

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 September 30, 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.)
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1655 Roberts Boulevard, NW
Kennesaw, Georgia 30144
(Address of principal executive offices)
(zip code)

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

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

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

YES X NO _____

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

YES X NO _____

The number of shares of common stock, par value \$0.01 per share, outstanding on October 29, 2004 was 23,332,773.

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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)	(Unaudited)		
Revenues:				
Products	\$ 9,151	\$ 6,831	\$ 27,213	\$ 20,362
Human tissue preservation services	6,955	8,097	19,234	25,842
Research grants	12	169	71	526
	-----	-----	-----	-----

Total revenues	16,118	15,097	46,518	46,730
Costs and expenses:				
Products	1,998	1,782	5,839	5,429
Human tissue preservation services (Including write-downs of \$1,236 for the three months and \$6,394 for the nine months ended September 30, 2004 and \$1,752 for the three months and \$3,180 for the nine months ended September 30, 2003)	7,124	7,481	23,770	15,084
General, administrative, and marketing	12,127	10,575	31,968	45,706
Research and development	904	823	2,716	2,828
Interest expense	54	87	156	366
Interest income	(71)	(101)	(201)	(348)
Other (income) expense, net	(10)	(94)	27	46
Total costs and expenses	22,126	20,553	64,275	69,111
Loss before income taxes	(6,008)	(5,456)	(17,757)	(22,381)
Income tax (benefit) expense	--	(761)	(1,371)	2,669
Net loss	\$ (6,008)	\$ (4,695)	\$ (16,386)	\$ (25,050)
Net loss per share:				
Basic	\$ (0.26)	\$ (0.24)	\$ (0.72)	\$ (1.27)
Diluted	(0.26)	\$ (0.24)	\$ (0.72)	\$ (1.27)
Weighted average shares outstanding:				
Basic	23,287	19,701	22,928	19,669
Diluted	23,287	19,701	22,928	19,669

See accompanying notes to summary consolidated financial statements.

Item 1. Financial Statements.

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

	September 30, 2004	December 31, 2003
	----- (Unaudited) -----	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 11,427	\$ 5,672
Marketable securities, at market	3,206	5,272
Restricted cash and securities	560	972
Trade receivables, net	8,938	6,377
Other receivables	1,505	1,865
Deferred preservation costs, net	8,038	8,811
Inventories	4,829	4,450
Prepaid expenses and other assets	3,395	2,344
Total current assets	----- 41,898	----- 35,763
Property and equipment, net	29,719	32,886
Patents, net	5,010	5,244
Other	1,898	1,134
TOTAL ASSETS	----- \$ 78,525	----- \$ 75,027
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,663	\$ 2,171
Accrued expenses and other current liabilities	11,756	11,570
Accrued compensation	1,400	1,136

Accrued procurement fees	2,687	4,358
Notes payable	1,197	--
Current maturities of capital lease obligations	1,435	1,738
	-----	-----
Total current liabilities	21,138	20,973
	-----	-----
Capital lease obligations, less current maturities	601	751
Other long-term liabilities	5,166	4,965
	-----	-----
Total liabilities	26,905	26,689
	-----	-----
Shareholders' Equity:		
Preferred stock	--	--
Common stock (24,696 issued shares in 2004 and 21,130 shares in 2003)	247	211
Additional paid-in capital	94,269	74,460
Retained deficit	(35,894)	(19,508)
Deferred compensation	--	(9)
Accumulated other comprehensive income	257	365
Less: Treasury stock at cost (1,382 shares in 2004 and 1,371 shares in 2003)	(7,259)	(7,181)
	-----	-----
Total shareholders' equity	51,620	48,338
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 78,525	\$ 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)

	Nine Months Ended September 30,	
	2004	2003
	(Unaudited)	
Net cash from operating activities:		
Net loss	\$ (16,386)	\$ (25,050)
Adjustments to reconcile net loss to net cash from operating activities:		
Gain on sale of marketable equity securities	--	(19)
Loss (Gain) on sale of assets	24	(80)
Depreciation and amortization	4,121	4,136
Provision for doubtful accounts	72	72
Write-down of deferred preservation costs and inventory	6,575	3,180
Other non-cash adjustments to income	8	328
Deferred income taxes	--	5,708
Tax effect of nonqualified option exercises	54	19
Changes in operating assets and liabilities:		
Receivables	(5,106)	(334)
Income taxes	2,404	8,320
Deferred preservation costs and inventories	(6,181)	(8,864)
Prepaid expenses and other assets	1,599	1,379
Accounts payable, accrued expenses, and other liabilities	893	10,860
	-----	-----
Net cash used in operating activities	(11,923)	(345)
	-----	-----
Net cash from investing activities:		
Capital expenditures	(697)	(456)
Net proceeds from sale of assets	--	1,080
Other assets	2	188
Purchases of marketable securities	(560)	--
Sales and maturities of marketable securities	2,000	4,699
	-----	-----
Net cash provided by investing activities	745	5,511
	-----	-----
Net cash from financing activities:		

Principal payments of debt	--	(5,600)
Payment of obligations under capital leases	(530)	(485)
Principal payments on short-term note payable	(2,188)	(1,642)
Proceeds from exercise of stock options and issuance of common stock	349	475
Proceeds from equity offering	19,364	--
	-----	-----
Net cash provided by (used in) financing activities	16,995	(7,252)
	-----	-----
Increase (Decrease) in cash and cash equivalents	5,817	(2,086)
Effect of exchange rate changes on cash	(62)	(12)
Cash and cash equivalents, beginning of period	5,672	10,277
	-----	-----
Cash and cash equivalents, end of period	\$ 11,427	\$ 8,179
	=====	=====

See accompanying notes to summary consolidated financial statements.

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

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited summary consolidated financial statements have been prepared in accordance with (i) accounting principles generally accepted in the United States for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the United States Securities and Exchange Commission ("SEC"). Accordingly, the statements do not include all of the information and disclosures required by accounting principles generally accepted in the United States for a complete presentation of financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 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 services revenues as compared to preservation revenues prior to the FDA Order, subsequent FDA activity, and related events (discussed in Note 2),
- o The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,
- o An expected use of cash related to the defense and resolution of lawsuits and claims (discussed in Note 12), and
- o The legal and professional costs related to ongoing FDA compliance.

The Company believes anticipated revenue generation, expense management, and the Company's existing cash, cash equivalents, and marketable securities will enable the Company to meet its liquidity needs through September 30, 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 by improving yields and increasing prices,
- 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 and any other similar claims (discussed in Note 12), and
- o The outcome of other litigation against the Company (discussed in Note 12).

If the Company is unable to address these issues and continues to experience negative cash flows, the Company anticipates that it will require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond September 30, 2005. The Company may elect to obtain financing prior to that time depending on the availability and terms of the financing agreement. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

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

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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, and executed thereafter. The corrective actions taken have been reviewed by the FDA during three subsequent inspections as discussed in "Other FDA Correspondence and Notices" below.

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

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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.

OTHER FDA CORRESPONDENCE AND NOTICES

FDA Form 483 Notices of Observations ("483") 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, April 2004, and June 2004. On September 24, 2004 CryoLife received an inquiry from the FDA Atlanta District Office seeking additional information on four items submitted by CryoLife in response to the February 2004 483. CryoLife has been in discussion with the agency regarding this request and will submit its response in the fourth quarter of 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(R) SG and that premarket approval marketing authorization should be obtained for the Company's CryoVein(R) SG when marketed or labeled as an arteriovenous ("A-V") access graft. The agency's position is that use of the SynerGraft(R) technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

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. On August 24, 2004, the Company submitted an amendment to its original 510(k) submission providing clarification and additional

information to address the issues raised by the FDA. The FDA may still 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 CryoValve SG. On September 14, 2004, the Company met with the FDA to discuss the data to be used to support a Request for Designation ("RFD") filing for SynerGraft processed cardiovascular tissue, including the CryoVein SG. The Company submitted the RFD on October 5, 2004. 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 has 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. During the three months ended June 30, 2004, the Company wrote down \$353,000 in SynerGraft processed cardiovascular and vascular tissues. As of September 30, 2004 the Company had no additional deferred preservation costs related to SynerGraft processed tissues on its Summary Consolidated Balance Sheet.

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. As of December 31, 2003 all marketable securities were designated as available-for-sale. As of September 30, 2004 \$3.2 million of marketable securities were designated as available-for-sale and \$560,000 of marketable securities were designated as held-to-maturity. These securities were designated held-to-maturity due to a contractual commitment to hold the security as pledged collateral relating to one of the Company's product liability insurance policies.

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. Held-to-maturity securities are stated at amortized cost.

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

September 30, 2004	Cost Basis	Unrealized Holding Gains/(Losses)	Estimated Market Value

	(Unaudited)		
Cash equivalents:			
Money market funds	\$ 7,246	\$ --	\$ 7,246
Municipal obligations	775	--	775

	\$	8,021	\$	--	\$	8,021
=====						
Marketable securities:						
Municipal obligations	\$	3,140	\$	66	\$	3,206
=====						
Restricted Securities:						
Debt securities	\$	560	\$	--	\$	560
=====						
December 31, 2003						
		Cost Basis		Unrealized Holding Gains/(Losses)		Estimated Market Value

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 September 30, 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 \$23,000 at September 30, 2004 and \$42,000 at December 31, 2003, are included as a separate component of other comprehensive income in shareholders' equity.

As of September 30, 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 \$3.2 million and \$3.3 million, respectively, had a maturity date between 1 and 5 years. The restricted securities mature on April 1, 2005.

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NOTE 4 - INVENTORIES

Inventories are comprised of the following (in thousands):

		September 30, 2004		December 31, 2003

		(Unaudited)		
Raw materials	\$	2,998	\$	2,906
Work-in-process		303		229
Finished goods		1,528		1,315

	\$	4,829	\$	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 and nine months ended September 30, 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 as of December 31, 2002. For the three and nine months ended September 30, 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 September 30, 2004 the Company had a total of \$21.2 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

During the quarter ended June 30, 2004, the Company received income tax refunds of \$2.4 million related to federal income tax losses from the year ended December 31, 2003 that were carried back to prior years and \$1.4 million related to product liability expenses incurred in 2003. The Company did not record a receivable for the \$1.4 million carryback in prior periods due to uncertainty regarding its realizability.

NOTE 6 - DEBT

On April 25, 2000 the Company entered into a loan agreement permitting the Company to borrow up to \$8.0 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. 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 related to the Term Loan. This \$199,000 payment represented the estimated fair value of the interest rate swap, as estimated by the lender based on its internal valuation models, as of the day of the termination of the agreement.

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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 Company insurance policies. The amount financed accrued interest at a 3.75% rate and was payable in equal monthly payments through December 2003. As of September 30, 2004 the outstanding balance of the agreements was zero and there are no available borrowings under this agreement.

In April 2004 the Company entered into two agreements to finance approximately \$1.9 million and \$1.5 million, respectively, in insurance premiums associated with the yearly renewal of certain Company 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 of September 30, 2004 the aggregate outstanding balance under the agreements was \$1.2 million.

NOTE 7 - 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 \$19.4 million, after commissions, filing fees, late

registration fees, and other related charges for general corporate purposes. 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 paid a total of \$466,000 in late registration penalties to the investors through May 18, 2004, the date the registration statement was declared effective. This amount was deducted from the PIPE proceeds in recording net proceeds from the PIPE in shareholders' equity.

NOTE 8 - COMPREHENSIVE LOSS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
Net loss	\$ (6,008)	\$ (4,695)	\$ (16,386)	\$ (25,050)
Unrealized loss on investments	(6)	(23)	(38)	(84)
Change in fair value of interest rate swap	--	--	--	172
Translation adjustment	(20)	9	(70)	(22)
Comprehensive loss	\$ (6,034)	\$ (4,709)	\$ (16,494)	\$ (24,984)

The tax effect on the change in unrealized gain/loss on investments is a benefit of \$3,000 and \$14,000 for the three months ended September 30, 2004 and September 30, 2003, respectively. The tax effect on the change in unrealized gain/loss on investments is a benefit of \$20,000 and \$48,000 for the nine months ended September 30, 2004 and September 30, 2003, respectively. The tax effect on the change in fair value of the interest rate swap is zero for both the three months ended September 30, 2004 and September 30, 2003. The tax effect on the change in fair value of the interest rate swap is zero and \$88,000 for the nine months ended September 30, 2004 and September 30, 2003, respectively. The tax effect on the translation adjustment is zero for both the three months ended September 30, 2004 and September 30, 2003. The tax effect on the translation adjustment is zero and \$110,000 for the nine months ended September 30, 2004 and September 30, 2003, respectively.

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

	September 30, 2004	December 31, 2003
	(Unaudited)	
Unrealized gain on investments	\$ 47	\$ 85
Translation adjustment	210	280
Total accumulated other comprehensive income	\$ 257	\$ 365

NOTE 9 - 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 September 30,		Nine Months Ended September 30,	
2004	2003	2004	2003
(Unaudited)		(Unaudited)	

Numerator for basic and diluted loss per share - loss available to common shareholders	\$ (6,008)	\$ (4,695)	\$ (16,386)	\$ (25,050)
Denominator for basic loss per share - weighted-average basis	23,287	19,701	22,928	19,669
Effect of dilutive stock options	--	--	--	--
Denominator for diluted loss per share - adjusted weighted-average shares	23,287	19,701	22,928	19,669
Net loss per share:				
Basic	\$ (0.26)	\$ (0.24)	\$ (0.72)	\$ (1.27)
Diluted	\$ (0.26)	\$ (0.24)	\$ (0.72)	\$ (1.27)

Since the Company had a net loss for the three and nine month periods ended September 30, 2004 and September 30, 2003, all potentially dilutive securities are anti-dilutive for those periods. During those periods, the Company had outstanding stock options that are considered potentially dilutive securities and would have resulted in additional dilutive shares of 325,000 and 419,000 for the three months ended September 30, 2004 and September 30, 2003, respectively, and 353,000 and 438,000 for the nine months ended September 30, 2004 and September 30, 2003, respectively, pursuant to the provisions of SFAS 128.

NOTE 10 - 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 loss and net loss 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:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	.589	.589	.600	.611
Risk-free interest rate	3.13%	2.36%	3.54%	2.40%
Expected life of options	3.7 Years	3.1 Years	4.4 Years	3.8 Years

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
Net loss--as reported	\$ (6,008)	\$ (4,695)	\$ (16,386)	\$ (25,050)
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of tax	189	204	1,195	1,109
Net loss--pro forma	\$ (6,197)	\$ (4,899)	\$ (17,581)	\$ (26,159)
Loss per share--as reported:				
Basic	\$ (0.26)	\$ (0.24)	\$ (0.72)	\$ (1.27)
Diluted	\$ (0.26)	\$ (0.24)	\$ (0.72)	\$ (1.27)
Loss per share--proforma				
Basic	\$ (0.27)	\$ (0.25)	\$ (0.77)	\$ (1.33)
Diluted	\$ (0.27)	\$ (0.25)	\$ (0.77)	\$ (1.33)

NOTE 11 - SEGMENT INFORMATION

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

The Implantable Medical Devices segment includes external revenue from product sales of BioGlue(R) Surgical Adhesive, bioprosthetic devices, including stentless porcine heart valves and SynerGraft treated bovine vascular grafts. The Human Tissue Preservation Services segment includes external revenue from cryopreservation services of cardiac, vascular, and orthopaedic allograft tissues. 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 products and preservation services. The Company does not segregate assets by segment, therefore, asset information is excluded from the segment disclosures below.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
Revenue:				
Implantable medical devices	9,151	6,831	27,213	20,362
Human tissue preservation services	6,955	8,097	19,234	25,842
All other a	12	169	71	526
	\$ 16,118	\$ 15,097	\$ 46,518	\$ 46,730
Cost of Products and Preservation Services:				
Implantable medical devices	1,998	1,782	5,839	5,429
Human tissue preservation services	7,124	7,481	23,770	15,084
All other a	--	--	--	--
	9,122	9,263	29,609	20,513
Gross Margin (Loss):				
Implantable medical devices	7,153	5,049	21,374	14,933
Human tissue preservation services	(169)	616	(4,536)	10,758
All other a	12	169	71	526

\$ 6,996 \$ 5,834 \$ 16,909 \$ 26,217

a The "All other" designation includes grant revenue.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(Unaudited)		(Unaudited)	
Revenue:				
BioGlue surgical adhesive	\$ 8,914	\$ 6,694	\$ 26,519	\$ 20,027
Other implantable medical devices	237	137	694	335
Human tissue preservation services:				
Cardiovascular tissue	3,476	4,547	9,737	14,308
Vascular tissue	2,636	3,083	7,771	10,637
Orthopaedic tissue	843	467	1,726	897
Total preservation services	6,955	8,097	19,234	25,842
Research grants	12	169	71	526
	\$ 16,118	\$ 15,097	\$ 46,518	\$ 46,730

NOTE 12 - 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 November 3, 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, four allege product liability claims arising out of

the Company's orthopaedic tissue services, four allege product liability claims arising out of the Company's allograft heart valve tissue services, one alleges product liability claims arising from BioGlue, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, Inc. 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, one by the 2003/2004 insurance policy and one by the 2004/2005 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 two remaining suits filed during this period. As of September 30, 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 and 2004/2005 insurance policies to be adequate to defend against the covered suit filed during each of these time periods.

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 September 30, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of September 30, 2004 the Company had accrued a total of \$1.8 million for pending product liability claims and recorded zero representing amounts to be recovered from the Company's insurance carriers. The \$1.8 million accrual is included as a component of accrued expenses and other current

liabilities on the September 30, 2004 Summary Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses related to six of the ten pending product liability claims. The Company has not recorded an accrual for the remaining four product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. Prior to 2004, 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. This policy is 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. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products sold. In July 2004,

the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2004 and December 31, 2004. 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 experiences and industry data,
- o The frequency of unreported claims for accident years 2001 through 2004 would be lower than the Company experienced during the 2002/2003 policy year, but higher than the Company's historical claim frequency

- o 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,
- o The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
- o The number of BioGlue claims per million dollars of BioGlue revenue would be 10% lower than non-BioGlue claims per million dollars to adjust for the increase of BioGlue revenue as a percentage of total revenues since 2002 and the BioGlue claims history to date.

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 and 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.

Beginning April 1, 2004 and concurrent with signing the claims-made insurance policy for the policy year from April 1, 2004 to March 31, 2005, the Company implemented the provisions of Emerging Issues Task Force Issue 03-8, Accounting for Claims-Made Insurance and Retroactive Contracts by the Insured Entity ("EITF 03-8"). Pursuant to EITF 03-8, the Company continues to record an estimated liability for unreported product liability claims and has begun to record a related recoverable from insurance. Prior to the effective date of EITF 03-8, the Company did not record a recoverable from insurance related to the unreported product liability claims.

Based on the actuarial valuation performed in July 2004 as of June 30, 2004 and December 31, 2004, the Company estimated that its liability for unreported product liability claims was \$8.0 million as of June 30, 2004 and would be \$8.7 million as of December 31, 2004. In accordance with EITF 03-8, the Company has accrued a prorated amount of \$8.4 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2004. The \$8.4 million balance is included as a component of accrued expenses and other current liabilities of \$4.3 million and other long-term liabilities of \$4.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$14.6 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2004, \$1.8 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.8 million insurance recoverable is included as a component of other receivables of \$700,000 and other assets of \$1.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries related to unreported product liability claims related to services performed and products sold prior to September 30, 2004. Actual results may differ from this estimate.

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, that principally alleges that the Company made misrepresentations and omissions relating to product safety and the Company did not comply 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 is in the expert 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 September 30, 2004 the Company had accrued \$571,000 for legal fees incurred but unpaid related to this case and recorded an asset of \$571,000 representing the anticipated recovery of these fees from the Company's insurance carrier. The \$571,000 accrual is included as a component of accrued expenses and other current liabilities and the \$571,000 insurance receivable is included as a component of other receivables, net on the September 30, 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. Based on the report of the independent committee, the Company moved to dismiss the derivative litigation in May 2004. That motion remains pending. 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 regarding 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 alleged 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 asserted 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 that the Company had a duty to notify governmental authorities and 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 alleged the recipient received an implant processed by the same co-defendant tissue processor, from the same donor as Mr. Payne, and contracted an infection. In late July 2004 a third action was filed against multiple defendants, including the Company, titled Anthony F. Spadaro v. Community Blood Center, et al., in the same court as the other two cases, seeking noneconomic damages of \$6.0 million, \$1.7 million in economic damages, and punitive and exemplary damages. This suit alleged that Mr. Spadaro received a tissue implant processed by the same defendant tissue processor that was named in the other two suits, and that he was subsequently diagnosed with an infection attributed to the implant. This claim also asserted that the Company had processed tissue from the same donor and been notified that a recipient of the tissue had contracted the same virus, and that the Company had a duty to notify governmental authorities and the other defendants.

The trial for the Payne and L.L.R. cases began on October 18, 2004. CryoLife reached a settlement agreement with the plaintiffs on October 25, 2004 concerning the Payne, L.L.R. and Spadaro cases totaling \$3.0 million in the aggregate, which CryoLife agreed to pay no later than November 5, 2004. The Company did not have insurance coverage for these claims. The \$3.0 million is included in the Company's general, administrative and marketing expenses for the three months ended September 30, 2004. A cross-claim for indemnification by another defendant was dismissed earlier in the lawsuit because the claim is subject to a contractual obligation to arbitrate. As of the date of this filing, the arbitration clause has not been invoked by either party. Although the Company believes there are defenses it can assert against such a claim and would defend it vigorously, such a claim, if successfully brought, would not be insured and could have a material impact on the Company's liquidity and financial condition.

PART I - FINANCIAL INFORMATION

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

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, and executed thereafter. The corrective actions taken have been reviewed by the FDA during three subsequent inspections as discussed in "Other FDA Correspondence and Notices" below.

OTHER FDA CORRESPONDENCE AND NOTICES

FDA Form 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, April 2004, and June 2004. On September 24, 2004 CryoLife received an inquiry from the FDA Atlanta District Office seeking additional information on four items submitted by CryoLife in response to the February 2004 483. CryoLife has been in discussion with the agency regarding this request and will submit its response in the fourth quarter of 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(R) SG and that premarket approval marketing authorization should be obtained for the Company's CryoVein(R) SG when marketed or labeled as an arteriovenous ("A-V") access graft. The agency's position is that use of the SynerGraft(R) technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

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. On August 24, 2004, the Company submitted an amendment to its original 510(k) submission providing clarification and additional

information to address the issues raised by the FDA. The FDA may still 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 CryoValve SG. On September 14, 2004, the Company met with the FDA to discuss the data to be used to support a Request for Designation ("RFD") filing for SynerGraft processed cardiovascular tissue, including the CryoVein SG. The Company submitted the RFD on October 5, 2004. 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 has 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. During the three months ended September 30, 2004, the Company wrote down \$353,000 in SynerGraft processed cardiovascular and vascular tissues. As of September 30, 2004 the Company has no additional deferred preservation costs related to SynerGraft processed tissues on its Summary Consolidated Balance Sheet.

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.

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 November 3, 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, four allege product liability claims arising out of the Company's orthopaedic tissue services, four allege product liability claims arising out of the Company's allograft heart valve tissue services, one alleges product liability claims arising from BioGlue, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, Inc. 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, one by the 2003/2004 insurance policy and one by the 2004/2005 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 September 30, 2004 the Company had an accrual of \$100,000 for the remaining retention levels related to the 2000/2001 insurance policy year. The Company believes its 2003/2004 and 2004/2005 insurance policies to be adequate to defend against the covered suit filed during each of these time periods.

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 September 30, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of September 30, 2004 the Company had accrued a total of \$1.8 million for pending product liability claims and recorded zero representing amounts to be recovered from the Company's insurance carriers. The \$1.8 million accrual is included as a component of accrued expenses and other current liabilities on the September 30, 2004 Summary Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses and anticipated recoveries related to six of the ten pending product liability claims. The Company has not recorded an accrual for the remaining four product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. Prior to 2004, 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. This policy is 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. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims, and records accruals as necessary for the estimated cost of unreported claims related to services performed and products sold. In July 2004, the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2004 and December 31, 2004. 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 experiences and industry data,
- o The frequency of unreported claims for accident years 2001 through 2004 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,

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- o The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
- o The number of BioGlue claims per million dollars of BioGlue revenue would be 10% lower than non-BioGlue claims per million dollars to adjust for the increase of BioGlue revenue as a percentage of total revenues since 2002 and the BioGlue claims history to date.

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 and 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.

Beginning April 1, 2004 and concurrent with signing the claims-made insurance policy for the policy year from April 1, 2004 to March 31, 2005, the Company implemented the provisions of Emerging Issues Task Force Issue 03-8, Accounting for Claims-Made Insurance and Retroactive Contracts by the Insured Entity ("EITF 03-8"). Pursuant to EITF 03-8, the Company continues to record an estimated liability for unreported product liability claims and has begun to record a related recoverable from insurance. Prior to the effective date of EITF 03-8, the Company did not record a recoverable from insurance related to the unreported product liability claims.

Based on the actuarial valuation performed in July 2004 as of June 30, 2004 and December 31, 2004, the Company estimated that its liability for unreported product liability claims was \$8.0 million as of June 30, 2004 and would be \$8.7 million as of December 31, 2004. In accordance with EITF 03-8, the Company has accrued a prorated amount of \$8.4 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2004. The \$8.4 million balance is included as a component of accrued expenses and other current liabilities of \$4.3 million and other long-term liabilities of \$4.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$14.6 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2004, \$1.8 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.8 million insurance recoverable is included as a component of other receivables of \$700,000 and other assets of \$1.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries related to unreported product liability claims related to services performed and products sold prior to September 30, 2004. Actual results may differ from this estimate.

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. These costs are adjusted for differences between estimated and actual fees when invoices for these services are received. 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 estimate to all tissues in process and in quarantine to estimate the portion of tissues that will

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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 \$1.2 million and \$6.0 million, respectively, in the three and nine months ended September 30, 2004 and \$1.8 million and \$3.2 million, respectively, in the three and nine months ended September 30, 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 September 30, 2004 deferred preservation costs were \$2.6 million for allograft heart valve tissues, \$268,000 for non-valved cardiac tissues, \$2.6 million for vascular tissues, and \$2.5 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

and nine months ended September 30, 2004 primarily as a result of operating losses and expects to do so for the remainder of 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 as of December 31, 2002. For the three and nine months ended September 30, 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 September 30, 2004 the Company had a total of \$21.2 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of zero.

VALUATION OF LONG-LIVED AND INTANGIBLE ASSETS: The Company assesses the impairment of its long-lived, identifiable intangible assets annually and whenever events or changes in circumstances indicate that the carrying value may

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not be recoverable. Factors that management considers important that could trigger an impairment review include the following:

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

Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), requires the write-down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. In applying SFAS 144, the Company defined the specific asset groups used to perform the cash flow analysis. The Company defined the asset groups at the lowest level possible, by identifying the cash flows from groups of assets that could be segregated from the cash flows of other assets and liabilities. Using this methodology, the Company determined that its asset groups consisted of the long-lived assets related to the Company's two reporting segments. As the Company does not segregate assets by segment, the Company allocated assets to the two reporting segments based on factors including facility space and revenues. The Company used an eleven-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 September 30, 2004 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 September 30, 2004 the Company did not believe that an impairment existed related to the other intangible assets that were assessed in accordance with SFAS No. 144.

NEW ACCOUNTING PRONOUNCEMENTS

The Company was required to adopt EITF issue 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments" ("EITF 03-1"). The Company adopted the recognition and measurement guidance of EITF 03-1 for the interim period ending September 30, 2004 and will adopt the annual disclosure requirements for its year ended December 31, 2004. EITF 03-1 clarifies the definition of and accounting treatment for other-than-temporary losses on debt and equity investments. The adoption of EITF 03-1 did not have a material effect on the results of operations or financial position of the Company.

RESULTS OF OPERATIONS
(IN THOUSANDS)

REVENUES

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues	\$ 16,118	\$ 15,097	\$ 46,518	\$ 46,730

Revenues increased 7% and 0%, respectively, for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003. The 7% increase in revenues for the three month period was primarily due to an increase in revenues from sales of BioGlue Surgical Adhesive, partially offset by decreases in cardiovascular and vascular tissue preservation service revenues compared to the prior year quarter. Revenues for the nine month period ended September 30, 2004 included an increase in revenues from sales of BioGlue Surgical Adhesive and decreases in cardiovascular and vascular tissue preservation service revenues compared to the prior year period.

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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues	\$ 8,914	\$ 6,694	\$ 26,519	\$ 20,027
BioGlue revenues as a percentage of total revenue	55%	44%	57%	43%

Revenues from the sale of BioGlue Surgical Adhesive increased 33% and 32%, respectively, for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003. The 33% increase in revenues for the three months ended September 30, 2004 was primarily due to an increase in average selling prices which increased revenues by 24%, and an

increase in BioGlue sales volume as a result of an increase in foreign and domestic demand which increased revenues by 9%. The 32% increase in revenues for the nine months ended September 30, 2004 was primarily due to an increase in average selling prices which increased revenues by 18%, and an increase in BioGlue sales volume as a result of an increase in foreign and domestic demand which increased revenues by 14%.

The Company experienced volume increases in the 2ml, 5ml, and 10ml sizes as well as BioGlue applicator tips and delivery devices in the nine months ended September 30, 2004. The Company introduced a new BioGlue syringe product in the second quarter of 2004, which resulted in volume growth in both the three and nine months ended September 30, 2004. Price increases in the three and nine months ended September 30, 2004 were largely due to list price increases for BioGlue that went into effect on December 1, 2003 domestically and in early 2004 internationally. Domestic revenues accounted for 78% of total BioGlue revenues for each of the three and nine month periods ended September 30, 2004, compared to 75% and 77%, respectively, of total BioGlue revenues for the three and nine months ended September 30, 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 domestic and foreign increases in sales volume and previously implemented price increases.

CARDIOVASCULAR PRESERVATION SERVICES

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues	\$ 3,476	\$ 4,547	\$ 9,737	\$ 14,308
Cardiovascular revenues as a percentage of total revenue	22%	30%	21%	31%

Revenues from cardiovascular preservation services decreased 24% and 32%, respectively, for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003. The 24% decrease in revenues for the three months ended September 30, 2004 was due to a decrease in cardiovascular volume, which reduced revenues by 23%, and a decrease in average service fees, which reduced revenues by 1%. The 32% decrease in revenues for the nine months ended September 30, 2004 was due to a decrease in cardiovascular volume, which reduced revenues by 22%, and a decrease in average service fees, which reduced revenues by 10%. Revenues for the nine months ended September 30, 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.

The volume decrease for the three months ended September 30, 2004 was largely due to a decrease in shipments of cryopreserved heart valves, which declined 26% over the prior year period. The volume decrease for the nine months ended September 30, 2004 was largely due to a decrease in shipments of cryopreserved heart valves, which declined 31% over the prior year period, partially offset by increases in shipments of non-valved cardiac tissues. 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 and 2004 as compared to prior to the FDA Order, 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 September 2003. Price decreases attributable to the suspension of SynerGraft processing were partially offset by an increase in average service fees due to a fee increase that went into effect in July 2004.

The Company's procurement of cardiac tissues during the three months ended September 30, 2004, from which heart valves and non-valved cardiac tissues are processed, decreased 14% as compared to the three months ended September 30, 2003. Procurement of cardiac tissues during the three months ended September 30, 2004 decreased 7% as compared to the three months ended June 30, 2004. Procurement of cardiac tissues remains significantly below procurement in the second quarter of 2002, prior to the FDA Order.

The Company anticipates that cardiovascular service revenues will be lower for the full year 2004 as compared to 2003. The previously implemented price increase is expected to be a factor in increasing revenues during the fourth quarter of 2004 as compared to the fourth quarter of 2003. 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 Other FDA Correspondence and Notices in February 2003, the Company has 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.

VASCULAR PRESERVATION SERVICES

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues	\$ 2,636	\$ 3,083	\$ 7,771	\$ 10,637
Vascular revenues as a percentage of total revenue	16%	20%	17%	23%

Revenues from vascular preservation services decreased 14% and 27%, respectively, for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003. The 14% decrease in revenues for the three months ended September 30, 2004 was due to a decrease in vascular volume, which reduced revenues by 28%, partially offset by an increase in average service fees, which increased revenues by 14%. The 27% decrease in revenues for the nine months ended September 30, 2004 was due to a decrease in vascular volume, which reduced revenues by 31%, partially offset by an increase in average service fees, which increased revenues by 4%. Revenues for the nine months ended September 30, 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 and femoral veins, which declined 28% and 33%, respectively, for the three and nine months ended September 30, 2004 over the prior year periods. The decrease in vein shipments was directly related to the reduced amount of tissues available for implantation due to a reduction in procurement levels during 2003 and 2004 as compared to prior to the FDA Order, the disposal of much of the Company's vascular 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 increases were largely due to an increase in average service fees due to a fee increase that went into effect in July 2004.

The Company's procurement of vascular tissues during the three months ended September 30, 2004 decreased 37% as compared to the three months ended September 30, 2003. Procurement of vascular tissues during the three months ended September 30, 2004 decreased 7% as compared to the three months ended June 30, 2004. Procurement of vascular tissues remains significantly below procurement in the second quarter of 2003, prior to the FDA Order.

The Company anticipates that vascular service revenues will be lower for the full year 2004 as compared to 2003. The previously implemented price increases are expected to be a factor in increasing revenues during the fourth quarter of 2004 as compared to the fourth quarter of 2003. 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, to increase 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 Other FDA Correspondence and Notices the Company has 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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenues	\$ 843	\$ 467	\$ 1,726	\$ 897
Orthopaedic revenues as a percentage of total revenue	5%	3%	4%	2%

Revenues from orthopaedic preservation services increased 81% and 92%, respectively, for the three and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 2003. Revenues in both periods were significantly below pre-FDA Order levels 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 nine months ended September 30, 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. During the three and nine months ended September 30, 2004, the Company distributed both boned and non-boned orthopaedic tissues.

The Company's procurement of orthopaedic tissues during the three months ended September 30, 2004 increased 64% as compared to three months ended September 30, 2003. Procurement of orthopaedic tissues during the three months ended September 30, 2004 increased 8% as compared to the three months ended June 30, 2004. Procurement of orthopaedic tissues remains significantly 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, an expected improvement in yields of implantable tissues, and the anticipated uninterrupted processing and shipping of orthopaedic tissue. 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 were \$12,000 and \$71,000, respectively, for the three and nine months ended September 30, 2004 as compared to \$169,000 and \$526,000 for the three and nine months ended September 30, 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 \$2.0 million and \$5.8 million, respectively, for the three and nine months ended September 30, 2004, representing 22% and 21%, respectively of total product revenues during such periods. Cost of products

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aggregated \$1.8 million and \$5.4 million, respectively, for the three and nine months ended September 30, 2003, representing 26% and 27%, respectively, of total product revenues during such periods. The decrease in cost of products as a percentage of total product revenues for the three and nine months ended September 30, 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 and by increasing margins on BioGlue Surgical Adhesive due to increased manufacturing throughput.

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 decreased 5% to \$7.1 million for the three months ended September 30, 2004 as compared to \$7.5 million for the three months ended September 30, 2003, representing 102% and 92%, respectively, of total human tissue preservation service revenues during such periods. Cost of human tissue preservation services increased 58% to \$23.8 million for the nine months ended September 30, 2004 as compared to \$15.1 million for the nine months ended September 30, 2003, representing 124% and 58%, respectively, of total human tissue preservation service revenues during such periods.

Cost of human tissue preservation services for the three and nine months ended September 30, 2004 includes an increase to cost of preservation services to adjust the value of certain deferred tissue preservation costs that exceeded market value of \$1.2 million and \$6.0 million, respectively, and \$353,000 in costs related to the write-down of SynerGraft processed tissues for the nine months ended September 30, 2004. Cost of human tissue preservation services for the three and nine months ended September 30, 2004 includes the favorable effect on gross margin of shipments of tissue with a zero cost basis of approximately \$189,000 and \$719,000, respectively 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 and nine months ended September 30, 2003 includes an

increase to cost of preservation services to adjust the value of certain deferred tissue preservation costs that exceeded market value of \$1.8 million and \$3.2 million, respectively, and the favorable effect on gross margin of shipments of tissue with a zero cost basis of approximately \$791,000 and \$4.2 million, respectively, 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 and nine months ended September 30, 2004 by higher overhead cost allocations per unit 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 and nine months ended September 30, 2004 as compared to the three and nine months ended September 30, 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. In the second and third quarter of 2004 the Company made changes to its processing methods, which improved its yields of implantable tissue per donor quarter over quarter in the third and second quarters of 2004. The Company will continue to make efforts to improve yields of implantable tissue per donor throughout the remainder of 2004. Continued improved yields of implantable tissue per donor as a result of these processing changes cannot be assured. 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 increased 15% to \$12.1 million for the three months ended September 30, 2004, compared to \$10.6 million for the three months ended September 30, 2003, representing 75% and 70%, respectively, of total revenues during such periods. General, administrative, and marketing expenses decreased 30% to \$32.0 million for the nine months ended September 30, 2004, compared to \$45.7 million for the nine months ended September 30, 2003, representing 69% and 98%, respectively, of total revenues during such periods. The increase in expense for the three months ended September 30, 2004 is primarily due to the accrual of additional legal expenses of \$2.4 million (see Legal Proceedings at Part II Item 1 for further discussion of these items), partially offset by a decrease in professional service fees (legal, consulting, and accounting) of approximately \$500,000. The decrease in expenses for the nine months ended September 30, 2004 was primarily due to legal accruals in the prior year periods that exceeded accruals in the current year periods by \$11.1 million, and a reduction in professional service fees (legal, consulting, and accounting) of approximately \$3.3 million, partially offset by an increase in insurance costs of \$875,000.

The Company expects to continue to incur significant legal costs and professional fees, as compared to pre-FDA Order periods, to defend and resolve

lawsuits filed against the Company and to address FDA compliance requirements.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses were \$904,000 for the three months ended September 30, 2004, compared to \$823,000 for the three months ended September 30, 2003, representing 6% and 5%, respectively, of total revenues during such periods. Research and development expenses were \$2.7 million for the nine months ended September 30, 2004, compared to \$2.8 million for the nine months ended September 30, 2003, representing 6% of total revenues during each such period. 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 \$54,000 for the three months ended September 30, 2004, compared to \$87,000 for the three months ended September 30, 2003. Interest expense decreased to \$156,000 for the nine months ended September 30, 2004, compared to \$366,000 for the nine months ended September 30, 2003. Interest expense for the three and nine months ended September 30, 2004 and 2003 included interest incurred related to the Company's capital leases. Interest expense for the nine months ended September 30, 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 \$71,000 for the three months ended September 30, 2004, compared to \$101,000 for the three months ended September 30, 2003. Interest income decreased to \$201,000 for the nine months ended September 30, 2004, compared to \$348,000 for the nine months ended September 30, 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 \$1.4 million for the nine months ended September 30, 2004 was due to the receipt of tax refunds related to product liability expenses incurred in 2003. The Company did not record a receivable for the \$1.4 million carryback in prior periods due to uncertainty regarding its realizability. The Company's income tax benefit of \$761,000 for the three months ended September 30, 2003 was due to the establishment of an income tax receivable for the carry back of operating losses and product liability expenses incurred during 2002. The Company's income tax expense of \$ 2.7 million for the nine months ended September 30, 2003 was due to the establishment of a valuation allowance against the Company's deferred tax assets of \$11.6 million, partially offset by income tax benefits, recorded at an effective income tax rate 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

As of September 30, 2004 net working capital (current assets of \$41.9 million less current liabilities of \$21.1 million) was \$20.7 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$14.8 million, with a current ratio of 2 to 1 at December 31, 2003. 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 have arisen out of working capital needs created by increasing costs of operations and settlements of litigation combined with losses incurred in the Company's tissue preservation services business. Operating results have also been negatively impacted by increases in general, administrative, and marketing costs over pre-FDA Order levels, as a result of legal and professional fees and litigation costs. For the nine months ended September 30, 2004 the Company funded these requirements primarily through sales and maturities of marketable securities and the proceeds of its equity financing, as discussed below.

OVERALL LIQUIDITY AND CAPITAL RESOURCES

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 \$19.4 million, after commissions, filing fees, late registration fees, and other related charges, for general corporate purposes. 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 paid a total of \$466,000 in late registration penalties to the investors through May 18, 2004, the date the registration statement was declared effective. This amount was deducted from the PIPE proceeds in recording net proceeds from the PIPE in shareholders' equity.

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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 services 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 high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and have decreased yields of implantable tissue per donor,
- o An expected use of cash related to the defense and resolution of lawsuits and claims, and
- o The legal and professional costs related to ongoing FDA compliance.

The Company believes anticipated revenue generation, expense management, and the Company's existing cash, cash equivalents, and marketable securities will enable the Company to meet its liquidity needs through September 30, 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 by improving yields and increasing prices,

- 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 and any other similar 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).

If the Company is unable to address these issues and continues to experience negative cash flows, the Company anticipates that it will require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond September 30, 2005. The Company may elect to obtain financing prior to that time depending on the availability and terms of the financing agreement. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

As discussed in Note 12 to the summary consolidated financial statements, as of September 30, 2004 the Company had accrued a total of \$4.8 million for pending product liability claims and other litigation. The \$4.8 million accrual 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 \$4.8 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 12 to the summary consolidated financial statements. In addition, the amount and timing of the resolution of the uninsured indemnification claim, if brought (see Part II. Item 1. Legal Proceedings), could have a material impact on the Company's financial condition and liquidity.

If the Company is unable to settle the outstanding claims, and any other similar claims that may be brought, for amounts within its ability to pay, or if one or more of the product liability lawsuits in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), 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 12 to the summary consolidated financial statements, as of September 30, 2004 the Company has \$8.4 million in an accrual for the estimated costs of unreported product liability claims related to services performed and products sold prior to September 30, 2004. The \$8.4 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 \$11.9 million for the nine months ended September 30, 2004, as compared to \$345,000 for the nine months ended September 30, 2003. The \$11.9 million of cash used in the nine months ended September 30, 2004 was primarily due to a decrease in revenues and an increase in cash expenditures, reflecting the long-term effect 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 and the Company's efforts to address the FDA's concerns. Spending, including the cost of employees and facilities was not sufficiently supported by cash received from revenues. Spending on general and administrative expenses including litigation settlement costs 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 nine months ended September 30, 2004, the Company's \$ 16.4 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 \$4.1 million in depreciation and amortization, a favorable \$6.6 million in write-downs for impairment of deferred preservation costs and inventories, an unfavorable \$5.1 million due to the timing differences between the recording of receivables and the actual receipt of cash and the receipt of income tax refunds of \$ 2.4 million in the second quarter of 2004, an unfavorable \$6.2 million due to the buildup of deferred preservation costs and inventories for which vendors and employees have already been paid, a favorable \$1.6 million primarily due to the timing differences associated with prepaid expenses and other assets, and a favorable \$893,000 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 deferred preservation costs and 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.

NET CASH FROM INVESTING ACTIVITIES

Net cash provided by investing activities was \$745,000 for the nine months ended September 30, 2004, as compared to \$5.5 million for the nine months ended September 30, 2003. The \$745,000 in current year cash provided was primarily due to \$1.4 million in cash generated from sales and maturities of marketable securities, net of purchases, partially offset by \$697,000 in capital expenditures.

NET CASH FROM FINANCING ACTIVITIES

Net cash provided by financing activities was \$17.0 million for the nine months ended September 30, 2004, as compared to net cash used of \$7.3 million for the nine months ended September 30, 2003. The \$17.0 million in current year cash provided was primarily due to \$19.4 million in proceeds from the Company's PIPE equity offering discussed above and \$349,000 in proceeds from the exercise of stock options, partially offset by \$2.7 million in principal payments on short-term notes payable and capital leases.

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	\$ 2,162	\$ 211	\$ 843	\$ 843	\$ 265	\$ --	\$ --
Operating Leases	24,651	623	2,360	2,112	2,068	2,108	15,380
Purchase Commitments	768	688	60	20	--	--	--
Litigation Settlement Oblig	3,325	3,275	50	--	--	--	--

Notes Payable	1,197	1,197	--	--	--	--	--
Total Contractual Obligations	\$ 32,103	\$ 5,994	\$ 3,313	\$ 2,975	\$ 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. 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 \$1.2 million due under these capital leases is reflected as a current liability on the Summary Consolidated Balance Sheets as of September 30, 2004. Additional capital lease obligations result from the lease of a building related to the Company's Ideas for Medicine, Inc. ("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 agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production.

The Company's litigation settlement obligations result from contractual agreements with plaintiffs to resolve outstanding legal matters through the payment of cash settlements.

The Company's notes payable result from the financing of insurance premiums associated with the yearly renewal of certain Company insurance policies.

CAPITAL EXPENDITURES

The Company expects that its capital expenditures for the full year 2004 will approximate its expenditures in 2003, which were approximately \$1 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.

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, expenses, 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.

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, subsequent FDA activity, and measures taken by the Company as a result, on anticipated 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 liability claims incurred but not reported;
- o Future costs of human tissue preservation services;
- o Changes in liquidity and capital resources;
- o Statements regarding the expected 2004 performance relative to that of 2003;
- o The Company's expectations regarding the adequacy of current financing arrangements;
- o Product demand and market growth; 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.

RISKS AND UNCERTAINTIES

The risks and uncertainties that might impact the forward-looking statements and could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows 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 Potential inability to reduce costs of processing tissues, to obtain increased yields of implantable tissue, and to increase fees for tissue preservation services;
- 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

- o 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 Sales prices for CryoLife shares on the New York Stock Exchange 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 September 30, 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 \$11.4 million and short-term investments in municipal obligations of \$3.2 million as of September 30, 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 September 30, 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 September 30, 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 November 3, 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, four allege product liability claims arising out of the Company's orthopaedic tissue services, four allege product liability claims arising out of the Company's allograft heart valve tissue services, one alleges product liability claims arising from BioGlue, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, Inc. 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, one by the 2003/2004 insurance policy and one by the 2004/2005 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 two remaining suits filed during this period. As of September 30, 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 and 2004/2005 insurance policies to be adequate to defend against the covered suit filed during each of these time periods.

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 September 30, 2004 of the pending product liability claims based on settlement negotiations to date and advice from counsel. As of September 30, 2004 the Company had accrued a total of \$1.8 million for pending product liability claims and recorded zero representing amounts to be recovered from the Company's insurance carriers. The \$1.8 million accrual is included as a component of accrued expenses and other current liabilities on the September 30, 2004 Summary Consolidated Balance Sheet. This amount represents the Company's estimate of the probable losses and anticipated

recoveries related to six of the ten pending product liability claims. The Company has not recorded an accrual for the remaining four product liability claims because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss cannot be made at this time. The amount recorded as a liability is reflective of estimated legal fees and settlement costs related to these claims and does not reflect actual settlement arrangements, actual judgments, including punitive damages, which may be assessed by the courts, or cash set aside for the purpose of making payments. 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 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. This policy is 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. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims, and records accruals as necessary for the estimated cost of unreported claims related to services performed and products sold. In July 2004, the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2004 and December 31, 2004. 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

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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 experiences and industry data,
- o The frequency of unreported claims for accident years 2001 through 2004 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,
 - o The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
 - o The number of BioGlue claims per million dollars of BioGlue revenue would be 10% lower than non-BioGlue claims per million dollars to adjust for the increase of BioGlue revenue as a percentage of total revenues since 2002 and the BioGlue claims history to date.

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 and 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.

Beginning April 1, 2004 and concurrent with signing the claims-made insurance policy for the policy year from April 1, 2004 to March 31, 2005, the Company implemented the provisions of Emerging Issues Task Force Issue 03-8, Accounting for Claims-Made Insurance and Retroactive Contracts by the Insured Entity ("EITF 03-8"). Pursuant to EITF 03-8, the Company continues to record an estimated liability for unreported product liability claims and has begun to record a related recoverable from insurance. Prior to the effective date of EITF 03-8, the Company did not record a recoverable from insurance related to the unreported product liability claims.

Based on the actuarial valuation performed in July 2004 as of June 30, 2004 and December 31, 2004, the Company estimated that its liability for unreported product liability claims was \$8.0 million as of June 30, 2004 and would be \$8.7 million as of December 31, 2004. In accordance with EITF 03-8, the Company has accrued a prorated amount of \$8.4 million, representing the Company's best estimate of the total liability for unreported product liability claims related to services performed and products sold prior to September 30, 2004. The \$8.4 million balance is included as a component of accrued expenses and other current liabilities of \$4.3 million and other long-term liabilities of \$4.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$14.6 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of September 30, 2004, \$1.8 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.8 million insurance recoverable is included as a component of other receivables of \$700,000 and other assets of \$1.1 million on the September 30, 2004 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries related to unreported product liability claims related to services performed and products sold prior to September 30, 2004. Actual results may differ from this estimate.

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 is in the expert 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 September 30, 2004 the Company had accrued \$571,000 for legal fees incurred but unpaid related to this case and recorded an asset of \$571,000 representing the anticipated recovery of these fees from the Company's insurance carrier. The \$571,000 accrual is included as a component of accrued expenses and other current liabilities and the \$571,000 insurance receivable is included as a component of other receivables, net on the September 30, 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. Based on the report of the independent committee, the Company moved to dismiss the derivative litigation in May 2004. That motion remains pending. 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 alleged 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 asserted 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 that the Company had a duty to notify governmental authorities and 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 alleged the recipient received an implant processed by the same co-defendant tissue processor, from the same donor as Mr. Payne, and contracted an infection. In late July 2004 a third action was filed against multiple defendants, including the Company, titled Anthony F. Spadaro v. Community Blood Center, et al., in the same court as the other two cases, seeking noneconomic damages of \$6.0 million, \$1.7 million in economic damages, and punitive and exemplary damages. This suit alleged that Mr. Spadaro received a tissue implant processed by the same defendant tissue processor that was named in the other two suits, and that he was subsequently diagnosed with an infection attributed to the implant. This claim also asserted that the Company had processed tissue from the same donor and been notified that a recipient of the tissue had contracted the same virus, and that the Company had a duty to notify governmental authorities and the other defendants.

The trial for the Payne and L.L.R. cases began on October 18, 2004. CryoLife reached a settlement agreement with the plaintiffs on October 25, 2004 concerning the Payne, L.L.R. and Spadaro cases totaling \$3.0 million in the aggregate, which CryoLife agreed to pay no later than November 5, 2004. The Company did not have insurance coverage for these claims. The \$3.0 million is included in the Company's general, administrative and marketing expenses for the three months ended September 30, 2004. A cross-claim for indemnification by another defendant was dismissed earlier in the lawsuit because the claim is subject to a contractual obligation to arbitrate. As of the date of this filing, the arbitration clause has not been invoked by either party. Although the Company believes there are defenses it can assert against such a claim and would defend it vigorously, such a claim, if successfully brought, would not be insured and could have a material impact on the Company's liquidity and financial condition.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

- (e) The following table provides information about purchases by the Company during the quarter ended September 30, 2004 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part Of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under The Plans or Programs
7/01/04-7/31/04	--	--	--	--
8/01/04-8/31/04	--	--	--	--
9/01/04-9/30/04	9,594	\$ 6.95	--	--
Total	9,594	\$ 6.95	--	--

The Company currently has no stock repurchase program, publicly announced or otherwise. All shares shown were tendered to the Company in payment of the exercise price of outstanding options.

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.

The exhibit index can be found below.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 to Form 10-Q for the quarter ended March 31, 2003.)
3.2	ByLaws of the Company, as amended. (Incorporated by reference to Exhibit 3.2 to Form 10-Q for the quarter ended March 31, 2003.)
3.3	Articles of Amendment to the Certificate of Incorporation of the Company. (Incorporated by reference to Exhibit 3.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).
10.1*	Form of Directors Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan.
10. 2*	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan.
10.3*	Form of Incentive Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan.

- 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.

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SIGNATURES

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

CRYOLIFE, INC.
(Registrant)

/s/ STEVEN G. ANDERSON

/s/ DAVID ASHLEY LEE

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

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

November 5, 2004

DATE

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CRYOLIFE, INC.
1655 ROBERTS BOULEVARD N.W.
KENNESAW, GEORGIA 30144

(Date)

Re: GRANT OF DIRECTOR STOCK OPTION

Dear _____:

This letter sets forth the agreement (the "Agreement") between you and CryoLife, Inc., a Florida corporation (the "Company"), regarding your option to acquire shares of the Company's Common Stock.

1. Grant of Option: Subject to the terms and conditions set forth herein, the Company hereby grants to you (the "Optionee") the option (the "Option") to purchase, in the aggregate, up to _____ shares of the Common Stock (the "Shares"). The Option shall be deemed granted by the Company to the Optionee as of _____ (the "Grant Date"). This Option is granted pursuant to the CryoLife, Inc. 2004 Non-Employee Directors Stock Option Plan (the "Plan"). The Option is not an incentive stock option under Section 422 of the Internal Revenue Code of 1986, as amended ("Code").

2. Option Price: The Option exercise price is \$_____ per share (the "Option Exercise Price").

3. Option Period: This Option shall vest and become exercisable on the Option's Grant Date. This Option may be exercised at any time after its Grant Date, provided that at the time of exercise all of the conditions set forth in the Plan have been met. Notwithstanding the foregoing, no Option may be exercised later than five years after the Grant Date.

4. The Plan. The Company's 2004 Directors Stock Option Plan, as amended from time to time by the Board of Directors of the Company, is hereby incorporated in this Agreement and to the extent that anything in this Agreement is inconsistent with the Plan, the terms of the Plan shall control. Optionee acknowledges that the Company has provided a copy of the Plan to Optionee.

5. Termination of Option: Except as herein otherwise stated, the Option, to the extent not previously exercised, shall terminate five (5) years following the Grant Date.

6. Cessation of Service: If Optionee leaves the Board of Directors while in good standing, for any reason, including without limitation resignation or death, Optionee's Options shall remain in effect and exercisable, and shall expire as if Optionee had remained a Non-Employee Director of the Company. Upon the death of the Optionee, his or her Options shall be exercisable by his/her legal representatives or heirs, but in no event may the Options be exercised beyond the last date which they could have been exercised had the Optionee not died.

7. Delivery of Notice: The Optionee may exercise the Option only by delivering written notice to the Company of his or her intent to exercise the Option (the "Notice"). The Notice shall be delivered to the Company at its principal office at:

1655 Roberts Blvd., N.W.
Kennesaw, Georgia 30144

or to such other address as may be designated by the Company. The Notice shall specify the number of Shares to be purchased in accordance with this Agreement and shall include payment in full of the Option Price.

8. Payment: The Option Exercise Price shall be paid in cash in U.S. Dollars at the time the Option is exercised or in shares of Common Stock of the Company having an aggregate value equal to the Option Exercise Price or by a combination

of cash and Common Stock. If the Option Exercise Price is paid by transfer of shares of Common Stock of the Company then the value of such shares will be

determined by the last closing price of the Company's Common Stock on the New York Stock Exchange prior to the exercise of the options. In addition, to the extent permitted by applicable law and regulations, Optionee may elect to pay the exercise price upon the exercise of the Option by authorizing a third party to sell shares of Common Stock (or a sufficient portion of the shares) acquired upon exercise of the Option and remit to the Company a sufficient portion of the sale proceeds to pay the entire exercise price and any tax withholding resulting from such exercise.

9. Delivery of Shares to Optionee: Upon the Optionee's proper exercise of the Option, the Company shall deliver to the Optionee one or more certificates evidencing the number of Shares purchased pursuant to the exercise of the Option and such Shares shall be fully paid and nonassessable.

10. Transferability: Except as otherwise provided in this paragraph 10, the Options granted under this Plan are not transferable other than as designated by the Optionee by will or by the laws of the descent and distribution, and during the Optionee's life, may be exercised only by the Optionee. However, the Optionee may transfer the Option for no consideration to or for the benefit of the Optionee's Immediate Family (including, without limitation, to a trust for the benefit of the Optionee's Immediate Family or to a partnership or limited liability company for one or more members of the Optionee's Immediate Family or to an IRA for the benefit of one or more members of his or her Immediate Family), subject to such limits as the Board may establish, and the transferee shall remain subject to all the terms and conditions applicable to such Option prior to such transfer. The foregoing right to transfer the Option shall apply to the right to consent to amendments to the grant agreement and shall also apply to the right to transfer ancillary rights associated with the Option. The term "Immediate Family" shall mean the Optionee's spouse, parents, children, stepchildren, adoptive relationships, sisters, brothers and grandchildren (and, for this purpose, shall also include the Optionee).

11. Optionee Not a Shareholder: The Optionee shall not be deemed, by reason of this option agreement, for any purposes to be a shareholder of the Company with respect to any of the shares of the capital stock of the Company or with respect to any of the Shares, except to the extent that the Option has been exercised, in whole or in part, and a stock certificate representing Shares has been issued to the Optionee. Notwithstanding this provision, it is understood and agreed that the Company and the Optionee shall make any required disclosure of the "beneficial ownership" of Shares which may be received upon a future exercise of the Option.

12. No Restrictions on the Company: The grant of the Option shall not affect in any way the right or power of the Company or its shareholders to make or authorize any or all adjustments, recapitalizations, reorganizations, or any other changes in the Company's capital structure or its business, or any merger or consolidation of the Company, or any issue of bonds, debentures, preferred or prior preference stock ahead of or affecting the Common Stock, or the rights thereof, or dissolution or liquidation of the Company, or any sale or transfer of all or any part of the assets or business of the Company, or any other corporate act or proceeding, whether of a similar character or otherwise.

13. Reclassification, Consolidation or Merger: The number of Option Shares shall be adjusted if certain events such as merger, reorganization, consolidation, recapitalization, stock dividends, stock splits, or other changes in the Company's corporate structure affecting its Common Stock occur, but only if such adjustments are made to options issued under any of the Company's plans then in effect pursuant to which incentive stock options may be granted. No adjustments or substitution provided for in this Subsection, however, shall require the Company to sell a fractional share, and the total substitution or adjustment herein is and shall be limited accordingly.

14. Optionee's Representations and Warranties: By execution of this Agreement, Optionee represents and warrants to the Company as follows:

A. Investment Representations and Warranties: The Optionee warrants and represents to the Company that he or she is acquiring the Option and, upon exercise of the Option, in whole or in part, the Shares for his or her own account for investment purposes and not with a view to distribution, as defined in the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations of the Securities and Exchange Commission promulgated thereunder. The Optionee further agrees that he or she will not sell, assign, transfer or pledge the Option or any of the Shares purchased by him or her pursuant to the exercise of the Option, unless and until either (i) a registration statement under the Securities Act covering the Shares becomes

effective or (ii) the Company has received an opinion of counsel in form and substance satisfactory to the Company and its counsel that such sale, transfer, assignment or pledge may be accomplished without registration under the Securities Act.

B. Compliance with Withholding Rules: The Company shall have the right to adopt and apply rules governing the exercise of the Option and the issuance of Shares pursuant thereto which will ensure that the Company will be able to comply with the applicable provisions of any federal, state or local laws relating to the withholding of taxes.

C. No Tax Advice: The Optionee understands that neither the Company nor any of its affiliates, has given any advice regarding the federal income tax consequences of (i) the Agreement, or (ii) the grant of the Option, or (iii) the acquisition of the Shares upon exercise of the Option. The Optionee acknowledges that he or she has been encouraged to seek independent advice regarding the grant and the exercise of the Option herein.

15. Legends: The Company shall have the discretion to require that the certificates representing the Shares shall bear such legends as are necessary to ensure the enforceability of the conditions and limitations set forth herein.

16. Binding Effect: This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors-in-interest. All parties bound by this Agreement shall take any and all actions necessary or appropriate to effectuate the purposes and provisions hereof.

17. Amendments and Waivers: Except as otherwise provided herein, no change or modification of this Agreement shall be valid unless the same is in writing and signed by all the parties hereto. No waiver of any provision of this Agreement shall be valid unless in writing and signed by the person against whom it is sought to be enforced. The failure of any party at any time to insist upon strict performance of any condition, promise, agreement or understanding set forth herein shall not be construed as a waiver or relinquishment of the right to insist upon strict performance of the same condition, promise, agreement or understanding at a future time.

18. Complete Agreement: This Agreement, together with the Plan, constitutes and sets forth all of the final and complete promises, agreements, conditions, understandings, warranties and representations among the parties hereto with respect to the Option and the Shares, and there are no promises, agreements, conditions, understandings, warranties or representations, oral or written, express or implied, among them with respect to the matters set forth herein other than as set forth herein or in the Plan as they may be amended from time to time.

19. Captions and Pronouns: The captions contained in this Agreement are for convenience of reference only and shall not in any way modify or limit the meaning or interpretation of this Agreement. All terms and words used in this Agreement, regardless of the number and gender in which they are used, shall be deemed and construed to include any other number, singular or plural, and any other gender, masculine, feminine, or neuter, as the context or sense of this Agreement or any section, paragraph or clause herein may require, as if such words had been fully and properly written in the appropriate number and gender.

20. Governing Law: This Agreement shall be governed by and construed in accordance with the laws of the State of Georgia.

21. Counterparts: Any number of counterparts of this Agreement may be signed and delivered, and each shall be considered an original and together they shall constitute one agreement.

22. Severability: This Agreement shall not be severable in any way, but if any provision should be held to be invalid, the invalidity shall not effect the validity of the remainder of this Agreement.

23. Restricted Securities: Optionee recognizes and understands that this Option and the Shares have not been and may not be in the future registered under the Securities Act of 1933, as amended (the "Act"), the Georgia Securities Act of 1973, as amended (the "Georgia Act"), or any other state securities law.

Any transfer of the Option (if otherwise permitted hereunder, and once exercised, the Shares) will not be recognized by the Company unless such transfer is registered under the Act, the Georgia Act, and any other applicable state securities laws or effected pursuant to an exemption from such

registration which may then be available. Any share certificates representing the Shares may be stamped with legends restricting transfer thereof in accordance with the Company's policy with respect to unregistered shares of its Common Stock issued as a result of exercise of options. The Company may make a notation in its stock transfer records of the aforementioned restrictions on transfers and legends. Optionee recognizes and understands that the Shares may be restricted securities within the meaning of Rule 144 promulgated under the Act; that the exemption from registration under Rule 144 may not be available under certain circumstances and that Optionee's opportunity to utilize such Rule 144 to sell the Shares may be limited or denied. The Company shall be under no obligation to maintain or promote a public trading market for the class of shares for which the option is granted or to make provision for adequate information concerning the Company to be available to the public as contemplated under Rule 144. The Company will be under no obligation to recognize any transfer or sale of any Shares unless the terms and conditions of Rule 144 are complied with by the Optionee. By acceptance hereof, Optionee agrees that no permitted disposition of this option or any Shares shall be made unless and until (i) there is then in effect a registration statement under the Act, the Georgia Act, and applicable state securities laws covering such proposed disposition and such disposition is made in accordance with such registration statement, or (ii) Optionee shall have notified the Company of a proposed disposition and shall have furnished to the Company a detailed statement of the circumstances surrounding such disposition, together with an opinion of counsel acceptable in form and substance to the Company that such disposition will not require registration of the shares so disposed under the Act, the Georgia Act, and any applicable state securities laws. The Company shall be under no obligation to permit such transfer or disposition on its stock transfer books unless counsel for the Company shall concur as to such matters.

24. APPLICABLE TAXES: No later than the date as of which an amount first becomes includable in the gross income of the Optionee for Federal income tax purposes with respect to the exercise of the Option, the Optionee shall pay to the Company, or make arrangements satisfactory to the Company regarding the payment of, any Federal, state, or local taxes of any kind required by law to be withheld with respect to such amount. The obligations of the Company under this Agreement shall be conditional upon such payment or arrangements and the Company shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the Optionee.

IN WITNESS WHEREOF, the Company has caused this instrument to be executed by its duly authorized officers and the Optionee has executed this Agreement as of the date and year first above written.

(SEAL)

THE COMPANY:
CRYOLIFE, INC.

Attest:

Secretary for the Company

OPTIONEE:

(Print name of Optionee)

CRYOLIFE, INC.
 1655 ROBERTS BOULEVARD N.W.
 KENNESAW, GEORGIA 30144

 (Date)

Re: GRANT OF NON-QUALIFIED STOCK OPTION

Dear _____:

This letter sets forth the agreement (the "Agreement") between you and CryoLife, Inc., a Florida corporation (the "Company"), regarding your option to acquire shares of the Company's Common Stock.

1. Grant of Option. Subject to the terms set forth below, the Company hereby grants to you (the "Employee") the right, privilege, and option to purchase up to shares (of Common Stock the "Option Shares") at the purchase price of \$_____ per share. The date of grant ("Grant Date") of the option is _____. This option is intended to be and shall be treated as a "Non-Qualified Stock Option", as that term is defined in Section 422 of the Internal Revenue Code of 1986, as amended. This option is granted pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan (the "Plan").

2. Time of Exercise of Option. Prior to its termination as set forth in Section 5 below, this option shall vest, and the Employee may exercise the option granted herein on the following dates, or thereafter provided the option is exercised prior to its termination:

Exercise Date -----	Cumulative Percentage of Option Shares Exercisable -----
First Anniversary of Grant Date	20%
Second Anniversary of Grant Date	40%
Third Anniversary of Grant Date	60%
Fourth Anniversary of Grant Date	80%
Fifth Anniversary of Grant Date	100%

3. Method of Exercise. The option shall be exercised by written notice directed to the Compensation Committee (the "Committee"), at the Company's principal executive office, and except as set forth below, must be accompanied by payment of the option price for the number of Option Shares purchased in accordance with the Plan's requirements. The payment for the number of Option Shares purchased may be payable in cash or by tendering (by actual delivery of shares) shares of the Company's common stock in accordance with the Plan. To the extent permitted by applicable law, you may elect to pay for the number of Option Shares purchased by irrevocably authorizing a third party to sell shares of the Company's common stock acquired upon exercise of the Option Shares and remitting to the Company a sufficient portion of the sale proceeds as payment of the entire option price for the number of Option Shares purchased, including any tax withholding resulting from such exercise. The Company shall make delivery of such shares in accordance with the Plan provided that if any law or regulation requires the Company to take any action with respect to the shares specified in such notice before the issuance thereof, then the date of delivery of such shares shall be extended for the period necessary to take such action.

4. The Plan. The Company's 2004 Employee Stock Incentive Plan, as amended from time to time by the Board of Directors of the Company, is hereby incorporated in this Agreement and to the extent that anything in this Agreement is inconsistent with the Plan, the terms of the Plan shall control. Employee acknowledges that the Company has provided a copy of the Plan to Employee.

5. Termination of Option. Except as herein otherwise stated, the option, to the extent not previously exercised, shall terminate in accordance with the Plan and upon the first to occur of the following events:

(a) Disability. The expiration of 36 months after the date on which

Employee's employment by the Company is terminated, if such termination be by reason of Employee's permanent and total disability, provided, however, that (i) the option shall be exercisable only to the extent that Employee had the right to exercise the option at the time of termination and (ii) if the Employee dies within such 36 month period, any unexercised option held by such Employee shall thereafter be exercisable in accordance with the provisions of and shall terminate upon the first to occur of the events described in Sections 5(b) and (d);

(b) Death. In the event of Employee's death while in the employ of the Company, the expiration of 12 months following the date of his or her death, provided that the option shall be exercisable following the Employee's death only to the extent that Employee had the right to exercise the option at the time of his or her death.

(c) Retirement. In the event Employee's employment with the Company terminates by reason of normal or early retirement, any option held by such Employee may be exercised by the Employee for a period of 36 months from the date of such termination; provided, however, that if the Employee dies within such 36 month period any unexercised option held by Employee shall thereafter be exercisable in accordance with the provisions of and shall terminate upon the first to occur of the events described in Section 5(b) and (d); or

(d) Other. Upon the earlier to occur of (i) 66 months following the Grant Date, or (ii) upon termination of Employee's employment by the Company (except if such termination be by reason of death, disability, or normal or early retirement). It is in Compensation Committee's sole discretion to determine whether the Employee's employment with the Company terminates by reason of disability, normal or early retirement.

Except as set forth above, the option may not be exercised unless Employee, at the time he or she exercises the option, is, and has been at all times since the date of grant of the option, an employee of the Company. Employee shall be deemed to be employed by the Company if he or she is employed by the Company or any of its subsidiaries. Notwithstanding the above, in no event may the option be exercised after 66 months following the Grant Date.

6. Reclassification, Consolidation, or Merger. The number of Option Shares may be adjusted in accordance with the Plan if certain events such as merger, reorganization, consolidation, recapitalization, stock dividends, stock splits, or other changes in the Company's corporate structure affecting its Common Stock occur.

7. Rights Prior to exercise of Option. This Option is not transferrable by Employee, except by will or by the laws of descent and distribution or as otherwise set forth in the Plan, and during Employee's lifetime shall be exercisable only by Employee. This option shall confer no rights to the holder hereof to act as stockholder with respect to any of the Option Shares until payment of the option price and delivery of a share certificate has been made.

8. Employee's Representations and Warranties. By execution of this Agreement, Employee represents and warrants to the Company as follows:

(a) The entire legal and beneficial interest of the option and the Option Shares are for and will be held for the account of the Employee only and neither in whole nor in part for any other person.

(b) Employee resides at the following address:

(c) Employee is familiar with the Company and its plans, operations, and financial condition. Prior to the acceptance of this option, Employee has received all information as he or she deems necessary and appropriate to enable an evaluation of the financial risk inherent in accepting the option and has

received satisfactory and complete information concerning the business and financial condition of the Company in response to all inquiries in respect

thereof.

9. Restricted Securities. Employee recognizes and understands that this option and the Option Shares are not currently registered under the Securities Act of 1933, as amended (the "Act"), and if registered in the future may not remain so registered and are not registered under any state securities law. Any transfer of the option (if otherwise permitted hereunder, and once exercised, the Option Shares) will not be recognized by the Company unless such transfer is registered under the Act, the Georgia Securities Act of 1973, as amended, (the "Georgia Act") and any other applicable state securities laws or effected pursuant to an exemption from such registration which may then be available. If the Option Shares are not registered, any share certificates representing the Option Shares may be stamped with legends restricting transfer thereof in accordance with the Company's policy with respect to unregistered shares of its Common Stock issued to employees as a result of exercise of options granted under the Plan. The Company may make a notation in its stock transfer records of the aforementioned restrictions on transfers and legends. Employee recognizes and understands that the Option Shares may be restricted securities within the meaning of Rule 144 promulgated under the Act; that the exemption from registration under Rule 144 may not be available under certain circumstances and that Employee's opportunity to utilize such Rule 144 to sell the Option Shares may be limited or denied. The Company shall be under no obligation to maintain or promote a public trading market for the class of shares for which the option is granted or to make provision for adequate information concerning the Company to be available to the public as contemplated under Rule 144. The Company will be under no obligation to recognize any transfer or sale of any Option Shares pursuant to Rule 144 unless the terms and conditions of Rule 144 are complied with by the Employee. By acceptance hereof, Employee agrees that no permitted disposition of any Option Shares shall be made unless and until (i) there is at the time of exercise of the option in effect a registration statement under the Act, or (ii) Employee shall have notified the Company of a proposed Option disposition and shall have furnished to the Company a detailed statement of the circumstances surrounding such disposition, together with an opinion of counsel acceptable in form and substance to the Company that such disposition will not require registration of the shares so disposed under the Act, the Georgia Act, and any applicable state securities laws. The Company shall be under no obligation to permit such transfer or disposition on its stock transfer books unless counsel for the Company shall concur as to such matters. Employee recognizes and understands that as long as Employee remains a designated Section 16 officer of the Company, and for up to six months thereafter, any sales of Option Shares will be subject to Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the regulations promulgated thereunder. Employee also recognizes and understands that any sale of the Option Shares will also be subject to Rule 10b-5 promulgated under the Exchange Act. Employee agrees that any disposition of the Option Shares shall be made only in compliance with the Act, the Exchange Act, and the rules and regulations promulgated thereunder.

10. Tax Matters. The Employee hereby agrees to comply with any applicable federal, state, and local income and employment tax requirements which might arise with regard to a disposition of any Option Shares and to inform the Company of any such disposition which occurs prior to the expiration of (i) two years from the date of grant of the option, and (ii) one year from the date of transfer to him of Option Shares. No later than the date as of which an amount first becomes includable in the gross income of the Employee for federal income tax purposes with respect to the exercise of any option under the Plan, Employee shall pay to the Company, or make arrangements satisfactory to the Committee regarding the payment of, any federal, state, or local taxes of any kind required by law to be withheld with respect to such amount. The obligations of the Company under the Plan are conditional on such payment or arrangements and the Company shall have the right to deduct any such taxes from any payment of any kind otherwise due to Employee.

11. Payment: Except as set forth below, the Option Exercise Price shall be paid in cash in U.S. Dollars at the time the Option is exercised or in shares of Common Stock of the Company held by the employee for at least six months and having an aggregate value equal to the Option Exercise Price. If the Option Exercise Price is paid by transfer of shares of Common Stock of the Company then the value of such shares will be the fair market value as of the day the shares are tendered, which is the closing sale price of the Stock on that day on the New York Stock Exchange. The Option Exercise Price may be paid by a combination of cash and Common Stock. Notwithstanding the foregoing, to the extent permitted by applicable law, Employee may elect to pay the Option Exercise Price by authorizing a third party to sell shares of stock (or a sufficient portion of the shares) acquired upon exercise of the Option and remit to the Company a

sufficient portion of the sale proceeds to pay the entire Option Exercise Price and any tax withholding resulting from such exercise.

12. Binding Effect. This Agreement shall inure to the benefit of and be

binding upon the parties hereto and their respective heirs, executors, administrators, successors, and permissible assigns.

13. Miscellaneous. This Agreement shall be governed by and construed under the laws of the State of Georgia. If any term or provision hereof shall be held invalid or unenforceable, the remaining terms and provisions hereof shall continue in full force and effect. Any modification to this Agreement shall not be effective unless the same shall be in writing and such writing shall be signed by authorized representatives of both of the parties hereto. The terms of paragraphs 8 and 9 hereof shall survive exercise of the option by Employee and shall attach to the Option Shares. The option contained in this letter shall not confer upon Employee any right to continued employment with the Company, nor shall it interfere in any way with the right of the Company to terminate the employment of Employee at any time. This letter can be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute but one and the same instrument.

Please signify your acceptance of the option and your agreement to be bound by the terms hereof by promptly signing one of the two original letters provided to you and returning the same to the President of the Company.

Thank you for your good work and service.

Sincerely,

(SEAL)

THE COMPANY:
CRYOLIFE, INC.

Attest:

Secretary for the Company

EMPLOYEE:

(Print name of Employee)

CRYOLIFE, INC.
 1655 ROBERTS BOULEVARD N.W.
 KENNESAW, GEORGIA 30144

 (Date)

Re: GRANT OF INCENTIVE STOCK OPTION

Dear _____:

This letter sets forth the agreement (the "Agreement") between you and CryoLife, Inc., a Florida corporation (the "Company"), regarding your option to acquire shares of the Company's Common Stock.

1. Grant of Option. Subject to the terms set forth below, the Company hereby grants to Employee the right, privilege, and option to purchase up to shares (of Common Stock the "Option Shares") at the purchase price of \$_____ per share. The date of grant ("Grant Date") of the option is _____. This option is intended to be and shall be treated as an "Incentive Stock Option", as that term is defined in Section 422 of the Internal Revenue Code of 1986, as amended ("Section 422"). Provided, however, that to the extent that the option fails for any reason to comply with the provisions of Section 422, it shall be treated as a "Non-Qualified Stock Option" (as defined in the Plan). The Company shall have no liability whatsoever to Employee in the event the option fails for any reason to satisfy the requirements for Incentive Stock Options set forth in Section 422. This option is granted pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan (the "Plan").

2. Time of Exercise of Option. Prior to its termination as set forth in Section 5 below, this option shall vest, and the Employee may exercise the option granted herein on the following dates, or thereafter provided the option is exercised prior to its termination:

Exercise Date -----	Cumulative Percentage of Option Shares Exercisable -----
First Anniversary of Grant Date	20%
Second Anniversary of Grant Date	40%
Third Anniversary of Grant Date	60%
Fourth Anniversary of Grant Date	80%
Fifth Anniversary of Grant Date	100%

3. Method of Exercise. The option shall be exercised by written notice directed to the Compensation Committee (the "Committee"), at the Company's principal executive office, and except as set forth below, must be accompanied by payment of the option price for the number of Option Shares purchased in accordance with the Plan's requirements. The payment for the number of Option Shares purchased may be payable in cash or by tendering (by actual delivery of shares) shares of the Company's common stock in accordance with the Plan. To the extent permitted by applicable law, you may elect to pay for the number of Option Shares purchased by irrevocably authorizing a third party to sell shares of the Company's common stock acquired upon exercise of the Option Shares and remitting to the Company a sufficient portion of the sale proceeds as payment of the entire option price for the number of Option Shares purchased, including any tax withholding resulting from such exercise. The Company shall make delivery of such shares in accordance with the Plan provided that if any law or regulation requires the Company to take any action with respect to the shares specified in such notice before the issuance thereof, then the date of delivery of such shares shall be extended for the period necessary to take such action.

4. The Plan. The Company's 2004 Employee Stock Incentive Plan, as amended from time to time by the Board of Directors of the Company, is hereby incorporated in this Agreement and to the extent that anything in this Agreement is inconsistent with the Plan, the terms of the Plan shall control. Employee acknowledges that the Company has provided a copy of the Plan to Employee.

5. Termination of Option. Except as herein otherwise stated, the option, to the extent not previously exercised, shall terminate in accordance with the Plan and upon the first to occur of the following events:

(a) Disability. The expiration of 36 months after the date on which Employee's employment by the Company is terminated, if such termination be by reason of Employee's permanent and total disability, provided, however, that (i) the option shall be exercisable only to the extent that Employee had the right to exercise the option at the time of termination and (ii) if the Employee dies within such 36 month period, any unexercised option held by such Employee shall thereafter be exercisable in accordance with the provisions of and shall terminate upon the first to occur of the events described in Sections 5(b) and (d);

(b) Death. In the event of Employee's death while in the employ of the Company, the expiration of 12 months following the date of his or her death, provided that the option shall be exercisable following the Employee's death only to the extent that Employee had the right to exercise the option at the time of his or her death.

(c) Retirement. In the event Employee's employment with the Company terminates by reason of normal or early retirement, any option held by such Employee may be exercised by the Employee for a period of 36 months from the date of such termination; provided, however, that if the Employee dies within such 36 month period any unexercised option held by Employee shall thereafter be exercisable in accordance with the provisions of and shall terminate upon the first to occur of the events described in Section 5(b) and (d); or

(d) Other. Upon the earlier to occur of (i) 66 months following the Grant Date, or (ii) upon termination of Employee's employment by the Company (except if such termination be by reason of death, disability, or normal or early retirement). It is in Compensation Committee's sole discretion to determine whether the Employee's employment with the Company terminates by reason of disability, normal or early retirement.

Except as set forth above, the option may not be exercised unless Employee, at the time he or she exercises the option, is, and has been at all times since the date of grant of the option, an employee of the Company. Employee shall be deemed to be employed by the Company if he or she is employed by the Company or any of its subsidiaries. Notwithstanding the above, in no event may the option be exercised after 66 months following the Grant Date.

6. Reclassification, Consolidation, or Merger. The number of Option Shares may be adjusted in accordance with the Plan if certain events such as merger, reorganization, consolidation, recapitalization, stock dividends, stock splits, or other changes in the Company's corporate structure affecting its Common Stock occur.

7. Rights Prior to exercise of Option. This Option is not transferrable by Employee, except by will or by the laws of descent and distribution or as otherwise set forth in the Plan, and during Employee's lifetime shall be exercisable only by Employee. This option shall confer no rights to the holder hereof to act as stockholder with respect to any of the Option Shares until payment of the option price and delivery of a share certificate has been made.

8. Employee's Representations and Warranties. By execution of this Agreement, Employee represents and warrants to the Company as follows:

(a) The entire legal and beneficial interest of the option and the Option Shares are for and will be held for the account of the Employee only and neither in whole nor in part for any other person.

(b) Employee resides at the following address:

(c) Employee is familiar with the Company and its plans, operations, and financial condition. Prior to the acceptance of this option, Employee has

received all information as he or she deems necessary and appropriate to enable an evaluation of the financial risk inherent in accepting the option and has received satisfactory and complete information concerning the business and financial condition of the Company in response to all inquiries in respect thereof.

9. Restricted Securities. Employee recognizes and understands that this option and the Option Shares are not currently registered under the Securities Act of 1933, as amended (the "Act"), and if registered in the future may not remain so registered and are not registered under any state securities law. Any transfer of the option (if otherwise permitted hereunder, and once exercised, the Option Shares) will not be recognized by the Company unless such transfer is registered under the Act, the Georgia Securities Act of 1973, as amended, (the "Georgia Act") and any other applicable state securities laws or effected pursuant to an exemption from such registration which may then be available. If the Option Shares are not registered, any share certificates representing the Option Shares may be stamped with legends restricting transfer thereof in accordance with the Company's policy with respect to unregistered shares of its Common Stock issued to employees as a result of exercise of options granted under the Plan. The Company may make a notation in its stock transfer records of the aforementioned restrictions on transfers and legends. Employee recognizes and understands that the Option Shares may be restricted securities within the meaning of Rule 144 promulgated under the Act; that the exemption from registration under Rule 144 may not be available under certain circumstances and that Employee's opportunity to utilize such Rule 144 to sell the Option Shares may be limited or denied. The Company shall be under no obligation to maintain or promote a public trading market for the class of shares for which the option is granted or to make provision for adequate information concerning the Company to be available to the public as contemplated under Rule 144. The Company will be under no obligation to recognize any transfer or sale of any Option Shares pursuant to Rule 144 unless the terms and conditions of Rule 144 are complied with by the Employee. By acceptance hereof, Employee agrees that no permitted disposition of any Option Shares shall be made unless and until (i) there is at the time of exercise of the option in effect a registration statement under the Act, or (ii) Employee shall have notified the Company of a proposed Option disposition and shall have furnished to the Company a detailed statement of the circumstances surrounding such disposition, together with an opinion of counsel acceptable in form and substance to the Company that such disposition will not require registration of the shares so disposed under the Act, the Georgia Act, and any applicable state securities laws. The Company shall be under no obligation to permit such transfer or disposition on its stock transfer books unless counsel for the Company shall concur as to such matters. Employee recognizes and understands that as long as Employee remains a designated Section 16 officer of the Company, and for up to six months thereafter, any sales of Option Shares will be subject to Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the regulations promulgated thereunder. Employee also recognizes and understands that any sale of the Option Shares will also be subject to Rule 10b-5 promulgated under the Exchange Act. Employee agrees that any disposition of the Option Shares shall be made only in compliance with the Act, the Exchange Act, and the rules and regulations promulgated thereunder.

10. Tax Matters. The Employee hereby agrees to comply with any applicable federal, state, and local income and employment tax requirements which might arise with regard to a disposition of any Option Shares and to inform the Company of any such disposition which occurs prior to the expiration of (i) two years from the date of grant of the option, and (ii) one year from the date of transfer to him of Option Shares. No later than the date as of which an amount first becomes includable in the gross income of the Employee for federal income tax purposes with respect to the exercise of any option under the Plan, Employee shall pay to the Company, or make arrangements satisfactory to the Committee regarding the payment of, any federal, state, or local taxes of any kind required by law to be withheld with respect to such amount. The obligations of the Company under the Plan are conditional on such payment or arrangements and the Company shall have the right to deduct any such taxes from any payment of any kind otherwise due to Employee.

11. Payment: Except as set forth below, the Option Exercise Price shall be paid in cash in U.S. Dollars at the time the Option is exercised or in shares of Common Stock of the Company held by the employee for at least six months and having an aggregate value equal to the Option Exercise Price. If the Option Exercise Price is paid by transfer of shares of Common Stock of the Company then the value of such shares will be the fair market value as of the day the shares are tendered, which is the closing sale price of the Stock on that day on the

New York Stock Exchange. The Option Exercise Price may be paid by a combination of cash and Common Stock. Notwithstanding the foregoing, to the extent permitted by applicable law, Employee may elect to pay the Option Exercise Price by authorizing a third party to sell shares of stock (or a sufficient portion of the shares) acquired upon exercise of the Option and remit to the Company a sufficient portion of the sale proceeds to pay the entire Option Exercise Price and any tax withholding resulting from such exercise.

12. Binding Effect. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors, and permissible assigns.

13. Miscellaneous. This Agreement shall be governed by and construed under the laws of the State of Georgia. If any term or provision hereof shall be held invalid or unenforceable, the remaining terms and provisions hereof shall continue in full force and effect. Any modification to this Agreement shall not be effective unless the same shall be in writing and such writing shall be signed by authorized representatives of both of the parties hereto. The terms of paragraphs 8 and 9 hereof shall survive exercise of the option by Employee and shall attach to the Option Shares. The option contained in this letter shall not confer upon Employee any right to continued employment with the Company, nor shall it interfere in any way with the right of the Company to terminate the employment of Employee at any time. This letter can be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute but one and the same instrument.

Please signify your acceptance of the option and your agreement to be bound by the terms hereof by promptly signing one of the two original letters provided to you and returning the same to the President of the Company.

Thank you for your good work and service.

Sincerely,

(SEAL)

THE COMPANY:
CRYOLIFE, INC.

Attest:

Secretary for the Company

EMPLOYEE:

(Print name of Employee)

CERTIFICATION

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 quarterly 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 quarterly 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: November 5, 2004

/s/ STEVEN G. ANDERSON

Chairman, President, and Chief
Executive Officer

CERTIFICATION

I, David Ashley Lee, Executive Vice President, Chief Operating Officer, 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 quarterly 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 quarterly 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: November 5, 2004

/s/ DAVID ASHLEY LEE

Executive Vice President,
Chief Operating Officer, 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 September 30, 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 Executive Vice President, Chief Operating Officer, 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

/s/ DAVID ASHLEY LEE

STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer
November 5, 2004

DAVID ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and
Chief Financial Officer
November 5, 2004