2003 483 in October 2003, November 2003, and April 2004, and responded to the February 2004 483 in March 2004 and April 2004. The Company continues to work with the FDA to review process improvements and address any outstanding observations.

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® SG and that premarket approval marketing authorization should be obtained for the Company's CryoVein® SG when marketed or labeled as an arteriovenous ("A-V") access graft. 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.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On February 4, 2004 the Company received a letter from the FDA requesting that additional information be provided to support the 510(k) premarket notification for the CryoValve SG. The requested information may require that additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed cardiovascular tissue, including the CryoValve SG. The Company is still in discussions with the FDA regarding the type of submissions necessary for the CryoVein SG. The outcome of the discussions and filing with the FDA regarding the use of the SynerGraft process on human tissue, including the CryoValve SG and CryoVein SG, could result in an inability to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted.

The Company voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular and vascular tissue and has suspended the distribution of tissues on hand that have been processed with the SynerGraft technology until the regulatory status of the CryoValve SG and CryoVein SG is resolved. Additionally, the Company 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 treated tissues 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 Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue on hand.

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. 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 classified as held-to-maturity or trading and marketable equity securities not classified as trading are classified as available-for-sale. At March 31, 2004 and December 31, 2003 all marketable 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
March 31, 2004			
Cash equivalents:			
Money market funds	\$ 18,195	\$ --	\$ 18,195
Municipal obligations	775	--	775
	<u>\$ 18,970</u>	<u>\$ --</u>	<u>\$ 18,970</u>

Marketable securities:			
Municipal obligations	\$ 3,144	\$ 118	\$ 3,262
	Cost Basis	Unrealized Holding Gains/(Losses)	Estimated Market Value
December 31, 2003			
Cash equivalents:			
Money market funds	\$ 1,079	\$ --	\$ 1,079
Municipal obligations	775	--	775
	\$ 1,854	\$ --	\$ 1,854
Marketable securities:			
Municipal obligations	\$ 5,148	\$ 124	\$ 5,272

Gross realized gains on sales of available-for-sale securities totaled zero as of March 31, 2004 and \$19,000 as of December 31, 2003. Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of \$40,000 at March 31, 2004 and \$42,000 at December 31, 2003, are included as a separate component of other comprehensive income in shareholders' equity.

At March 31, 2004 and December 31, 2003 approximately zero and \$2.0 million, respectively, of marketable securities had a maturity date of less than 90 days, and approximately \$3.3 million and \$3.3 million, respectively, had a maturity date between 1 and 5 years.

Note 4 — Inventories

Inventories are comprised of the following (in thousands):

	March 31, 2004	December 31, 2003
	(Unaudited)	
Raw materials	\$ 2,642	\$ 2,906
Work-in-process	164	229
Finished goods	1,357	1,315
	\$ 4,163	\$ 4,450

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 beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses, reflecting reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activity, and reported tissue infections. The Company continued to generate deferred tax assets for the three months ended March 31, 2004 primarily as a result of operating losses. 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.

The Company evaluated several factors to determine if a valuation allowance relative to its deferred tax assets was necessary during 2003. The Company reviewed its historic operating results, including the reasons for its operating losses in 2003 and 2002, uncertainties regarding projected future operating results due to the effects of the adverse publicity resulting from the FDA Order, subsequent FDA activity, and reported tissue infections, the changes in processing methods resulting from the FDA Order, and the uncertainty of the outcome of product liability claims. Based on the results of this analysis, the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, during 2003 the Company recorded valuation allowances totaling \$13.7 million due to the effect of temporary differences between book and tax income, the net deferred tax assets generated in 2003, and the net deferred tax asset balance at December 31, 2002. For the three months ended March 31, 2004 the Company did not experience any changes that would materially affect the Company's analysis of and valuation of its deferred tax assets. As of March 31, 2004 the Company had a total of \$16.8 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

As of March 31, 2004, the Company had income tax receivables related to federal income tax losses from the year ended December 31, 2003 that can be carried back to prior years to offset income taxes paid and should result in approximately \$2.4 million in refunds to the Company.

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. 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%. On August 15, 2003 the Company made a voluntary payment of \$4.5 million to pay off the outstanding balance of the Term Loan. The Company also paid approximately \$11,000 to the lender in fees associated with the Term Loan payoff. As of March 31, 2004 the balance of the Term Loan was zero.

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 accrued interest at a 3.75% rate and was payable in equal monthly payments through December 2003. As of March 31, 2004 the outstanding balance of the agreements was zero and there are no available borrowings under this agreement.

Note 7 – Derivatives

The Company's Term Loan, which was paid in full on August 15, 2003, accrued interest computed at Adjusted LIBOR plus 1.5%, and exposed the Company to changes in interest rates. On March 16, 2000 the Company entered into a \$4.0 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and was to expire in 2006. On August 15, 2003 in conjunction with the payoff of the outstanding balance of the Term Loan, the Company paid \$199,000 to terminate the swap agreement. This \$199,000 payment represented the estimated fair value of the interest rate swap, as estimated by the bank based on its internal valuation models, as of the day of the termination of the agreement.

Note 8 – Private Equity Placement

On January 7, 2004 the Company's Board of Directors authorized an agreement with a financial advisory company to sell shares of the Company's common stock in a private investment in public equity transaction (the "PIPE"). The PIPE was consummated on January 27, 2004, and resulted in the sale of approximately 3.4 million shares of stock at a price of \$6.25 per share. The sale generated net proceeds of approximately \$19.9 million, after commissions, registration fees, and other related charges, which will be used for general corporate purposes. On February 10, 2004 the Company filed a Registration Statement on Form S-3 with the SEC covering the resale of the shares sold in the PIPE by the investors. The Company must pay 1% of the aggregate price paid per month, subject to certain limitations, if the registration statement is not declared effective on or before April 11, 2004.

Note 9 – Comprehensive Loss

The following is a summary of comprehensive loss (in thousands):

	March 31,	
	2004	2003
	(Unaudited)	
Net loss	\$ (7,026)	\$ (434)
Unrealized loss on investments	(4)	(34)
Change in fair value of interest rate swap	--	13
Translation adjustment	(61)	(158)
Comprehensive loss	<u>\$ (7,091)</u>	<u>\$ (613)</u>

The tax effect on the change in unrealized loss on investments is \$2,000 and \$17,000 for the three months ended March 31, 2004 and 2003, respectively. The tax effect on the change in fair value of the interest rate swap is zero and \$6,000 for the three months ended March 31, 2004 and 2003, respectively. The tax effect on the translation adjustment is zero and \$110,000 for the three months ended March 31, 2004 and 2003, respectively.

Components of accumulated other comprehensive income consist of the following, net of tax (in thousands):

	March 31, 2004	December 31, 2003
	(Unaudited)	
Unrealized gain on investments	\$ 81	\$ 85
Translation adjustment	219	280
Total accumulated other comprehensive loss	<u>\$ 300</u>	<u>\$ 365</u>

Note 10 – Loss per Share

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

	Three Months Ended March 31,	
	2004	2003
	(Unaudited)	
Numerator for basic and diluted loss per share - loss available to common shareholders	<u>\$ (7,026)</u>	<u>\$ (434)</u>
Denominator for basic loss per share -		

weighted-average basis	22,241	19,634
Effect of dilutive stock options	--	--
	<hr/>	<hr/>
Denominator for diluted loss per share - adjusted weighted-average shares	22,241	19,634
	<hr/>	<hr/>
Loss per share:		
Basic	\$ (0.32)	\$ (0.02)
	<hr/>	<hr/>
Diluted	\$ (0.32)	\$ (0.02)
	<hr/>	<hr/>

Since the Company has a net loss for the three months ended March 31, 2004 and 2003, all common stock equivalents are anti-dilutive for those periods. For the quarters ended March 31, 2004 and 2003 the Company had stock options that are considered common stock equivalents and would have resulted in 366,000 and 364,000, respectively, in additional dilutive shares for those periods, pursuant to the provisions of SFAS 128.

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Note 11 – Stock-Based Compensation

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 No. 123, “Accounting for Stock-Based Compensation” as amended by SFAS No. 148, “Accounting for Stock-Based Compensation – Transition and Disclosure” 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 148 and SFAS 123. 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 March 31,	
	2004	2003
	(Unaudited)	
Expected dividend yield	0%	0%
Expected stock price volatility	.650	.617
Risk-free interest rate	0.93%	2.49%
Expected life of options	3.0 Years	4.0 Years

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that 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 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.

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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 March 31,	
	2004	2003
	(Unaudited)	
Net loss--as reported	\$(7,026)	\$(434)
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of tax	286	266
Net loss--pro forma	\$(7,312)	\$(700)
	<hr/>	<hr/>
Loss per share--as reported:		
Basic	\$ (0.32)	\$(0.02)
	<hr/>	<hr/>
Diluted	\$ (0.32)	\$(0.02)
	<hr/>	<hr/>
Loss per share--proforma:		
Basic	\$ (0.33)	\$(0.04)

Diluted

\$ (0.33) \$(0.04)

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® Surgical Adhesive, bioprosthetic devices, including stentless porcine heart valves, SynerGraft treated porcine heart valves, and SynerGraft treated bovine vascular grafts, and Cerasorb® 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.

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

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	Three Months Ended March 31	
	2004	2003
	(Unaudited)	
Revenue:		
Human tissue preservation services	6,225	9,130
Implantable medical devices	8,859	6,599
All other ^a	2	191
	\$ 15,086	\$ 15,920
Cost of Preservation Services and Products:		
Human tissue preservation services	9,103	2,443
Implantable medical devices	1,947	1,641
All other ^a	--	--
	11,050	4,084
Gross (Loss) Margin:		
Human tissue preservation services	(2,878)	6,687
Implantable medical devices	6,912	4,958
All other ^a	2	191
	\$ 4,036	\$ 11,836

^a The "All other" designation includes grant revenue.

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

	Three Months Ended March 31	
	2004	2003
	(Unaudited)	
Revenue:		
Human tissue preservation services:		
Cardiovascular tissue	\$ 3,430	\$ 4,725
Vascular tissue	2,486	4,255
Orthopaedic tissue	309	150
Total preservation services	6,225	9,130
BioGlue surgical adhesive	8,643	6,494
Other implantable medical devices	216	105
Research grants	2	191

\$	15,086	\$	15,920
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Note 13 – Commitments and Contingencies

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 experienced have been filed. As of May 10, 2004 the Company was aware of ten pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, six allege product liability claims arising out of the Company's orthopaedic tissue services, three 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 ten open lawsuits a total of four are covered by the Company's insurance coverage as follows: two lawsuits by the 2000/2001 insurance policy and two by the 2003/2004 insurance policy. For the 2000/2001 insurance policy year the Company maintained claims-made insurance policies which the Company believes to be adequate to defend against the suits filed during this period. As of March 31, 2004 the Company has an accrual of \$100,000 for the remaining retention levels related to the 2000/2001 insurance policy year. The Company believes its 2003/2004 insurance policy to be adequate to defend against the two covered suits filed during this time period.

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

The Company performed an analysis as of March 31, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of March 31, 2004 the Company had accrued a total of \$5.1 million for pending product liability claims and recorded \$1.1 million representing amounts to be recovered from the Company's insurance carriers. The \$5.1 million accrual is included as a component of accrued expenses and other current liabilities and the \$1.1 million amount recoverable is included as a component of other receivables, net on the March 31, 2004 Summary Consolidated Balance Sheet. These amounts represent the Company's estimate of the probable losses and anticipated recoveries related to these pending product liability claims. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims, and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. The amount recorded as a receivable is reflective of the estimated amount recoverable from the Company's insurance carrier, based on the Company's estimate of the liability and analysis of the policy terms. The Company believes that these amounts are fully collectible. Prior to March 31, 2004, the Company recorded accruals for the uninsured portion of product liability claims for which the amount of probable loss was reasonably estimable. Had the Company recorded the total amounts of the reasonably estimable probable losses as a liability and recorded an asset for the estimated amount recoverable from the insurance carrier the impact on the financial statements as of December 31, 2003 would not have been material. The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as many of the claims do not specify the damages sought and the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims 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. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

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

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. During 2003 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed as of December 31, 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 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. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

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- o A ceiling of \$5 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5 million,
 - o The future claim reporting lag time would be a blend of the Company's experiences and industry data,
 - o The frequency of unreported claims for accident years 2001 through 2003 would be lower than the Company experienced during the 2002/2003 policy year but higher than the Company's historical claim frequency in prior policy years,
 - o The average cost per claim would be lower than the Company experienced during the 2002/2003 policy year but higher than the Company's historical cost per claim in prior policy years, and
 - o The number of claims per million dollars of revenues and the average cost per claim associated with BioGlue would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but actual developments could differ materially from the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity and uncertainties surrounding the assumptions used as well as due to Company specific conditions including the FDA Order, the Company's recent levels of litigation activity, the Company's low volume of historical claims, and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors actual results may differ significantly from the amounts accrued.

Based on the actuarial valuation, the Company estimated that its liability for unreported product liability claims was \$7.5 million, and accrued this amount, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to December 31, 2003. Further analysis indicated that the liability could be estimated to be as high as \$14.2 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. This accrual reflected management's estimate based on information available to it at the time the estimate was made. Actual results may differ from this estimate. 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 Sheet. As of March 31, 2004 the accrual for unreported product liability claims remained unchanged for services performed and products sold prior to March 31, 2004.

Class Action Lawsuit

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 made misrepresentations and omissions relating to product safety and the Company's alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the U.S. District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003, the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. At present, the case remains in the discovery phase. Although the Company carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment in excess of the Company's available insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows. At this time, the Company is unable to predict the outcome of this litigation. Therefore, the Company has not recorded any accruals for future expenses related to this case, as the Company is currently unable to estimate these amounts. As of March 31, 2004 the Company had accrued \$600,000 for legal fees incurred but unpaid related to this case and recorded an asset of \$600,000 representing the anticipated recovery of these fees from the Company's insurance carrier. The \$600,000 accrual is included as a component of accrued expenses and other current liabilities and the \$600,000 insurance receivable is included as a component of other receivables, net on the March 31, 2004 Summary Consolidated Balance Sheet. The Company believes that the receivable will be fully collectible.

Shareholder Derivative Action

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names 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 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. As previously disclosed, the Company's Board of Directors has established an independent committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel, evaluated the consolidated amended complaint and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of the Company. At this time, the Company is unable to predict the outcome of this litigation. Although the derivative suit is brought nominally on behalf of the Company, the Company expects to continue to incur defense costs and other expenses in connection with the derivative litigation.

SEC Investigation

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

Other Litigation

In October 2003 an action was filed against multiple defendants, including the Company, titled Donald Payne and Candace Payne v. Community Blood Center, et al, in the Circuit Court of the State of Oregon, County of Multnomah, seeking noneconomic damages of \$9.0 million and other damages of \$4.7 million. The suit alleges that Mr. Payne received a tissue implant processed by one of the other defendants, and that he was subsequently diagnosed with an infection attributed to the implant. The claim against the Company asserts that CryoLife had processed tissue from the same donor and been notified that a recipient of that tissue had contracted the same virus, and further asserts that the Company had a duty to notify governmental authorities and two of the other defendants. A second action, titled L.L.R. and W.C.R. v. Community Blood Center, et al, was filed in October 2003 in the same court as the Payne case,

against the same defendants, seeking the same amounts of damages. In this case the plaintiffs allege the recipient received an implant processed by the same co-defendant tissue processor, from the same donor as Mr. Payne, and contracted an infection. A tentative trial date for these actions has been set for November 22, 2004. The Company intends to vigorously defend against these claims, although the Company is presently unable to predict the outcome.

Note 14 – Subsequent Events

In April 2004 the Company entered into two agreements to finance approximately \$1.9 million and \$1.5 million in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. The amounts financed accrue interest at a 3.25% rate and are payable in equal monthly payments over a nine month period and an eight month period, respectively.

As discussed in Note 8, as of April 11, 2004 the Registration Statement for the PIPE transaction had not been declared effective and, therefore, the Company began accruing approximately \$7,000 per day in penalties to be paid to the purchasers. As of May 10, 2004 the Registration Statement had not been declared effective.

PART I — FINANCIAL INFORMATION

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

Recent Events

On January 7, 2004 the Company's Board of Directors authorized an agreement with a financial advisory company to sell shares of the Company's common stock in a private investment in public equity transaction (the "PIPE"). The PIPE was consummated on January 27, 2004, and resulted in the sale of approximately 3.4 million shares of stock at a price of \$6.25 per share. The sale generated net proceeds of approximately \$19.9 million, after commissions, registration fees, and other related charges, which will be used for general corporate purposes. On February 10, 2004 the Company filed a Registration Statement on Form S-3 with the SEC covering the resale of the shares sold in the PIPE by the investors. The Company must pay 1% of the aggregate price paid per month, subject to certain limitations, if the registration statement is not declared effective on or before April 11, 2004.

As of April 11, 2004 the Registration Statement for the PIPE transaction had not been declared effective and, therefore, the Company began accruing approximately \$7,000 per day in penalties to be paid to the purchasers. As of May 10, 2004 the Registration Statement had not been declared effective.

FDA Order on Human Tissue Preservation

On August 13, 2002 the Company received an order from the Atlanta district office of the FDA regarding the non-valved cardiac, vascular, and orthopaedic tissues 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"). Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order (i.e. processed since October 3, 2001) on quality assurance quarantine and recalled the portion of those tissues 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 entered into an agreement with the FDA (the "Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to the recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company had completed steps to ensure that the tissue was used for approved purposes and that patients were notified of risks associated with tissue use. The Agreement had a renewable 45-business day term, and the final renewal expired on September 5, 2003. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and September 5, 2002). A renewal of the Agreement that expired on September 5, 2003 was not needed in order for the Company to continue to distribute non-valved cardiovascular, vascular, and orthopaedic tissues processed after September 5, 2002.

In addition, pursuant to the Agreement, the Company agreed to perform additional procedures in the processing of non-valved cardiac and vascular tissues and subsequently resumed processing these tissues. 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.

Other FDA Correspondence and Notices

FDA 483 Notices of Observations were issued in connection with the FDA inspections of the Company's facilities in February 2003, October 2003, and February 2004. The Company responded to the February 2003 483 in March 2003, responded to the October 2003 483 in October 2003, November 2003, and April 2004, and responded to the February 2004 483 in March 2004 and April 2004. The Company continues to work with the FDA to review process improvements and address any outstanding observations.

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® SG and that premarket approval marketing authorization should be obtained for the Company's CryoVein® SG when marketed or labeled as an arteriovenous ("A-V") access graft. 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.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On February 4, 2004 the Company received a letter from the FDA requesting that additional information be provided to support the 510(k)

premarket notification for the CryoValve SG. The requested information may require that additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed cardiovascular tissue, including the CryoValve SG. The Company is still in discussions with the FDA regarding the type of submissions necessary for the CryoVein SG. The outcome of the discussions and filing with the FDA regarding the use of the SynerGraft process on human tissue, including the CryoValve SG and CryoVein SG, could result in an inability to distribute tissues with the SynerGraft technology until further submissions and FDA clearances are granted.

The Company voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular and vascular tissue and has suspended the distribution of tissues on hand that have been processed with the SynerGraft technology until the regulatory status of the CryoValve SG and CryoVein SG is resolved. Additionally, the Company 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 treated tissues 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 Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue on hand.

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, 2003. 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 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 direct labor and materials including laboratory expenses, tissue procurement fees, freight-in charges, and fringe benefits, and indirect costs including allocations of costs from departments that support processing activities and facility allocations. Deferred preservation costs are stated, net of reserve, on a first-in, first-out basis.

The calculation of deferred preservation costs includes a high degree of judgment and complexity. The costs included in deferred preservation costs contain several estimates due to the timing differences between the occurrence of the cost and receipt of final bills for services. Costs that contain estimates include tissue procurement fees, which are estimated based on the Company's contracts with independent procurement agencies, and freight-in charges, which are estimated based on the Company's prior experiences with these charges. Management believes that its estimates approximate the actual costs of these services, but estimates could differ from actual costs. Total deferred preservation costs are then allocated among the different tissues processed during the period based on specific cost drivers such as the number of donors and the number of tissues processed. At each balance sheet date a portion of the deferred preservation costs relates to tissues currently in active processing or held in quarantine pending release to implantable status. The Company applies a yield to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management determines this estimate of quarantine yields based on its experience in prior periods and reevaluates this estimate periodically. Due to the nature of this estimate and the length of the processing times experienced by the Company, actual yields could differ from the Company's estimates. A significant change in quarantine yields could materially affect the deferred preservation costs per tissue, which could impact the value of deferred preservation costs on the Company's balance sheet and the cost of preservation services, including the lower of cost or market write-down, on the Company's Summary Consolidated Statement of Operations.

During 2002 the Company recorded write-downs of deferred preservation costs totaling \$32.7 million. These write-downs were recorded as a result of the FDA Order as discussed in "FDA Order on Human Tissue Preservation" above. The amount of these write-downs reflected management's estimates based on information available to it at the time the estimates were made and actual results did differ from these estimates. The write-down created a new cost basis, which cannot be written back up if these tissues become available for distribution. The cost of human tissue preservation services has been favorably affected by tissue shipments that were related to previously written-down deferred preservation costs. The cost of human tissue preservation services may continue to be favorably affected depending on the future level of tissue shipments related to previously written-down deferred preservation costs, but such impact is not expected to be material. Management continues to evaluate the recoverability of the deferred preservation costs and will record additional write-downs if it becomes clear that additional impairments have occurred.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company recorded \$3.7 million and \$297,000, respectively, in the three months ended March 31, 2004 and 2003 as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs from tissues that exceeded market value. The amount of these write-downs reflects management's estimates of market value based on recent average service fees. Actual results may differ from these estimates.

As of March 31, 2004 deferred preservation costs were \$3.3 million for allograft heart valve tissues, \$308,000 for non-valved cardiac tissues, \$2.7 million for vascular tissues, and \$1.1 million 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 beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses, reflecting reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activity, and reported tissue infections. The Company continued to generate deferred tax assets for the three months ended March 31, 2004 primarily as a result of operating losses and expects to do so throughout 2004. 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.

The Company evaluated several factors to determine if a valuation allowance relative to its deferred tax assets was necessary during 2003. The Company reviewed its historic operating results, including the reasons for its operating losses in 2003 and 2002, uncertainties regarding projected future operating results due to the effects of the adverse publicity resulting from the FDA Order, subsequent FDA activity, and reported tissue infections, the changes in processing methods resulting from the FDA Order, and the uncertainty of the outcome of product liability claims. Based on the results of this analysis, the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, during 2003 the Company recorded valuation allowances totaling \$13.7 million due to the effect of temporary differences between book and tax income, the net deferred tax assets generated in 2003, and the net deferred tax asset balance at December 31, 2002. For the three months ended March 31, 2004 the Company did not experience any changes that would materially affect the Company's analysis of and valuation of its deferred tax assets. As of March 31, 2004 the Company had a total of

\$16.8 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

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:

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- 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 segments based on factors including facility space and revenues. The Company used a twelve-year period for the undiscounted future cash flows. This period of time was selected based upon the approximate 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 December 31, 2003 and, therefore, management has concluded that there was 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 and the future effects of events surrounding the FDA Order, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), requires goodwill resulting from business acquisitions and other intangible assets be subject to periodic impairment testing. The Company's intangible assets consist of patent costs, which are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method, trademarks, which are non-amortizing, and other intangibles, which consist primarily of manufacturing rights and agreements and are amortized over the expected useful lives of the related assets (primarily five years). As of December 31, 2003 the Company did not believe that an impairment existed related to the other intangible assets that were assessed in accordance with SFAS No. 144.

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 experienced have been filed. As of May 10, 2004 the Company was aware of ten pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, six allege product liability claims arising out of the Company's orthopaedic tissue services, three 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 ten open lawsuits a total of four are covered by the Company's insurance coverage as follows: two lawsuits by the 2000/2001 insurance policy and two by the 2003/2004 insurance policy. For the 2000/2001 insurance policy year the Company maintained claims-made insurance policies which the Company believes to be adequate to defend against the suits filed during this period. As of March 31, 2004 the Company has an accrual of \$100,000 for the remaining retention levels related to the 2000/2001 insurance policy year. The Company believes its 2003/2004 insurance policy to be adequate to defend against the two covered suits filed during this time period.

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

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The Company performed an analysis as of March 31, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of March 31, 2004 the Company had accrued a total of \$5.1 million for pending product liability claims and recorded \$1.1 million representing amounts to be recovered from the Company's insurance carriers. The \$5.1 million accrual is included as a component of accrued expenses and other current liabilities and the \$1.1 million amount recoverable is included as a component of other receivables, net on the March 31, 2004 Summary Consolidated Balance Sheet. These amounts represent the Company's estimate of the probable losses and anticipated recoveries related to these pending product liability claims. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims, and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. The amount recorded as a receivable is reflective of the estimated amount recoverable from the Company's insurance carrier, based on the Company's estimate of the liability and analysis of the policy terms. The Company believes that these amounts are fully collectible. Prior to March 31, 2004, the Company recorded accruals for the uninsured portion of product liability claims for which the amount of probable loss was reasonably estimable. Had the Company recorded the total amounts of the reasonably estimable probable losses as a liability and recorded an asset for the estimated amount recoverable from the insurance carrier the impact on the financial statements as of December 31, 2003 would not have been material. The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as many of the claims do not specify the damages sought and the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims 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. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

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

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. During 2003 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed as of December 31, 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 Bomhuetter-Ferguson method using a blend of the Company's historical claim 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. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- o A ceiling of \$5 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5 million,
- o The future claim reporting lag time would be a blend of the Company's historical experiences and industry data,
- o The frequency of unreported claims for accident years 2001 through 2003 would be lower than the Company experienced during the 2002/2003 policy year but higher than the Company's historical claim frequency in prior policy years,
- o The average cost per claim would be lower than the Company experienced during the 2002/2003 policy year but higher than the Company's historical cost per claim in prior policy years, and
- o The number of claims per million dollars of revenues and the average cost per claim associated with BioGlue would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line.

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The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but actual results could differ materially from the scenarios contained in the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity and uncertainties surrounding the assumptions used as well as due to Company specific conditions including the FDA Order, the Company's recent levels of litigation activity, the Company's low volume of historical claims, and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors actual results may differ significantly from the amounts accrued.

Based on the actuarial valuation, the Company estimated that its liability for unreported product liability claims was \$7.5 million, and accrued this amount, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to December 31, 2003. Further analysis indicated that the liability could be estimated to be as high as \$14.2 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. This accrual reflected management's estimate based on information available to it at the time the estimate was made. Actual results may differ from this estimate. 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 Sheet. As of March 31, 2004 the accrual for unreported product liability claims remained unchanged for services performed and products sold prior to March 31, 2004.

New Accounting Pronouncements

There have been no recent accounting pronouncements beyond those we reported in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as filed with the Securities and Exchange Commission on March 1, 2004.

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Results of Operations (In thousands)

Revenues

	Three Months Ended March 31,	
	2004	2003
Revenues	\$ 15,086	\$ 15,920

Revenues decreased 5% for the three months ended March 31, 2004 as compared to the three months ended March 31, 2003. This decrease was primarily due to the inclusion of \$848,000 in favorable adjustments to the estimated tissue recall returns for the three months ended March 31, 2003 due to lower actual tissue returns under the FDA Order than were originally estimated and decreases in cardiovascular and vascular tissue preservation service revenues compared to the prior year period, partially offset by an increase in revenues from sales of BioGlue Surgical Adhesive.

Further discussion of the increase in BioGlue revenues and the decrease in cryopreservation service revenues for each of the three major tissue types processed by the Company continues in the detailed sections below.

BioGlue Surgical Adhesive

Three Months Ended
March 31,

	2004	2003
Revenues	\$ 8,643	\$ 6,494
BioGlue revenues as a percentage of total revenue	57%	41%

Revenues from the sale of BioGlue Surgical Adhesive increased 33% for the three months ended March 31, 2004 as compared to the three months ended March 31, 2003. The 33% increase in revenues for the three months ended March 31, 2003 was primarily due to an increase in BioGlue sales volume due to an increase in demand in both domestic and foreign markets which increased revenues by 20%, and an increase in average selling prices which increased revenues by 13%.

Volume increases in the three months ended March 31, 2004 were led by large percentage increases in the BioGlue 2ml and 5ml product sizes and in sales of BioGlue applicator tips and delivery devices. Price increases in the three months ended March 31, 2004 were largely due to a list price increase for BioGlue, which went into effect on December 1, 2003.

The BioGlue 10ml size continued to generate the largest amount of BioGlue revenue, accounting for 69% and 77%, respectively, of total BioGlue revenues during the three months ended March 31, 2004 and 2003. Domestic revenues accounted for 80% of total BioGlue revenues for the three months ended March 31, 2004, and 79% of total BioGlue revenues for the three months ended March 31, 2003.

The Company anticipates that revenues from BioGlue Surgical Adhesive will continue to grow for the full year 2004 when compared to 2003 due to increases in sales volume in domestic and foreign markets and due to the price increase that went into effect in late 2003.

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Cardiovascular Preservation Services

Three Months Ended
March 31,

	2004	2003
Revenues	\$ 3,430	\$ 4,725
Cardiovascular revenues as a percentage of total revenue	23%	30%

Revenues from cardiovascular preservation services decreased 27% for the three months ended March 31, 2004 as compared to the three months ended March 31, 2003. The 27% decrease in revenues for the three months ended March 31, 2004 was due to a decrease in cardiovascular volume, which reduced revenues by 14%, and a decrease in average service fees, which reduced revenues by 13%. Revenues for the three months ended March 31, 2003 include \$92,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

Volume decreases were largely due to a decrease in shipments of cryopreserved heart valves, which declined 20% over the prior year period. The decrease in heart valve shipments is directly related to the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2003, the disposal of much of the Company's heart valve tissue processed prior to October 3, 2001, and increased tissue processing and release times and lower yields of implantable tissue per donor as a result of process changes implemented in the latter half of 2002 and during 2003. Price decreases were largely driven by lower average service fees due to a change in product mix as shipments of heart valves and non-valved cardiac tissues processed with the SynerGraft process decreased, while shipments of lower fee cardiac tissues processed using traditional processes increased. This was due to the Company's suspension of shipments of SynerGraft processed cardiac tissues in 2003.

The Company's procurement of cardiac tissues during the three months ended March 31, 2004, from which heart valves and non-valved cardiac tissues are processed, increased 3% as compared to the three months ended March 31, 2003. Procurement of cardiac tissues during the three months ended March 31, 2004 decreased 8% as compared to the three months ended December 31, 2003. Procurement of cardiac tissues during the three months ended March 31, 2004 was 26% below procurement in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that cardiovascular service revenues will continue to decrease for the full year 2004 as compared to 2003, if the Company continues to process and ship tissues using only its traditional cryopreservation process. Increases in cardiovascular revenues in the long term are contingent on the Company's ability to increase the amount of tissues available for implantation by decreasing tissue processing and release times and increasing yields of implantable tissue per donor and to resume processing and shipping tissues processed using SynerGraft technology.

As discussed in Recent Events the Company has voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular tissue and in late September 2003 suspended the distribution of tissues on hand that were processed with the SynerGraft technology until the regulatory status of the CryoValve SG is resolved. At this time, the Company cannot estimate when or if it will resume processing allograft cardiovascular tissue using the SynerGraft technology.

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Vascular Preservation Services

Three Months Ended
March 31,

	2004	2003
Revenues	\$ 2,486	\$ 4,255

Vascular revenues as a percentage of total revenue	16%	27%
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Revenues from vascular preservation services decreased 42% for the three months ended March 31, 2004 as compared to the three months ended March 31, 2003. The 42% decrease in revenues for the three months ended March 31, 2004 was due to a decrease in vascular volume, which reduced revenues by 42%. Revenues for the three months ended March 31, 2003 include \$711,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

Volume decreases were largely due to a decrease in shipments of saphenous veins, which represented 80% and 78%, respectively, of vascular preservation service revenues for the three months ended March 31, 2004 and 2003. The decrease in saphenous vein shipments is directly related to the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2003, the disposal of much of the Company's tissues processed prior to October 3, 2001 in accordance with the FDA Order, and increased tissue processing and release times and lower yields of implantable tissue per donor as a result of process changes implemented in the latter half of 2002 and during 2003.

The Company's procurement of vascular tissues during the three months ended March 31, 2004 increased 34% as compared to the three months ended March 31, 2003. Procurement of vascular tissues during the three months ended March 31, 2004 decreased 12% as compared to the three months ended December 31, 2003. Procurement of vascular tissues during the three months ended March 31, 2004 was 56% below procurement in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that vascular service revenues will increase for the full year 2004 as compared to 2003 based on expected procurement levels, consumer demand, and an expected improvement in yields of implantable tissues. Increases in vascular revenues in the long term are contingent on the Company's ability to increase the amount of tissues available for implantation by decreasing tissue processing and release times and increasing yields of implantable tissue per donor and to increase the level of procurement as necessary based on customer demand and processing capacity.

As discussed in Recent Events the Company has voluntarily suspended the use of the SynerGraft technology in the processing of allograft vascular tissue and in late September 2003 suspended the distribution of tissues on hand that were processed with the SynerGraft technology until the regulatory status of the CryoVein SG is resolved. Additionally, the Company has discontinued labeling its vascular grafts for use as A-V access grafts. At this time, the Company cannot estimate when or if it will resume processing allograft vascular tissue using the SynerGraft technology.

Orthopaedic Preservation Services

	Three Months Ended March 31,	
	2004	2003
Revenues	\$ 309	\$ 150
Orthopaedic revenues as a percentage of total revenue	2%	1%

Revenues from orthopaedic preservation services increased to \$309,000 for the three months ended March 31, 2004 as compared to \$150,000 for the three months ended March 31, 2003. Revenues in both periods were minimal due to a severe reduction in processing and shipments of orthopaedic tissues following the FDA Order and subsequent FDA activity as discussed in "FDA Order on Human Tissue Preservation" and "Other FDA Correspondence and Notices" above. Revenues as reported for the three months ended March 31, 2003 include \$45,000 in favorable adjustments to estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002.

During several periods in 2002 and 2003 the Company temporarily suspended the processing and distribution of all or portions of the Company's orthopaedic tissues as a result of the FDA Order, and subsequent system reviews. These suspensions of processing, combined with the disposal of much of the Company's orthopaedic tissue processed prior to October 3, 2001 in accordance with the FDA Order, resulted in low levels of orthopaedic tissues available for shipment in the latter half of 2002 and much of 2003. For the three months ended March 31, 2004, the Company was distributing both boned and non-boned orthopaedic tissues.

The Company's procurement of orthopaedic tissues during the three months ended March 31, 2004 increased 575% as compared to three months ended March 31, 2003. Procurement of orthopaedic tissues during the three months ended March 31, 2004 increased 6% as compared to the three months ended December 31, 2003. Procurement of orthopaedic tissues during the three months ended March 31, 2004 was 74% below procurement in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that orthopaedic service revenues will show an increase for the full year 2004 as compared to 2003 based on expected procurement levels, consumer demand, and an expected improvement in yields of implantable tissues. Revenues from orthopaedic tissue services are still expected to be well below 2002 levels prior to the FDA Order. Increases in orthopaedic revenues in the long term are contingent on the Company's ability to increase the amount of tissues available for implantation by decreasing tissue processing and release times and increasing yields of implantable tissue per donor and to increase the level of procurement as necessary based on processing capacity and customer demand.

Grant Revenues

Grant revenues decreased to \$2,000 for the three months ended March 31, 2004 from \$191,000 for the three months ended March 31, 2003. Grant revenues in 2004 and 2003 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.

The Company does not anticipate that significant amounts of grant revenue will be recognized during 2004.

Cost of Products

Cost of products aggregated \$1.9 million for the three months ended March 31, 2004 compared to \$1.6 million for the three months ended March 31, 2003, representing 22% and 25%, respectively, of total product revenues during such periods. The increase in cost of products for the three months ended March 31, 2004 was primarily due to increases in revenues for the corresponding products. The decrease in cost of products as a percentage of total product revenues for the three months ended March 31, 2004 was 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.

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The Company anticipates cost of products will increase for the full year 2004 when compared to 2003, due to the projected increase in product revenues during 2004. The cost of products as a percentage of product revenues for the full year 2004 is expected to continue to be lower than 2003 due to favorable product mix.

Cost of Human Tissue Preservation Services

Cost of human tissue preservation services increased to \$9.1 million for the three months ended March 31, 2004 as compared to \$2.4 million for the three months ended March 31, 2003, representing 146% and 27%, respectively, of total human tissue preservation service revenues during such periods.

Cost of human tissue preservation services for the three months ended March 31, 2004 includes an increase to cost of preservation services to adjust the value of certain deferred tissue preservation costs that exceeded market value of \$3.7 million and the favorable effect on gross margin of shipments of tissue with a zero cost basis of approximately \$357,000, due to write-downs of deferred preservation costs in the second and third quarter of 2002. Cost of human tissue preservation services for the three months ended March 31, 2003 includes an increase to cost of preservation services to adjust the value of certain deferred tissue preservation costs that exceeded market value of \$297,000 and the favorable effect on gross margin of shipments of tissue with a zero cost basis of approximately \$2.3 million, due to write-downs of deferred preservation costs in the second and third quarter of 2002. Additionally, cost of human tissue preservation services was negatively impacted for the three months ended March 31, 2004 by higher overhead cost allocations associated with the decreased volume of tissues processed, changes in processing methods resulting from the FDA Order, and a decrease in tissue shipments of tissues treated with the SynerGraft process as compared to traditional processing. These increases in cost of human tissue preservation services occurred during a period of decreased human tissue preservation service revenues, resulting in an increase in the cost of human tissue preservation services as a percentage of total human tissue preservation service revenues for the three months ended March 31, 2004 as compared to the three months ended March 31, 2003.

The Company anticipates cost of human tissue preservation services will increase for the full year 2004 when compared to 2003, due to increased costs due to changes in processing methods, increased tissue processing and release times, and decreased yields of implantable tissue per donor. The cost of human tissue preservation services as a percentage of preservation service revenues is expected to 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. Decreases in cost of human tissue preservation services as a percentage of preservation service revenues in the long term are contingent on the Company's ability to reestablish sufficient margins on its tissue preservation services by increasing the amount of tissues processed, decreasing tissue processing and release times, and increasing yields of implantable tissue per donor.

The cost of human tissue preservation services may continue to be favorably affected throughout 2004 by shipments of tissue with a cost basis that has previously been written-down to zero, but the impact is not expected to be material. The write-downs of deferred preservation costs during 2002 created a new cost basis, which cannot be written back up when these tissues are shipped or become available for shipment.

General, Administrative, and Marketing Expenses

General, administrative, and marketing expenses decreased 12% to \$10.1 million for the three months ended March 31, 2004, compared to \$11.6 million for the three months ended March 31, 2003, representing 67% and 73%, respectively, of total revenues during such periods. The decrease in expenses for the three months ended March 31, 2004 was primarily due to a \$1.1 million decrease in expenses related to product liability lawsuits and settlements and \$609,000 in decreased professional fees (legal, consulting, and accounting), partially offset by \$283,000 in increased insurance costs. (See Legal Proceedings at Part II Item 1 for further discussion of these items.)

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

Research and Development Expenses

Research and development expenses were \$921,000 for the three months ended March 31, 2004, compared to \$917,000 for the three months ended March 31, 2003, representing 6% of total revenues during such periods. Research and development spending in 2004 and 2003 was primarily focused on the Company's core tissue cryopreservation, SynerGraft, and Protein Hydrogel Technologies ("PHT"). PHT includes BioGlue and related products.

Other Costs and Expenses

Interest expense decreased to \$43,000 for the three months ended March 31, 2004, compared to \$132,000 for the three months ended March 31, 2003. Interest expense for the three months ended March 31, 2004 and 2003 included interest incurred related to the Company's capital leases. Interest expense for the three months ended March 31, 2003 also included interest incurred on the Company's Term Loan, which was paid in full in the third quarter of 2003.

Interest income decreased to \$66,000 for the three months ended March 31, 2004, compared to \$131,000 for the three months ended March 31, 2003. Interest income in both periods was primarily due to interest earned on the Company's cash, cash equivalents, and marketable securities.

The Company's income tax benefit of \$214,000 for the three months ended March 31, 2003 was recorded on the pre-tax net loss at the Company's effective tax rate for the period of 33%.

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 for school aged patients, who drive the demand for a large percentage of CryoLife's cardiovascular tissues.

The demand for the Company's BioGlue Surgical Adhesive appears to experience some seasonality, with a flattening or slight decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to fewer surgeries being performed on adult patients in the summer months. As BioGlue is a recently introduced product that has not fully penetrated the marketplace, the full nature of any seasonal trends in BioGlue sales may be obscured. The Company will continue to evaluate the seasonal nature of BioGlue sales.

The demand for the Company's human vascular and orthopaedic tissue preservation services and bioprosthetic cardiovascular and vascular devices does not appear to experience seasonal trends.

Liquidity and Capital Resources

Net Working Capital

At March 31, 2004 net working capital (current assets of \$49.7 million less current liabilities of \$20.6 million) was \$29.1 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$14.8 million, with a current ratio of 2 to 1 at December 31, 2003. The Company's primary capital requirements historically arose out of general working capital needs, capital expenditures for facilities and equipment, and funding of research and development projects, and the Company funded those requirements through cash generated by operations, equity offerings, and bank credit facilities.

In recent periods the Company's primary capital requirements arose out of working capital needs created by increasing costs of operations combined with decreasing revenues due to the effects of the FDA Order, subsequent FDA activity, and related events as discussed in "FDA Order on Human Tissue Preservation" and "Other FDA Correspondence and Notices" above. Operating results have also been negatively impacted by increases in general, administrative, and marketing costs over pre-FDA Order levels, as a result of increased legal and professional fees and settlement costs. For the three months ended March 31, 2004 the Company funded these requirements primarily through sales and maturities of marketable securities and equity financing, as discussed below.

Overall Liquidity and Capital Resources

The Company expects that its operations will continue to generate negative cash flows throughout the remainder of 2004 due to:

- o The anticipated lower preservation revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activity, and related events (discussed in "FDA Order on Human Tissue Preservation" and "Other FDA Correspondence and Notices"),
- o 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,
- o An expected use of cash related to the defense and resolution of lawsuits, and
- o The legal and professional costs related to ongoing FDA compliance.

The Company believes anticipated revenue generation, expense management, tax refunds expected to be approximately \$2.4 million, and the Company's existing cash, cash equivalents, and marketable securities will enable the Company to meet its liquidity needs through at least March 31, 2005.

On January 7, 2004 the Company's Board of Directors authorized an agreement with a financial advisory company to sell shares of the Company's common stock in a private investment in public equity transaction (the "PIPE"). The PIPE was consummated on January 27, 2004, and resulted in the sale of approximately 3.4 million shares of stock at a price of \$6.25 per share. The sale generated net proceeds of approximately \$19.9 million, after commissions, registration fees, and other related charges, which will be used for general corporate purposes. On February 10, 2004 the Company filed a Registration Statement on Form S-3 with the Securities and Exchange Commission ("SEC") covering the resale of the shares sold in the PIPE by the investors. The Company has agreed to pay 1% of the aggregate purchase price per month, subject to certain limitations, if the registration statement is not declared effective on or before April 11, 2004.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including:

- o The Company's ability to return to the level of demand for its tissue services that existed prior to the FDA Order,
- o The Company's ability to reestablish sufficient margins on its tissue preservation services in the face of increased processing costs,
- o The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- o The amount and the timing of the resolution of the remaining outstanding product liability claims (see Part II. Item 1. Legal Proceedings), and
- o The outcome of other litigation against the Company (see Part II. Item 1. Legal Proceedings).

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 March 31, 2005. 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.

As discussed in Note 13 to the summary consolidated financial statements, as of March 31, 2004 the Company had accrued a total of \$5.1 million for pending product liability claims and recorded a receivable of \$1.1 million representing amounts to be paid by the Company's insurance carriers. The \$5.1 million accrual less the \$1.1 million receivable is an estimate of the Company's portion of the costs required to resolve outstanding claims, and does not reflect actual settlement arrangements or actual judgments, including punitive damages, which may be assessed by the courts. The \$5.1 million accrual is not a cash reserve. The timing and amount of actual future payments is dependent on when and if judgments are rendered, and/or settlements are reached. Should

payments related to the accrual be required, the Company's portion of these monies would have to be paid from liquid assets. The Company continues to attempt to reach settlements of these outstanding claims in order to minimize the potential cash payout. See additional discussion of these matters in Note 13 to the summary consolidated financial statements.

If the Company is unable to settle the outstanding claims for amounts within its ability to pay or 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), such verdict(s) could exceed the Company's liquid assets. 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 to the summary consolidated financial statements, at March 31, 2004 the Company had \$7.5 million remaining in an accrual for the estimated costs of unreported product liability claims related to services performed and products sold prior to March 31, 2004. The \$7.5 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.

Net Cash from Operating Activities

Net cash used in operating activities was \$5.3 million for the three months ended March 31, 2004, as compared to \$3.9 million for the three months ended March 31, 2003. The \$5.3 million of cash used in the three months ended March 31, 2004 was primarily due to a decrease in revenues and an increase in cash expenditures, both of which are related to the FDA Order, subsequent FDA activity, and related events, as discussed in "FDA Order on Human Tissue Preservation" and "Other FDA Correspondence and Notices" above. Spending, including the cost of employees and facilities was not sufficiently supported by cash received from revenues. Spending on general and administrative expenses also contributed to the cash shortfall in operations.

The Company uses the indirect method to prepare its cash flow statement, and as such the operating cash flows are based on the Company's net loss, which is then adjusted to remove non-cash items. For the three months ended March 31, 2004, the Company's \$7.0 million net loss from operations included significant recurring non-cash items that generated favorable and unfavorable adjustments to net loss. These adjustments included a favorable \$1.3 million in depreciation and amortization, an unfavorable \$3.2 million due to the timing differences between the recording of receivables and the actual receipt of cash, a favorable \$3.7 million in write-downs for impairment of deferred preservation costs, an unfavorable \$2.0 million due to the buildup of deferred preservation costs and inventories for which vendors and employees have already been paid, a favorable \$1.1 million primarily due to the timing differences associated with prepaid expenses and other assets, and a favorable \$729,000 due to the timing differences between the recording of accounts payable, accrued expenses, and other current liabilities and the actual payment of cash.

The Company expects that its operations will continue to generate negative cash flows throughout the remainder of 2004. This cash used will primarily be a result of the Company's projected net loss for 2004. The Company does not currently expect that it will be required to record significant additional non-cash write-downs of inventory or additional significant accruals related to product liabilities during 2004, but such items would not have a direct effect on net cash from operations. Significant additional cash payments related to settlements and tissue product costs, as discussed above, could have a negative impact on future cash flows. The Company expects to receive tax refunds totaling \$2.4 million during 2004, which is substantially less than the \$12.2 million received in 2003.

Net Cash from Investing Activities

Net cash provided by investing activities was \$2.1 million for the three months ended March 31, 2004, as compared to \$1.1 million for the three months ended March 31, 2003. The \$2.1 million in current year cash provided was primarily due to \$2.0 million in cash generated from sales and maturities of marketable securities. This cash was used to fund the Company's operations, which used \$5.3 million in cash for the three months ended March 31, 2004 as discussed above.

Net Cash from Financing Activities

Net cash provided by financing activities was \$19.8 million for the three months ended March 31, 2004, as compared to cash used of \$423,000 for the three months ended March 31, 2003. The \$19.8 million in current year cash provided was primarily due to \$19.9 million in proceeds from the Company's PIPE equity offering discussed above.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments are as follows (in thousands):

	Total	Remainder of 2004	2005	2006	2007	2008	Thereafter
Capital Lease Obligations	\$ 2,583	\$ 632	\$ 843	\$ 843	\$ 265	\$ --	\$ --
Operating Leases	25,475	1,692	2,197	2,030	2,068	2,108	15,380
Purchase Commitments	1,034	1,034	--	--	--	--	--
Total Contractual Obligations	\$29,092	\$ 3,358	\$3,040	\$2,873	\$2,333	\$2,108	\$15,380

The Company's capital lease obligations result from the financing of certain of the Company's equipment and leasehold improvements during the renovation of the corporate headquarters and manufacturing facilities in previous years. Due to cross default provisions included in the Company's Term Loan which was paid in full on August 15, 2003, the Company was in default of certain capital lease agreements maintained with the lender under the Term Loan as described in Note 6 to the summary consolidated financial statements. Therefore, the \$1.4 million due under these capital leases is reflected as a current liability on the Summary Consolidated Balance Sheets as of March 31, 2004. Additional capital lease obligations result from the lease of a building related to Company's Ideas for Medicine ("IFM") manufacturing business, which the Company sold in 2000. The Company has a sublease agreement with a wholly

owned subsidiary of LeMaitre Vascular, Inc., the current parent of IFM, to sublet the building housing the IFM manufacturing facilities, which effectively reduces the Company's future obligations under this capital lease to zero.

The Company's operating lease obligations result from the lease of land and buildings that comprise the Company's corporate headquarters and manufacturing facilities, leases related to additional manufacturing, office, and warehouse space rented by the Company, leases on Company vehicles, and leases on a variety of office equipment.

The Company's purchase commitments result from an exclusive agreement with curasan AG for U.S. distribution of Cerasorb® Ortho bone graft substitute. CryoLife is in the process of negotiating a settlement with curasan for the dissolution of the distribution agreement and resolution of the guaranteed purchase requirements for 2004. Additional purchase commitments result from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production.

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Capital Expenditures

The Company expects that its capital expenditures for the full year 2004 will show a modest increase over its expenditures in 2003, which were approximately \$1.0 million. Capital expenditures in 2003 were restricted due to the Company's cash position. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to rebuild its tissue processing business and maintain adequate cash flows. The Company does not currently anticipate any major purchase of equipment as a result of the FDA inspections of its facilities.

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FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements and information made or provided by the Company that are based on the beliefs of its management as well 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. Investors are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates. Such forward-looking statements reflect the views of our management at the time such statements are made and are subject to a number of risks, uncertainties, estimates and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under "Risks and Uncertainties" and elsewhere in this filing.

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

- o The impact of recent accounting pronouncements;
- o Adequacy of product liability insurance to defend against lawsuits;
- o The outcome of lawsuits filed against the Company;
- o The impact of the FDA Order and subsequent FDA activity on future revenues, profits and business operations;
- o The effect of the FDA Order and subsequent FDA activity on sales of BioGlue;
- o Future tissue procurement levels;
- o Expected future impact of BioGlue on revenues;
- o The impact of the FDA's Form 483 Notices of Observation;
- o The estimates of the amounts accrued for the retention levels under the Company's product liability and directors' and officers' insurance policies, as well as the estimates of the amounts accrued for product loss claims incurred but not reported;
- o Future costs of human tissue preservation services;
- o Changes in liquidity and capital resources;
- o The outcome of any evaluation of allograft heart valves by the FDA;
- o The Company's competitive position;
- o Estimated dates relating to the Company's proposed regulatory submissions;
- o The Company's expectations regarding the adequacy of current financing arrangements;
- o Product demand and market growth;
- o The impact on the Company of adverse results of surgery utilizing tissue processed by it;
- o The expected receipt of tax refunds; and
- o Other statements regarding future plans and strategies, anticipated events or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including 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, 2003 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 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, and its ability to continue as a going concern, include concerns that:

- o The August 2002 FDA order on human tissue and subsequent FDA activity continue to adversely impact CryoLife's business, including demand for its services and processing costs;
- o The FDA order and subsequent activity have had and continue to have an adverse impact on liquidity and capital resources;
- o Revenue from orthopaedic tissue preservation services is minimal and may not return;
- o Physicians may be reluctant to implant CryoLife's preserved tissues;
- o Products and services not included in the FDA recall may come under increased scrutiny;
- o Demand for heart valves processed by CryoLife has decreased and may continue to decrease;
- o Adverse publicity may reduce demand for products and services not affected by the FDA recall;
- o The Company may be unable to address the concerns raised by the FDA in its form 483 notices of observations;
- o The FDA has notified CryoLife of its belief that marketing of CryoValve SG and CryoVein SG require additional regulatory submissions and/or approvals;
- o Regulatory action outside of the U.S. may also affect CryoLife's business;
- o CryoLife is the subject of an ongoing SEC investigation;
- o CryoLife's insurance coverage may be insufficient;
- 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;
- o Intense competition may affect CryoLife's ability to recover from the FDA order;
- o CryoLife may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and such products and services may not achieve market acceptance;
- o Investments in new technologies or distribution rights may not be successful;
- o Funding for the ACT technology may not be available;
- o CryoLife is dependent on its key personnel;
- o The Company's consolidated financial statements as of and for the year ended December 31, 2001 and included in CryoLife's 10-K were audited by Arthur Andersen LLP, which has been found guilty of obstruction of justice and the subject of additional litigation;
- o Extensive government regulation may adversely affect the ability to develop and sell products and services;
- o Uncertainties related to patents and protection of proprietary technology may adversely affect the value of intellectual property;
- o Uncertainties regarding future health care reimbursement may affect the amount and timing of revenues;
- o Rapid technological change could cause services and products to become obsolete;
- o Securities prices for CryoLife shares have been, and may continue to be, volatile;
- o Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of CryoLife;
- o Dividends are not likely to be paid in the foreseeable future; and
- o CryoLife may be unable to raise the funds needed to continue operations after March 31, 2005.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company's interest income and expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents of \$22.1 million and short-term investments in municipal obligations of \$3.3 million as of March 31, 2004. A 10% adverse change in interest rates affecting the Company's cash equivalents and short-term investments would not have a material impact on the Company's financial position, results of operations, and cash flows.

Item 4. Controls and Procedures.

The Company's management, including the Company's President and Chief Executive Officer ("CEO") and 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.

Based upon the Company's most recent Disclosure Controls evaluation as of March 31, 2004, the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that 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 U.S. Securities and Exchange Commission's rules and forms.

During the quarter ended March 31, 2004, 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.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings.

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 experienced have been filed. As of May 10, 2004 the Company was aware of ten pending

product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, six allege product liability claims arising out of the Company's orthopaedic tissue services, three 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 ten open lawsuits a total of four are covered by the Company's insurance coverage as follows: two lawsuits by the 2000/2001 insurance policy and two by the 2003/2004 insurance policy. For the 2000/2001 insurance policy year the Company maintained claims-made insurance policies which the Company believes to be adequate to defend against the suits filed during this period. As of March 31, 2004 the Company has an accrual of \$100,000 for the remaining retention levels related to the 2000/2001 insurance policy year. The Company believes its 2003/2004 insurance policy to be adequate to defend against the two covered suits filed during this time period.

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

The Company performed an analysis as of March 31, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of March 31, 2004 the Company had accrued a total of \$5.1 million for pending product liability claims and recorded \$1.1 million representing amounts to be recovered from the Company's insurance carriers. The \$5.1 million accrual is included as a component of accrued expenses and other current liabilities and the \$1.1 million amount recoverable is included as a component of other receivables, net on the March 31, 2004 Summary Consolidated Balance Sheet. These amounts represent the Company's estimate of the probable losses and anticipated recoveries related to these pending product liability claims. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims, and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. The amount recorded as a receivable is reflective of the estimated amount recoverable from the Company's insurance carrier, based on the Company's estimate of the liability and analysis of the policy terms. The Company believes that these amounts are fully collectible. Prior to March 31, 2004, the Company recorded accruals for the uninsured portion of product liability claims for which the amount of probable loss was reasonably estimable. Had the Company recorded the total amounts of the reasonably estimable probable losses as a liability and recorded an asset for the estimated amount recoverable from the insurance carrier the impact on the financial statements as of December 31, 2003 would not have been material. The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company is currently unable to reasonably estimate the maximum amount of the possible loss related to these claims, as many of the claims do not specify the damages sought and the Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims 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. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

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

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. During 2003 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims, the latest of which was performed as of December 31, 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 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. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- o A ceiling of \$5 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5 million,
- o The future claim reporting lag time would be a blend of the Company's historical experiences and industry data,

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- o The frequency of unreported claims for accident years 2001 through 2003 would be lower than the Company experienced during the 2002/2003 policy year but higher than the Company's historical claim frequency in prior policy years,
 - o The average cost per claim would be lower than the Company experienced during the 2002/2003 policy year but higher than the Company's historical cost per claim in prior policy years, and
 - o The number of claims per million dollars of revenues and the average cost per claim associated with BioGlue would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line.

The Company believes that these assumptions provide a reasonable basis for the calculation of the unreported product liability loss, but actual results could differ materially from the scenarios contained in the assumptions above. The accuracy of the actuarial firm's estimates is limited by the general uncertainty that exists for any estimate of future activity and uncertainties surrounding the assumptions used as well as due to Company specific conditions including the FDA Order, the Company's recent levels of litigation activity, the Company's low volume of historical claims, and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors actual results may differ significantly from the amounts accrued.

Based on the actuarial valuation, the Company estimated that its liability for unreported product liability claims was \$7.5 million, and accrued this amount,

representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to December 31, 2003. Further analysis indicated that the liability could be estimated to be as high as \$14.2 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. This accrual reflected management's estimate based on information available to it at the time the estimate was made. Actual results may differ from this estimate. 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 Sheet. As of March 31, 2004 the accrual for unreported product liability claims remained unchanged for services performed and products sold prior to March 31, 2004.

Class Action Lawsuit

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 made misrepresentations and omissions relating to product safety and the Company's alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the U.S. District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. On December 16, 2003, the Court certified a class of individuals and entities who purchased or otherwise acquired CryoLife stock from April 2, 2001 through August 14, 2002. At present, the case remains in the discovery phase. Although the Company carries directors' and officers' liability insurance policies, the directors' and officers' liability insurance carriers have issued reservation of rights letters reserving their rights to deny or rescind coverage under the policies. An adverse judgment in excess of the Company's available insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows. At this time, the Company is unable to predict the outcome of this litigation. Therefore, the Company has not recorded any accruals for future expenses related to this case, as the Company is currently unable to estimate these amounts. As of March 31, 2004 the Company had accrued \$600,000 for legal fees incurred but unpaid related to this case and recorded a receivable of \$600,000 representing that the total amount of these fees would be paid by the Company's insurance carrier. The \$600,000 accrual is included as a component of accrued expenses and other current liabilities and the \$600,000 receivable is included as a component of other receivables, net on the March 31, 2004 Summary Consolidated Balance Sheet. The Company believes that the receivable will be fully collectible.

Shareholder Derivative Action

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names 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 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. As previously disclosed, the Company's Board of Directors has established an independent committee to investigate the allegations of Ms. Lichtenberger and Mr. Frailey. The independent committee engaged independent legal counsel to assist in the investigation, which culminated in a report by the committee concluding that no officer or director breached any fiduciary duty. In October 2003 the two derivative suits were consolidated into one action in the Superior Court of Fulton County, and a consolidated amended complaint was filed. The independent committee, along with its independent legal counsel, evaluated the consolidated amended complaint and concluded that its prior report and determination addressed the material allegations contained in the consolidated amended complaint. The committee reiterated its previous conclusions and determinations, including that maintaining the derivative litigation is not in the best interests of the Company. At this time, the Company is unable to predict the outcome of this litigation. Although the derivative suit is brought nominally on behalf of the Company, the Company expects to continue to incur defense costs and other expenses in connection with the derivative litigation.

SEC Investigation

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

Other Litigation

>In October 2003 an action was filed against multiple defendants, including the Company, titled Donald Payne and Candace Payne v. Community Blood Center, et al, in the Circuit Court of the State of Oregon, County of Multnomah, seeking noneconomic damages of \$9.0 million and other damages of \$4.7 million. The suit alleges that Mr. Payne received a tissue implant processed by one of the other defendants, and that he was subsequently diagnosed with an infection attributed to the implant. The claim against the Company asserts that CryoLife had processed tissue from the same donor and been notified that a recipient of that tissue had contracted the same virus, and further asserts that the Company had a duty to notify governmental authorities and two of the other defendants. A second action, titled L.L.R. and W.C.R. v. Community Blood Center, et al, was filed in October 2003 in the same court as the Payne case, against the same defendants, seeking the same amounts of damages. In this case the plaintiffs allege the recipient received an implant processed by the same co-defendant tissue processor, from the same donor as Mr. Payne, and contracted an infection. A tentative trial date for these actions has been set for November 22, 2004. The Company intends to vigorously defend against these claims, although the Company is presently unable to predict the outcome.

Item 2. Changes in Securities, Use of Proceeds, and Issuer Purchases of Securities.

In the quarter ended March 31, 2004 the Company issued 3,444,000 shares of unregistered common stock at a price of \$6.25 per share to certain accredited institutional investors. The sale closed on January 27, 2004 with an aggregate offering price of \$21,525,000. The net proceeds from the sale of approximately \$19.9 million, after commissions, registration fees, and other related charges will be used for general corporate purposes. Piper Jaffray & Co. served as the exclusive placement agent for the equity financing and received a commission of \$1,506,750. The issuance of these securities was exempt from registration under the Securities Act in reliance on Regulation D and Section 4(2) of the Securities Act as the offering was conducted by a means not involving any general solicitation and was offered only to accredited investors. On February 10, 2004 the Company filed a Registration Statement on Form S-3 (Commission File No. 333-112673) with the SEC covering the resale of the shares by the investors. Further information regarding the sale by CryoLife to the accredited investors, including details of the shares purchased and the identities of the purchasers, is set forth in the Form S-3.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Submission of Matters to a Vote of Security Holders.

None

Item 5. Other information.

None.

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

- (a) The exhibit index can be found below.

<u>Exhibit Number</u>	<u>Description</u>
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).
10.1	Form of Stock Purchase Agreement between CryoLife, Inc. and Investors. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Commission on January 26, 2004.)
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.

* Filed herewith.

(b) Current Reports on Form 8-K.

The Registrant filed a Current Report on Form 8-K with the Commission on January 7, 2004 with respect to the Press Release dated January 7, 2004 announcing the registrant's revenues for the year ending December 31, 2003.

The Registrant filed a Current Report on Form 8-K with the Commission on January 26, 2004 with respect to the Press Release dated January 26, 2004 announcing a \$20 million private placement of the registrant's common stock.

The Registrant filed a Current Report on Form 8-K with the Commission on February 9, 2004 with respect to the Press Release dated February 6, 2004 announcing an update on its 510K premarket notification for CryoValve SG decellularized human heart valves.

The Registrant filed a Current Report on Form 8-K with the Commission on February 26, 2004 with respect to the Press Release dated February 26, 2004 announcing the registrant's results of operations for the quarter ended December 31, 2003.

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

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

May 13, 2004

DATE

CERTIFICATIONS

I, Steven G. Anderson, Chairman, President, and Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: May 13, 2004

/s/ STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer

I, David Ashley Lee, Vice President, Treasurer, and Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: May 13, 2004

/s/ DAVID ASHLEY LEE
Vice President, Treasurer, and
Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of CryoLife Inc. (the "Company") on Form 10-Q for the quarter ending March 31, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Steven G. Anderson, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Vice President, Treasurer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN G. ANDERSON
STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer
May 13, 2004

/s/ DAVID ASHLEY LEE
DAVID ASHLEY LEE
Vice President, Treasurer, and
Chief Financial Officer
May 13, 2004