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, 2003
Commission File Number 1-13165

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

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

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 31, 2003 was 19,727,613.

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,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Revenues:				
Human tissue preservation services, net	$ 8,097	$ 11,300	$ 25,842	$ 49,074
Products	6,831	5,354	20,362	15,892
Distribution and grant	169	235	526	658
	15,097	16,889	46,730	65,624
Costs and expenses:				
Human tissue preservation services (including write-down of $1,752 and $22,691 for the three months ended September 30, 2003 and 2002, respectively, and $3,180 and $32,715 for the nine months ended September 30, 2003 and 2002, respectively)	7,481	27,978	15,084	53,244
Products	1,782	4,739	5,429	8,817
General, administrative, and marketing	10,575	11,193	45,706	32,118
Research and development	823	1,347	2,828	3,696

Goodwill impairment	--	1,399	--	1,399
Interest expense	87	155	366	543
Interest income	(101)	(188)	(348)	(725)
Other (income) expense, net	(94)	35	46	(37)
	20,553	46,658	69,111	99,055
Loss before income taxes	(5,456)	(29,769)	(22,381)	(33,431)
Income tax (benefit) expense	(761)	(10,123)	2,669	(11,367)
Net loss	$ (4,695)	$(19,646)	$(25,050)	$(22,064)
Net loss per share:				
Basic	$ (0.24)	$ (1.01)	$ (1.27)	$ (1.14)
Diluted	$ (0.24)	$ (1.01)	$ (1.27)	$ (1.14)
Weighted average shares outstanding:				
Basic	19,701	19,526	19,669	19,388
Diluted	19,701	19,526	19,669	19,388

See accompanying notes to summary consolidated financial statements.

Item 1. Financial Statements

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

	September 30, 2003	December 31, 2002
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,179	$ 10,277
Marketable securities, at market	9,703	14,583
Trade receivables, net	7,336	6,930
Other receivables, net	3,360	11,824
Deferred preservation costs, net	9,666	4,332
Inventories	4,935	4,585
Prepaid expenses and other assets	3,246	2,182
Deferred income taxes	--	6,734
Total current assets	46,425	61,447
Property and equipment, net	33,680	38,130
Patents, net	5,276	5,324
Other, net	1,142	1,513
TOTAL ASSETS	$ 86,523	$ 106,414
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,686	$ 3,874
Accrued expenses and other current liabilities	15,159	6,823
Accrued compensation	1,591	1,627
Accrued procurement fees	4,089	3,769
Note payable	801	--
Current maturities of capital lease obligations	1,848	2,169
Current maturities of long-term debt	--	5,600
Total current liabilities	26,174	23,862
Capital lease obligations, less current maturities	807	971
Deferred income taxes	--	986
Other long-term liabilities	4,223	795
Total liabilities	31,204	26,614

Shareholders' equity:		
Preferred stock	--	--
Common stock (issued 21,076 shares in 2003 and 20,935 shares in 2002)	211	209
Additional paid-in capital	74,217	73,630
Retained (deficit) earnings	(12,264)	12,786
Deferred compensation	(12)	(21)
Accumulated other comprehensive income	348	282
Less: Treasury stock at cost (1,371 shares in 2003 and 1,361 shares in 2002)	(7,181)	(7,086)
Total shareholders' equity	55,319	79,800
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 86,523	$ 106,414

See accompanying notes to summary consolidated financial statements.

Item 1. Financial Statements

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

	Nine Months Ended September 30,	
	2003	2002
	(Unaudited)	
Net cash from operating activities:		
Net loss	$(25,050)	$(22,064)
Adjustments to reconcile net loss to net cash from operating activities:		
(Gain) loss on sale of marketable equity securities	(19)	240
Gain on sale of assets	(80)	--
Depreciation and amortization	4,136	3,926
Provision for doubtful accounts	72	72
Write-down of deferred preservation costs and inventories	3,180	35,816
Other non-cash adjustments to income	328	1,399
Deferred income taxes	5,708	(11,674)
Tax effect of nonqualified option exercises	19	481
Changes in operating assets and liabilities:		
Receivables	(334)	8,190
Income taxes	8,320	(3,083)
Deferred preservation costs and inventories	(8,864)	(11,679)
Prepaid expenses and other assets	1,379	(1,309)
Accounts payable, accrued expenses, and other liabilities	10,860	321
Net cash flows (used in) provided by operating activities	(345)	636
Net cash flows from investing activities:		
Capital expenditures	(456)	(3,877)
Net proceeds from sale of assets	1,080	--
Other assets	188	(2,575)
Purchases of marketable securities	--	(10,025)
Sales and maturities of marketable securities	4,699	20,496
Proceeds from note receivable	--	1,169
Net cash flows provided by investing activities	5,511	5,188
Net cash flows from financing activities:		
Principal payments of debt	(5,600)	(1,200)
Payment of obligations under capital leases	(485)	(454)
Principal payments on short-term note payable	(1,642)	--
Proceeds from exercise of stock options and issuance of common stock	475	1,313
Purchase of treasury stock	--	(663)
Net cash flows used in financing activities	(7,252)	(1,004)

(Decrease) increase in cash	(2,086)	4,820
Effect of exchange rate changes on cash	(12)	203
Cash and cash equivalents, beginning of period	10,277	7,204
Cash and cash equivalents, end of period	$ 8,179	$ 12,227

See accompanying notes to summary consolidated financial statements.

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

Note 1 — Basis of Presentation

The accompanying unaudited summary consolidated financial statements have been prepared in accordance with (i) accounting principles generally accepted in the United States for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the United States Securities and Exchange Commission ("SEC"). Accordingly, the statements do not include all of the information and disclosures required by accounting principles generally accepted in the United States for a complete presentation of financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Certain prior year balances have been reclassified to conform to the 2003 presentation. Operating results for the three and nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. For further information, refer to the consolidated financial statements and notes thereto included in the CryoLife Form 10-K for the year ended December 31, 2002, as amended.

The Company expects its liquidity to continue to decrease significantly over the next twelve months due to 1) the anticipated continuation of decreased levels of preservation revenues as compared to preservation revenues prior to the FDA Order (defined in Note 2 below) as a result of reported tissue infections, the FDA Order, and associated adverse publicity, 2) the increase in cost of human tissue preservation services as a percent of revenue as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue, 3) an expected use of cash due to the increased costs relating to the defense and resolution of lawsuits (discussed in Note 13), and 4) the legal and professional costs relating to the ongoing FDA compliance. The Company believes that anticipated revenue generation, expense management, tax refunds expected to be approximately $3.0 to $3.5 million, continued savings resulting from the reduction in the number of employees in September 2002 necessitated by the reduction in revenues, and the Company's existing cash and marketable securities will enable the Company to meet its liquidity needs through at least September 30, 2004.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including the Company's ability to return to the level of demand and gross margins for its tissue services that existed prior to the FDA Order, the timing and amount of settlements or other outcomes of the product liability claims (discussed in Note 13), the outcome of other litigation against the Company (discussed in Note 13), the ability to arrange and fund a settlement of outstanding claims for an amount substantially below the amount accrued (discussed in Note 13), the resolution of outstanding issues with the FDA (discussed in Note 2), and the Company's ability to find suitable sources of financing. The Company may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond September 30, 2004. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows. In addition, if the Company is unsuccessful in arranging settlements of product liability claims 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), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. The items described above are factors that indicate that the Company may be unable to continue operations beyond September 30, 2004.

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

FDA Order

On August 13, 2002 the Company received an order from the Atlanta district office of the U.S. Food and Drug Administration ("FDA") regarding the non-valved cardiac, vascular, and orthopaedic tissue processed by the Company since October 3, 2001 (the "FDA Order"). The FDA Order followed an April 2002 FDA Form 483 Notice of Observations ("April 2002 483") and an FDA Warning Letter dated June 17, 2002, ("Warning Letter"). Revenue from human tissue preservation services accounted for 78% of the Company's revenues for the six months ended June 30, 2002, (the last period ended prior to the issuance of the FDA Order) and of those revenues 67%, or $26.9 million, were derived from preservation of tissues subject to the FDA Order. The FDA Order contained the following principal provisions:

- The FDA alleged that, based on its inspection of the Company's facility on March 25 through April 12, 2002, certain human tissue processed and distributed by the Company may be in violation of 21 Code of Federal Regulations ("CFR") Part 1270. (Part 1270 requires persons or entities engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue to perform certain medical screening and testing on human tissue intended for transplantation. The rule also imposes requirements regarding procedures for the prevention of contamination or cross-contamination of tissues during processing and the maintenance of certain records related to these activities.)

- The FDA alleged that the Company had not validated procedures for the prevention of infectious disease contamination or cross-contamination of tissue during processing at least since October 3, 2001.

- Non-valved cardiac, vascular, and orthopaedic tissue processed by the Company from October 3, 2001 to September 5, 2002 must be retained until it is recalled, destroyed, the safety is confirmed, or an agreement is reached with the FDA for its proper disposition under the supervision of an authorized official of the FDA.

- The FDA strongly recommended that the Company perform a retrospective review of all tissue in inventory (i.e. currently in storage at the Company) that was not referenced in the FDA Order to assure that it was recovered, processed, stored, and distributed in conformance with 21 CFR 1270.

- The Center for Devices and Radiological Health ("CDRH"), a division of the FDA, would evaluate whether there are similar risks that may be posed by the Company's allograft heart valves, and would take further regulatory action if appropriate.

Pursuant to the FDA Order, the Company placed non-valved cardiac, vascular, and orthopaedic tissue subject to the FDA Order on quality assurance quarantine and recalled the non-valved cardiac, vascular, and orthopaedic tissues subject to the FDA Order (i.e. processed since October 3, 2001) that had been distributed but not implanted. In addition, the Company ceased processing non-valved cardiac, vascular, and orthopaedic tissues. On September 5, 2002 the Company reached an agreement with the FDA (the "Agreement") that supplemented the FDA Order and allowed non-valved cardiac and vascular tissues subject to recall (processed between October 3, 2001 and September 5, 2002) to be released for distribution after the Company had completed steps to assure that the tissue was used for approved purposes and that patients were notified of risks associated with tissue use. Specifically, the Company was required to obtain physician prescriptions, and tissue packaging was required to contain specified warning labels. The Agreement called for the Company to undertake to identify third-party records of donor tissue testing and to destroy tissue from donors in whom microorganisms associated with an infection were found. The Agreement had a 45-business day term and was renewed on November 8, 2002, January 8, 2003, March 17, 2003, and June 13, 2003. This most recent renewal expired on September 5, 2003 and was not renewed. The Company is no longer shipping tissue subject to the recall (processed between October 3, 2001 and 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 Agreement contained the requirement that tissues subject to the FDA Order be replaced with tissues processed under validated methods. The Company also agreed to establish a corrective action plan within 30 days from September 5, 2002 with steps to validate processing procedures. The corrective action plan was submitted on October 5, 2002.

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

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

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

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

Accounting Treatment

As a result of the FDA Order the Company recorded a reduction to pretax income of $12.6 million in the quarter ended June 30, 2002. The reduction was comprised of a net $8.9 million increase to cost of human tissue preservation services, a $2.4 million reduction to revenues (and accounts receivable) for the estimated return of the tissues subject to recall by the FDA Order, and a $1.3 million accrual recorded in general, administrative, and marketing expenses consisting of an accrual for retention levels under the Company's product liability and directors' and officers' insurance policies of $1.2 million (see Note 13) and for estimated expenses for packaging and handling for the return of affected tissues under the FDA Order of $75,000. The net increase of $8.9 million to cost of preservation services was comprised of a $10.0 million write-down of deferred preservation costs for tissues subject to the FDA Order, offset by a $1.1 million decrease in cost of preservation services due to the estimated tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the $10.0 million write-down). The Company evaluated multiple factors in determining the magnitude of impairment to deferred preservation costs as of June 30, 2002, including the impact of the FDA Order, the possibility of continuing action by the FDA or other United States and foreign government agencies, and the possibility of unfavorable actions by physicians, customers, procurement organizations, and others. As a result of this evaluation, management believed that since all non-valved cardiac, vascular, and orthopaedic allograft tissues processed since October 3, 2001 were under recall pursuant to the FDA Order, and since the Company did not know if it would obtain a favorable resolution of its appeal and request for modification of the FDA Order, the deferred preservation costs for tissues subject to the FDA Order had been significantly impaired. The Company estimated that this impairment approximated the full balance of the deferred preservation costs of the tissues subject to the FDA Order, which included the tissues stored by the Company and the tissues to be returned to the Company, and, therefore, recorded a write-down of $10.0 million for these assets.

In the quarter ended September 30, 2002 the Company recorded a reduction to pretax income of $24.6 million as a result of the FDA Order. The reduction was comprised of a net $22.2 million increase to cost of human tissue preservation services, a $1.4 million write-down of goodwill, and a $1.0 million reduction to revenues (and accounts receivable) for the estimated return of the tissues shipped during the third quarter subject to recall by the FDA Order. The net $22.2 million increase to cost of preservation services was comprised of a $22.7 million write-down of deferred preservation costs, offset by a $535,000 decrease in

cost of preservation services due to the estimated and actual tissue returns resulting from the FDA Order (the costs of such recalled tissue are included in the $22.7 million write-down).

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

As a result of the write-down of deferred preservation costs, the Company recorded $6.3 million in income tax receivables and $4.5 million in deferred tax assets as of December 31, 2002. Upon destruction or shipment of the remaining tissues associated with the deferred preservation costs write-down, the related cost of the tissue becomes deductible in the Company's related tax return and the deferred tax asset is realized assuming there is sufficient taxable income to offset the tax deduction. 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 in 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 recorded accrued restructuring costs of approximately $690,000, for severance and related costs of the employee force reduction. The expense was recorded in general, administrative, and marketing expenses and was included as a component of accrued expenses and other current liabilities on the Summary Consolidated Balance Sheet. During the year ended December 31, 2002 the Company utilized $580,000 of the accrued restructuring costs, including $505,000 for salary and severance payments, $64,000 for placement services for affected employees, and $11,000 in other related costs. During the quarter ended March 31, 2003 the Company utilized $64,000 of the accrued restructuring costs, including $57,000 for salary and severance payments and $7,000 in other related costs. In March 2003 the Company reversed the remaining accrual of $46,000 in unused restructuring costs, which was primarily due to lower than anticipated medical claims costs for affected employees. The Company has not incurred and does not expect to incur any additional restructuring costs associated with the employee force reduction subsequent to March 31, 2003.

In the quarter ended March 31, 2003 the Company recorded a favorable adjustment of $848,000 to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated in 2002. The adjustment increased cardiac tissue revenues by $92,000, vascular tissue revenues by $711,000, and orthopaedic tissue revenues by $45,000 in the first quarter of 2003. In the quarter ended September 30, 2003 the Company recorded a favorable adjustment of $52,000 to reverse the remaining unused portion of the estimated tissue recall returns due to lower overall actual tissue returns under the FDA Order than were estimated. Although vascular and orthopaedic returns were lower than expected, cardiac returns were higher than expected. Therefore, the $52,000 adjustment decreased cardiac tissue revenues by $7,000 and increased vascular tissue revenues by $41,000 and orthopaedic tissue revenues by $18,000 in the third quarter of 2003. As of September 30, 2003 there is no accrual for estimated return of tissues subject to recall by the FDA Order.

During the three and nine months ended September 30, 2003 the Company recorded $1.8 million and $3.2 million, respectively, as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs from tissues processed in the three and nine months ended September 30, 2003 that exceeded market value. As of September 30, 2003 the balance of deferred preservation costs was $4.1 million for allograft heart valve tissues, $553,000 for non-valved cardiac tissues, $4.0 million for vascular tissues, and $1.1 million for orthopaedic tissues.

Other FDA Correspondence and Notices

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

The Company has voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular and vascular tissue and has suspended the distribution of tissues on hand that have been preserved with the SynerGraft technology until the regulatory status of the CryoValve SG and CryoVein SG is resolved. Additionally, the Company has discontinued labeling its vascular grafts for use as A-V access grafts. The FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SynerGraft tissues are resolved, the Company will employ its traditional processing methods on these tissues. Distribution of allograft heart valves and vascular tissue processed using the Company's traditional processing protocols will continue. The Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue on hand.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume processing and distribution of SynerGraft processed cardiovascular tissue. The Company is still in discussions with the FDA regarding the type of submissions necessary for the CryoVein SG. The outcome of the discussions and filing with the FDA regarding the use of the SynerGraft process on human tissue could result in an inability to process tissues with the SynerGraft technology until further submissions and FDA clearances are granted.

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

Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of tax, reported in the accumulated other comprehensive income account 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.

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

	Cost Basis	Unrealized Holding Gains/(Losses)	Estimated Market Value
September 30, 2003			
Cash equivalents:			
Money market funds	$ 109	$ --	$ 109
Municipal obligations	5,600	--	5,600
	$ 5,709	$ --	$ 5,709
Marketable securities:			
Municipal obligations	$ 9,528	$ 175	$ 9,703

	Cost Basis	Unrealized Holding Gains/(Losses)	Estimated Market Value
December 31, 2002			
Cash equivalents:			
Money market funds	$ 52	$ --	$ 52
Municipal obligations	7,175	--	7,175
	$ 7,227	$ --	$ 7,227
Marketable securities:			
Municipal obligations	$ 14,276	$ 307	$ 14,583

Differences between cost and market listed above, consisting of a net unrealized holding gain less deferred taxes of $56,000 at September 30, 2003 and $104,000 as of December 31, 2002, are included in the accumulated other comprehensive income account of shareholders' equity. The Company has recorded a valuation against its net deferred tax assets during 2003. See Note 5 for additional discussion of the deferred tax asset valuation.

The marketable securities of $9.7 million on September 30, 2003 and $14.6 million on December 31, 2002 had maturity dates as follows: approximately $4.4 million and $1.2 million, respectively, of marketable securities had a maturity date of less than 90 days, approximately $2.0 million and $8.0 million, respectively, had a maturity date between 90 days and 1 year, and approximately $3.3 million and $5.4 million, respectively, had a maturity date between 1 and 5 years.

Note 4 — Inventories

Inventories are comprised of the following (in thousands):

	September 30, 2003	December 31, 2002
	(Unaudited)	
Raw materials	$ 2,863	$ 2,341
Work-in-process	170	306
Finished goods	1,902	1,938
	$ 4,935	$ 4,585

Note 5 –Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets in 2002 and 2003 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, FDA Warning Letter, and reported tissue infections. The Company periodically assesses the recoverability of deferred tax assets and provides a valuation allowance when management believes it is more likely than not that its deferred tax assets will not be realized.

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

The Company updated its analysis to determine if a valuation allowance relative to its deferred tax assets was necessary at September 30, 2003. Based on the results of this analysis, the Company determined that it was more likely than not that the Company's deferred tax assets as of September 30, 2003 would not be realized in future periods. The Company recorded an additional $1.9 million in deferred tax valuations to reflect changes in the deferred tax asset balance during the third quarter of 2003, due to current quarter losses and the effect of temporary differences between book and tax income. During the third quarter of 2003, $1.3 million in deferred tax assets not subject to valuation at June 30, 2003 became recoverable and were reclassified to income taxes receivable as of September 30, 2003. The Company also recorded approximately $800,000 in income taxes receivable, related to a carry back of operating losses and product liability expenses incurred during 2002.

As a result of recording the valuation allowances and other items listed above, the Company has reported an income tax benefit of $761,000 and an income tax expense of $2.7 million for the three and nine months ended September 30, 2003, respectively. As of September 30, 2003 the Company had a total of $11.6 million in valuation allowances against deferred tax assets.

Note 6 – Debt

On April 25, 2000 the Company entered into a loan agreement permitting the Company to borrow up to $8 million under a line of credit during the expansion of the Company's corporate headquarters and manufacturing facilities. Borrowings under the line of credit accrued interest equal to Adjusted LIBOR plus 2% adjusted monthly. On June 1, 2001 the line of credit was converted to a term loan (the "Term Loan") to be paid in 60 equal monthly installments of principal plus interest computed at Adjusted LIBOR plus 1.5%. The Term Loan was secured by substantially all of the Company's assets. The Term Loan contained certain restrictive covenants including, but not limited to, maintenance of certain financial ratios, a minimum tangible net worth requirement, and the requirement that no materially adverse event had occurred.

In the third quarter of 2002, the lender notified the Company that the FDA Order, as described in Note 2, and the inquiries of the SEC, as described in Note 13, had had a material adverse effect on the Company that constituted an event of default. Additionally, since June 30, 2002, the Company had been in violation of the debt coverage ratio and net worth financial covenants of the Term Loan. Therefore, all amounts due under the Term Loan from June 30, 2002 to June 30, 2003 have been reflected as a current liability on the Summary Consolidated Balance Sheet. In the quarter ended June 30, 2003, the lender indicated its intention to enter into a forbearance agreement with the Company and to accelerate the principal payments on the Term Loan. As a result, on August 15, 2003 the Company made a voluntary payment of $4.5 million to pay off the outstanding balance of the Term Loan. The Company also paid approximately $11,000 to the lender in fees associated with the Term Loan payoff. As of September 30, 2003 the balance of the Term Loan was zero.

In the quarter ended June 30, 2003 the Company entered into two agreements to finance $2.9 million in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. The amount financed accrues interest at a 3.75% rate and is payable in equal monthly payments through December 2003. As of September 30, 2003 the outstanding balance of the agreements was $801,000.

Note 7 – Derivatives

The Company's Term Loan, which was paid in full on August 15, 2003, accrued interest computed at Adjusted LIBOR plus 1.5%, and exposed the Company to changes in interest rates. On March 16, 2000 the Company entered into a $4.0 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and was to expire in 2006. This swap agreement was designated as a cash flow hedge to effectively convert a portion of the Term Loan balance to a fixed rate basis, thus reducing the impact of interest rate changes on future income. This agreement involved the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement, without an exchange of the underlying principal amounts. The differential to be paid or received was recognized in the period in which it accrued as an adjustment to interest expense on the Term Loan.

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

During the quarter ended June 30, 2003 the Company became aware of the lender's intention to accelerate the payment of the Term Loan, as discussed in Note 6 above. Therefore, the Company recorded an expense of $222,000, to reclassify the unamortized portion of the other comprehensive loss to other expense/income on the Summary Consolidated Statements of Operations. In conjunction with the payoff of the outstanding balance of the Term Loan, the Company paid $199,000 to terminate the swap agreement. This $199,000 payment represents the estimated fair value of the interest rate swap, as estimated by the bank based on its internal valuation models, as of the day of the termination of the agreement. For the three months ended September 30, 2003 the Company recorded a benefit of $39,000 on the interest rate swap, and for the nine months ended September 30, 2003 the Company recorded a total expense of $168,000 on the interest rate swap.

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,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Net loss	$ (4,695)	$(19,646)	$(25,050)	$(22,064)
Unrealized (loss)/gain on investments	(23)	56	(84)	98
Change in fair value of interest rate swap	--	(6)	172	17
Translation adjustment	9	(12)	(22)	205
Comprehensive loss	$ (4,709)	$(19,608)	$(24,984)	$(21,744)

The tax effect of the change in unrealized gain/loss on investments is a benefit of $14,000 and an expense of $29,000 for the three months ended September 30, 2003 and 2002, respectively. The tax effect of the change in unrealized gain/loss on investments is a benefit of $48,000 and an expense of $56,000 for the nine months ended September 30, 2003 and 2002, respectively. The tax effect of the change in fair value of the interest rate swap is zero and $4,000 for the three months ended September 30, 2003 and 2002, respectively. The tax effect of the change in fair value of the interest rate swap is $88,000 and $2,000 for the nine months ended September 30, 2003 and 2002, respectively. The tax effect of the translation adjustment is zero for the three months ended September 30, 2003 and 2002, respectively. The tax effect of the translation adjustment is $110,000 and zero for the nine months ended September 30, 2003 and 2002, respectively. The Company has recorded a valuation against its net deferred tax assets during 2003. See Note 5 for additional discussion of the deferred tax asset valuation.

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,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Numerator for basic and diluted loss per share - loss available to common shareholders	$ (4,695)	$ (19,646)	$ (25,050)	$ (22,064)
Denominator for basic loss per share - weighted-average basis	19,701	19,526	19,669	19,388
Effect of dilutive stock options	--	--	--	--
Denominator for diluted loss per share - adjusted weighted-average shares	19,701	19,526	19,669	19,388
Net loss per share:				
Basic	$ (0.24)	$ (1.01)	$ (1.27)	$ (1.14)
Diluted	$ (0.24)	$ (1.01)	$ (1.27)	$ (1.14)

The effect of dilutive stock options of 419,000 and 791,000 shares for the three months ended September 30, 2003 and 2002, respectively, was excluded from the calculation of adjusted weighted average shares because these amounts are antidilutive due to the net loss in the periods presented. The effect of dilutive stock options of 438,000 and 975,000 shares for the nine months ended September 30, 2003 and 2002, respectively, was excluded from the calculation of adjusted weighted average shares because these amounts are antidilutive due to the net loss in the periods presented.

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

Note 10 – Stock-Based Compensation

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

The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations

("APB 25") in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under SFAS 123 requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of the grant, no compensation expense is recognized.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	.589	.630	.611	.630
Risk-free interest rate	2.36%	3.67%	2.40%	3.67%
Expected life of options	3.1 Years	5.3 Years	3.8 Years	5.3 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,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Net loss--as reported	$ (4,695)	$ (19,646)	$ (25,050)	$ (22,064)
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of tax	437	1,439	1,109	2,171
Net loss--pro forma	$ (5,132)	$ (21,085)	$ (26,159)	$ (24,235)
Net loss per share--as reported:				
Basic	$ (0.24)	$ (1.01)	$ (1.27)	$ (1.14)
Diluted	$ (0.24)	$ (1.01)	$ (1.27)	$ (1.14)
Net loss per share--proforma:				
Basic	$ (0.26)	$ (1.08)	$ (1.33)	$ (1.25)
Diluted	$ (0.26)	$ (1.08)	$ (1.33)	$ (1.25)

Note 11 – Accounting Pronouncements

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

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

The Company was required to adopt SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146") on January 1, 2003. SFAS 146 requires that costs associated with exit or disposal activities be recorded at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The

adoption of SFAS 146 did not have a material effect on the results of operations, financial position, or cash flows of the Company.

Note 12 – Segment Information

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

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Revenue:				
Human tissue preservation services, net	8,097	11,300	25,842	49,074
Implantable medical devices	6,831	5,354	20,362	15,892
All other [a]	169	235	526	658
	$ 15,097	$ 16,889	$ 46,730	$ 65,624
Cost of Preservation Services and Products:				
Human tissue preservation services	7,481	27,978	15,084	53,244
Implantable medical devices	1,782	4,739	5,429	8,817
All other [a]	--	--	--	--
	$ 9,263	$ 32,717	$ 20,513	$ 62,061
Gross Margin (Loss):				
Human tissue preservation services	616	(16,678)	10,758	(4,170)
Implantable medical devices	5,049	615	14,933	7,075
All other [a]	169	235	526	658
	$ 5,834	$(15,828)	$ 26,217	$ 3,563

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(Unaudited)		(Unaudited)	
Revenue:				
Human tissue preservation services, net				
Cardiovascular tissue	$ 4,547	$ 5,487	$ 14,308	$ 20,131
Vascular tissue	3,083	3,260	10,637	14,918
Orthopaedic tissue	467	2,553	897	14,025
Total preservation services	8,097	11,300	25,842	49,074
BioGlue surgical adhesive	6,694	5,183	20,027	15,308
Other implantable medical devices	137	171	335	584
Distribution and grant	169	235	526	658
	$ 15,097	$ 16,889	$ 46,730	$ 65,624

Note 13 – Commitments and Contingencies

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. Following the FDA Order, a greater number of lawsuits than has historically been the case have been filed. As of November 12, 2003 the Company was aware of approximately 13 pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, eight 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, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, when it was a subsidiary of the Company.

Included in these lawsuits is the complaint filed against the Company in the Superior Court of Cobb County, Georgia, on October 8, 2002 by Jeffrey Andronaco and Christina Andronaco. This complaint alleges strict liability, negligence, professional negligence, and breach of warranties related to cardiac tissue implanted in October 2000. The plaintiff seeks unspecified compensatory and punitive damages in the filed complaint.

Included in these lawsuits is the complaint filed against the Company in the Third District Court Salt Lake City, Utah, on January 31, 2003 by Jolene and Robert Moulton, husband and wife, on behalf of Hayley Moulton, their minor child. This complaint alleges strict liability, negligence, professional negligence, and breach of implied and express warranties related to cardiac tissue implanted in July 2001. The plaintiff seeks unspecified compensatory and punitive damages in the filed complaint.

Of the 13 open lawsuits, two lawsuits were filed in the 2000/2001 insurance policy year, two were filed in the 2001/2002 insurance policy year, eight were filed in the 2002/2003 insurance policy year and one was filed in the 2003/2004 policy year. For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. The first $10 million layer of coverage and approximately $1.8 million of the second layer of coverage has been used in the settlement and defense of lawsuits. The insurance carriers with the second and third layers of coverage totaling $15 million have tendered their remaining limits of approximately $13.2 million to the Company and made the funds available to settle all claims outstanding in the relevant policy period. The Company continues to attempt to reach settlements of the outstanding litigation. Of the eight open lawsuits filed in the 2002/2003 insurance policy year, four have agreed in principle to settlement offers.

Other product liability claims have been asserted against the Company that have not resulted in lawsuits. The Company has offers of settlement outstanding for a matter arising in the 2002/2003 insurance policy year and for two matters arising in the 2003/20004 year. The Company is investigating several other claims.

Based on an analysis of the product liability claims now pending against the Company, settlement negotiations to date, and advice from counsel, the Company has recorded a liability of $9.0 million in the accrued expenses and other current liabilities line of the Summary Consolidated Balance Sheet and a related expense of $9.0 million in general, administrative, and marketing expenses which represents the Company's best estimate of the costs and expenses related to resolving these claims and reflecting the uninsured portion of the estimated liability. The amounts recorded are reflective of estimated legal fees and settlement costs related to these claims, and do not reflect actual settlement arrangements or final judgments, which could include punitive damages.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. If the Company is unable to settle the product liability claims for an amount substantially below the amount accrued, there may not be sufficient insurance coverage and liquid assets to meet these obligations. 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 lawsuits in which the Company is a defendant should be tried and a substantial verdict rendered in favor of the plaintiffs(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. If the Company is unable to meet required future cash payments to resolve the outstanding product liability claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims, and records accruals as necessary for the estimated cost of unreported claims related to services performed and products sold. As of December 31, 2002 the Company had accrued $3.6 million for estimated costs for unreported product claims. On May 2, 2003 the insurance carrier for the 2003/2004 policy altered the policy effective April 1, 2003 to be a first year claims made policy, i.e. only claims incurred and reported during the policy period April 1, 2003 through March 31, 2004 are covered by this policy. During the second quarter of 2003 the Company engaged an independent actuarial firm to update the analysis of the unreported product claims as of June 30, 2003. As a result of the actuarial valuation, the Company accrued an additional $3.9 million for estimated costs for unreported product liability claims related to services performed and products sold prior to June 30, 2003. The $3.9 million expense was recorded in the second quarter of 2003 in general, administrative, and marketing expenses. During the third quarter of 2003 the Company recorded an additional $213,000 in estimated costs for unreported product liability claims related to services performed and products sold during the quarter ended September 30, 2003 to increase the total accrual to $7.7 million. The $7.7 million balance is included as a component of accrued expenses and other current liabilities of $4.4 million and other long-term liabilities of $3.3 million on the Summary Consolidated Balance Sheets. As of September 30, 2003 there were no other changes in the amounts accrued for unreported product liability claims as the underlying assumptions used to calculate the liability for unreported product liability claims did not materially change during the third quarter of 2003.

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

Several putative class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that the Company failed to disclose its alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the United States District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. The Company carries directors' and officers' liability insurance policies, which the Company presently believes to be adequate to defend

against this action. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names the Company as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in certain inappropriate practices that caused the Company to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that the Company's Board of Directors take certain actions in response to her allegations. On January 16, 2003 another purported derivative suit alleging claims similar to those of the Lichtenberger suit was filed in the Superior Court of Fulton County by complainant Robert F. Frailey. As in the Lichtenberger suit, the filing of the complaint in the Frailey action was preceded by a 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, is currently evaluating the consolidated amended complaint.

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

PART I — FINANCIAL INFORMATION

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

Recent Events

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

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

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

The Company has voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular and vascular tissue and in late September of 2003 suspended the distribution of tissues on hand that have been preserved with the SynerGraft technology until the regulatory status of the CryoValve SG and CryoVein SG is resolved. Additionally, the Company has discontinued labeling its vascular grafts for use as A-V access grafts. The FDA has not suggested that these tissues be recalled. Until such time as the issues surrounding the SynerGraft tissue are resolved, the Company will employ its traditional processing methods on these tissues. Distribution of allograft heart valves and vascular tissue processed using the Company's traditional processing protocols will continue. The Company currently has nominal amounts of SynerGraft processed cardiovascular and vascular tissue on hand. On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume processing and distribution of SynerGraft processed cardiovascular tissue. The Company is still in discussions with the FDA regarding the type of submissions necessary for the CryoVein SG. The outcome of the discussions and filing with the FDA regarding the use of the SynerGraft process on human tissue could result in an inability to process tissues with the SynerGraft technology until further submissions and FDA clearances are granted.

During the second quarter of 2003, the insurance carriers with the second and third layers of coverage totaling $15 million for the 2002/2003 policy year have tendered their remaining limits of approximately $12.5 million to the Company and made the funds available to settle all claims outstanding in the relevant policy period. The Company continues to attempt to reach settlements of the outstanding litigation. See further discussion regarding product liability claims in Part II. Item 1. Legal Proceedings.

During the second quarter of 2003, the lender under the Term Loan indicated its intention to enter into a forbearance agreement with the Company and to accelerate the principal payments on the Term Loan. As a result, 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.

Critical Accounting Policies

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

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

During 2002 the Company recorded a write-down of deferred preservation costs of $8.7 million for valved cardiac tissues, $2.9 million for non-valved cardiac tissues, $11.9 million for vascular tissues, and $9.2 million for orthopaedic tissue, totaling $32.7 million. These write-downs were recorded as a result of the adverse publicity surrounding the FDA Order as discussed in Note 2 to the Summary Consolidated Financial Statements in this Form 10-Q. The amount of these write-downs reflected managements' estimates based on information available to it at the time the estimates were made. These estimates may prove inaccurate, as the ultimate impact of the FDA Order is not yet known. Management continues to evaluate the recoverability of these deferred preservation costs based on the factors discussed in Note 2 to Summary Consolidated Financial Statements and will record additional write-downs if it becomes clear that additional impairments have occurred. The write-down created a new cost basis, which cannot be written back up if these tissues become available for distribution. The cost of human tissue preservation services has been favorably affected by tissue shipments which 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. As of September 30, 2003 nominal amounts of tissues processed prior to October 3, 2001, the start date of the FDA Order time period, which were previously written-down, remain available for shipment.

The Company regularly evaluates its deferred preservation costs to determine if the carrying value is appropriately recorded at the lower of cost or market value. During the three and nine months ended September 30, 2003 the Company recorded $1.8 million and $3.2 million, respectively, as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs from tissues processed in the three and nine months ended September 30, 2003 that exceeded market value. The amount of these write-downs reflects managements' estimates of market value based on information available to it at the time the estimates were made and actual results may differ from these estimates.

As of September 30, 2003 the balance of deferred preservation costs was $4.1 million for allograft heart valve tissues, $553,000 for non-valved cardiac tissues, $4.0 million for vascular tissues, and $1.1 million for orthopaedic tissues.

Deferred Income Taxes: Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets in 2002 and 2003 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, FDA Warning Letter, and reported tissue infections. The Company periodically assesses the recoverability of deferred tax assets and provides a valuation allowance when management believes it is more likely than not that its deferred tax assets will not be realized.

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

The Company updated its analysis to determine if a valuation allowance relative to its deferred tax assets was necessary at September 30, 2003. Based on the results of this analysis, the Company determined that it was more likely than not that the Company's deferred tax assets as of September 30, 2003 would not be realized in future periods. The Company recorded an additional $1.9 million in deferred tax valuations to reflect changes in the deferred tax asset balance during the third quarter of 2003, due to current quarter losses and the effect of temporary differences between book and tax income. During the third quarter of 2003, $1.3 million in deferred tax assets not subject to valuation at June 30, 2003 became recoverable and were reclassified to income taxes receivable as of September 30, 2003. The Company also recorded approximately $800,000 in income tax receivables, related to a carry back of operating losses and product liability expenses incurred during 2002.

As a result of recording the valuation allowances and other items listed above, the Company has reported an income tax benefit of $761,000 and an income tax expense of $2.7 million for the three and nine months ended September 30, 2003, respectively. As of September 30, 2003 the Company had a total of $11.6 million in valuation allowances against deferred tax assets.

Valuation of Long-lived and Intangible Assets and Goodwill: The Company assesses the impairment of its long-lived, identifiable intangible assets and related goodwill annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that management considers important that could trigger an impairment review include the following:

- Significant underperformance relative to expected historical or projected future operating results;

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

Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), requires the write-down of a long-lived asset to be held and used if the carrying value of the asset or the asset group to which the asset belongs is not recoverable. The carrying value of the asset or asset group is not recoverable if it exceeds the sum of the undiscounted future cash flows expected to result from the use and eventual disposition of the asset or asset group. In applying SFAS 144, the Company defined the specific asset groups used to perform the cash flow analysis. The Company defined the asset groups at the lowest level possible, by identifying the cash flows from groups of assets that could be segregated from the cash flows of other assets and liabilities. Using this methodology, the Company determined that its asset groups consisted of the long-lived assets related to the Company's two reporting segments. As the Company does not segregate assets by segment, the Company allocated assets to the two reporting segments based on factors including facility space and revenues. The Company used a fourteen-year period for the undiscounted future cash flows. This period of time was selected based upon the remaining life of the primary assets of the asset groups, which are leasehold improvements. The undiscounted future cash flows related to these asset groups exceeded their carrying values as of September 30, 2003 and, therefore, management has concluded that there is not an impairment of the Company's long-lived intangible assets and tangible assets related to the tissue preservation business or medical device business. However, depending on the Company's ability to rebuild demand for its tissue preservation services, the outcome of discussions with the FDA regarding the shipping of orthopaedic tissues, and the future effects of adverse publicity surrounding the FDA Order and reported infections on preservation revenues, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144.

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

Product Liability Claims: In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. Following the FDA Order, a greater number of lawsuits than has historically been the case have been filed. The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims, and records accruals as necessary for the estimated cost of unreported claims related to services performed and products sold. As of December 31, 2002 the Company had accrued $3.6 million in estimated costs for unreported product liability claims related to services performed and products sold prior to December 31, 2002. The Company retained an independent actuarial firm to estimate the unreported claims. During the second quarter of 2003 the independent actuarial firm updated the analysis of the unreported product claims as of June 30, 2003. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby, projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. As a result of the actuarial valuation, the Company accrued an additional $3.9 million for estimated costs for unreported product liability claims related to services performed and products sold prior to June 30, 2003. The $3.9 million expense was recorded in the second quarter of 2003 in general, administrative, and marketing expenses. During the third quarter of 2003 the Company recorded an additional $213,000 in estimated costs for unreported product liability claims related to services performed and products sold during the quarter ended September 30, 2003 to increase the total accrual to $7.7 million. The $7.7 million balance is included as a component of accrued expenses and other current liabilities of $4.4 million and other long-term liabilities of $3.3 million on the Summary Consolidated Balance Sheets. As of September 30, 2003 there were no other changes in the amounts accrued for unreported product liability claims as the underlying assumptions used to calculate the liability for unreported product liability claims did not materially change during the third quarter of 2003.

For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. The first $10 million layer of coverage and approximately $1.8 million of the second layer of coverage has been used in the settlement and defense of lawsuits. The insurance carriers with the second and third layers of coverage totaling $15 million have tendered their remaining limits of approximately $13.2 million to the Company and made the funds available to settle all claims outstanding in the relevant policy period. The Company continues to attempt to reach settlements of the outstanding litigation. Based on an analysis of the product liability claims now pending against the Company, settlement negotiations to date, and advice from counsel, the Company has recorded a liability of $9.0 million in the accrued expenses and other current liabilities line of the Summary Consolidated Balance Sheet and a corresponding expense in general, administrative, and marketing expenses for the estimated expense of resolving these claims and reflecting the uninsured portion of the estimated liability. The amounts recorded are reflective of potential legal fees and settlement costs related to these claims, and do not reflect actual settlement arrangements or final judgments, which could include punitive damages. The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. If the Company is unsuccessful in arranging settlements of product liability claims for an amount substantially below the amount accrued, there may not be sufficient insurance coverage and liquid assets to meet these obligations, even if the Company satisfactorily resolves the restrictions on the upper layer excess insurance coverage. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay and one or more of the product liability claims in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiffs(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. If the Company is unable to meet required future cash payments to resolve the outstanding product liability claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

New Accounting Pronouncements

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

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

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

Results of Operations
(In thousands)

Revenues

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues as reported	$ 15,097	$ 16,889	$ 46,730	$ 65,624
Estimated tissue recall returns	--	1,031	--	3,464
Adjustment to estimated tissue recall returns	(52)	--	(900)	--
Adjusted revenues[a]	$ 15,045	$ 17,920	$ 45,830	$ 69,088

Revenues as reported decreased 11% and 29% for the three and nine months ended September 30, 2003, respectively, as compared to the three and nine months ended September 30, 2002. Revenues as reported for the three and nine months ended September 30, 2003 include $52,000 and $900,000, respectively, in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were originally estimated. Revenues as reported for the three and nine months ended September 30, 2002 were adversely affected by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of $1.0 million and $3.5 million, respectively, in preservation service revenues. As of September 30, 2003 nothing remains in the accrual for estimated return of tissues subject to recall by the FDA Order.

Adjusted revenues decreased 16% and 34% for the three and nine months ended September 30, 2003, respectively, as compared to the three and nine months ended September 30, 2002. This decrease in adjusted revenues for the three and nine months ended September 30, 2003 was primarily due to a 35% and 53% decrease, respectively, in human tissue preservation service revenues as a result of the FDA Order's restriction on shipments of certain tissues, the Company's cessation of orthopaedic processing until late February 2003, a decrease in 2003 processing levels relative to processing levels prior to the issuance of the FDA Order in August of 2002, and decreased demand as a result of the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections. These decreases were partially offset by an increase in BioGlue Surgical Adhesive revenues for the three and nine months ended September 30, 2003 of 29% and 31%, respectively, due to increased demand.

The ongoing corrective actions taken by the Company regarding the FDA issues and the anticipated resolution of the FDA issues should assist the Company in increasing the number of tissues available for distribution and assist the Company in rebuilding demand for its preservation services. In the event the Company is not successful in rebuilding demand for its preservation services, future revenues can be expected to remain significantly below historical levels prior to the issuance of the FDA Order. As discussed in Note 2 to the Summary Consolidated Financial Statements, the outcome of the discussions and the 510(k) premarket notification application with the FDA regarding the use of the SynerGraft process on human tissue could result in the elimination of SynerGraft processed cardiovascular and vascular tissue which would reduce revenues and gross margins with respect to cardiovascular and vascular tissues.

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[a] The measurement "adjusted revenues" is defined as revenues prior to estimated tissue recall returns and adjustments made to estimated tissue recall returns. This measurement may be deemed to be a "non-GAAP" financial measure as that term is defined in Regulation G and Item 10(e) of Regulation S-K and is included for informational purposes to provide comparable disclosure in the current and prior periods of revenues derived from services provided with respect to tissues and products shipped in the normal course of business. The GAAP number revenue as reported in the prior year periods was calculated by deducting the amount of estimated tissue recall returns for subsequent returns of FDA recalled tissues from revenue related to tissues and products shipped in the normal course of business. In order to compute revenues as adjusted this unfavorable item from the prior periods was added back to show a clearer comparison to current year periods and to illustrate the magnitude of the decrease in current year revenues. The adjustment to estimated tissue recall returns was recorded during the current year periods to reduce the original estimate of the effect of returns of FDA recalled tissues based on revised estimates. Although the overall effect of these adjustments was an aggregate decrease of the estimated returns, the adjustment had the effect of increasing the estimated returns with respect to non-valved cardiac tissues for the three months ended September 30, 2003. In order to compute revenues as adjusted this item from the current year periods

was added back for the reasons discussed above with respect to estimated tissue returns. The presentation of revenue as reported without the presentation of adjusted revenues might mislead investors with respect to the magnitude of the decrease in the Company's current year revenues relative to the prior year.

BioGlue Surgical Adhesive

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues as reported	$ 6,694	$ 5,183	$ 20,027	$ 15,308
BioGlue revenues as reported as a percentage of total revenue as reported	44%	31%	43%	23%
BioGlue revenues as reported as a percentage of total adjusted revenues[a]	44%	29%	44%	22%

Revenues as reported from the sale of BioGlue Surgical Adhesive increased 29% and 31%, respectively, for the three and nine months ended September 30, 2003 as compared to the three and nine months ended September 30, 2002. The 29% increase in revenues as reported for the three months ended September 30, 2003 was primarily due to an increase in BioGlue sales volume due to an increase in demand in both foreign and domestic markets which increased revenues by 37%, partially offset by a decrease in average selling prices which decreased revenues by 8%. The 31% increase in revenues as reported for the nine months ended September 30, 2003 was due to an increase in BioGlue sales volume due to an increase in demand in both foreign and domestic markets which increased revenues by 29%, and by an increase in average selling prices which increased revenues by 2%. Volume increases in both the three and nine months ended September 30, 2003 were led by increases in the BioGlue 2ml and 5ml product sizes. Domestic revenues accounted for 75% and 77% of total BioGlue revenues for the three and nine months ended September 30, 2003, respectively, and 78% of total BioGlue revenues for both the three and nine months ended September 30, 2002.

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

Cardiovascular Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues as reported	$ 4,547	$ 5,487	$ 14,308	$ 20,131
Estimated tissue recall returns	170	510		
Adjustment to estimated tissue recall returns	7	--	(85)	--
Adjusted revenues[a]	$ 4,554	$ 5,657	$ 14,223	$ 20,641
Cardiovascular revenues as reported as a percentage of total revenue as reported	30%	32%	31%	31%
Cardiovascular adjusted revenues as a percentage of total adjusted revenues[a]	30%	32%	31%	30%

Revenues as reported from cardiovascular preservation services decreased 17% and 29%, respectively, for the three and nine months ended September 30, 2003 as compared to the three and nine months ended September 30, 2002. Cardiovascular revenues as reported for the three months ended September 30, 2003 include $7,000 in unfavorable adjustments to the estimated tissue recall returns due to a greater amount of actual cardiac tissue returns under the FDA Order than were anticipated based on earlier estimates. Cardiovascular revenues as reported for the nine months ended September 30, 2003 include $85,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were estimated in the prior year. Cardiovascular revenues as reported for the three and nine months ended September 30, 2002 were adversely affected by the estimated effect of the tissues returned subject to the FDA Order on service revenues for non-valved cardiac tissues, which resulted in an estimated decrease of $170,000 and $510,000, respectively, in service revenues.

Adjusted revenues from cardiovascular preservation services decreased 19% and 31%, respectively, for the three and nine months ended September 30, 2003 as compared to the three and nine months ended September 30, 2002. The 19% decrease in adjusted revenues for the three months ended September 30, 2003 was due to a decrease in cardiovascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, the FDA public health web notification, and reported tissue infections, and the restrictions on shipments of certain non-valved cardiac tissues subject to the FDA Order which reduced revenues by 15%, and a decrease in average service fees which reduced revenues by 4%. The 31% decrease in adjusted revenues for the nine months ended September 30, 2003 was due to a decrease in cardiovascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, the FDA public health web notification, and reported tissue infections, and the restrictions on shipments of certain non-valved cardiac tissues subject to the FDA Order which reduced revenues by 35%, partially offset by an increase in average service fees which increased revenues by 4%. The decrease in average service fees for the three months ended September 30, 2003 was primarily due to a lower percentage of tissue shipments of valves treated with the SynerGraft process than traditional processing when compared to the corresponding prior year periods. This reduction was due to a lower level of available SynerGraft processed tissue as a result of Company actions surrounding the February 2003 FDA letter as discussed in the Recent Events section above. The increase in average service fees for the nine months ended September 30, 2003 was due to a higher percentage of heart valve shipments, which were not subject to the FDA Order, than non-valved cardiac tissue shipments and due to a higher

percentage of tissue shipments of valves treated with the SynerGraft process than traditional processing when compared to the corresponding prior year periods.

As a result of the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, the Company's procurement of cardiac tissues during the three and nine months ended September 30, 2003, from which heart valves and non-valved cardiac tissues are processed, decreased 6% and 19%, respectively, as compared to the three and nine months ended September 30, 2002. The Company's third quarter 2003 procurement of cardiac tissues increased 4% from the second quarter of 2003.

On June 27, 2003 the FDA modified its public health web notification on the Company by labeling it "archived document – no longer current information – not for official use." This action may assist the Company in rebuilding demand for its cardiovascular tissues. If the Company is unable to rebuild demand for its preservation services for these tissues, future cardiac preservation revenue could continue to decrease. The Company has voluntarily suspended the use of the SynerGraft technology in the processing of allograft cardiovascular tissue and in late September of 2003 suspended the distribution of tissues on hand that have been preserved with the SynerGraft technology until the regulatory status of the CryoValve SG is resolved. On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume processing and distribution of SynerGraft processed cardiovascular tissue. As discussed in Note 2 to the Summary Consolidated Financial Statements, the outcome of the 510(k) premarket notification application with the FDA regarding the use of the SynerGraft process on human tissue could result in the elimination of SynerGraft processed cardiovascular tissue.

Vascular Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues as reported	$ 3,083	$ 3,260	$ 10,637	$ 14,918
Estimated tissue recall returns	833	2,546		
Adjustment to estimated tissue recall returns	(41)	--	(752)	--
Adjusted revenues[a]	$ 3,042	$ 4,093	$ 9,885	$ 17,464
Vascular revenues as reported as a percentage of total revenue as reported	20%	19%	23%	23%
Vascular adjusted revenues as a percentage of total adjusted revenues[a]	20%	23%	22%	25%

Revenues as reported from vascular preservation services decreased 5% and 29%, respectively, for the three and nine months ended September 30, 2003 as compared to the three and nine months ended September 30, 2002. Vascular revenues as reported for the three and nine months ended September 30, 2003 include $41,000 and $752,000, respectively, in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were estimated in the prior year. Vascular revenues as reported for the three and nine months ended September 30, 2002 were adversely affected by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of $833,000 and $2.5 million, respectively, in service revenues.

Adjusted revenues from vascular preservation services decreased 26% and 43%, respectively, for the three and nine months ended September 30, 2003 as compared to the three and nine months ended September 30, 2002. The 26% decrease in adjusted revenues for the three months ended September 30, 2003 was due to a decrease in vascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, and the restrictions on shipments of certain vascular tissues subject to the FDA Order which reduced revenues by 24% and a decrease in average service fees, which reduced revenues by 2%. The 43% decrease in adjusted revenues for the nine months ended September 30, 2003 was due to a decrease in vascular volume primarily due to a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, and the restrictions on shipments of certain vascular tissues subject to the FDA Order which reduced revenues by 40% and by a decrease in average service fees which reduced revenues by 3%.

The Company's procurement of vascular tissue increased 15% for the three months ended September 30, 2003 and decreased 43% for the nine months ended September 30, 2003, as compared to the three and nine months ended September 30, 2002, respectively. The Company's third quarter 2003 procurement of vascular tissues increased 12% from second quarter of 2003.

The ongoing corrective actions taken by the Company regarding the FDA issues and the anticipated resolution of the FDA issues should assist the Company in increasing the number of tissues available for distribution and assist the Company in rebuilding demand for its preservation services. In the event the Company is not successful in rebuilding demand for its preservation services, future vascular preservation service revenues can be expected to remain significantly below historical levels prior to the issuance of the FDA Order. As discussed in Note 2 to the Summary Consolidated Financial Statements, the outcome of the discussions with the FDA regarding the use of the SynerGraft process on human tissue could result in the elimination of SynerGraft processed vascular tissue.

Orthopaedic Preservation Services

	Three Months Ended September 30,	Nine Months Ended September 30,

	2003	2002	2003	2002
Revenues as reported	$ 467	$ 2,553	$ 897	$14,025
Estimated tissue recall returns	--	28	--	408
Adjustment to estimated tissue recall returns	(18)	--	(63)	--
Adjusted revenues[a]	$ 449	$ 2,581	$ 834	$14,433
Orthopaedic revenues as reported as a percentage of total revenue as reported	3%	15%	2%	21%
Orthopaedic adjusted revenues as a percentage of total adjusted revenues[a]	3%	14%	2%	21%

Revenues as reported from orthopaedic preservation services decreased 82% and 94%, respectively, for the three and nine months ended September 30, 2003 as compared to the three and nine months ended September 30, 2002. Orthopaedic revenues as reported for the three and nine months ended September 30, 2003 include $18,000 and $63,000 in favorable adjustments to the estimated tissue recall returns due to lower actual tissue returns under the FDA Order than were estimated in the prior year. Orthopaedic revenues as reported for the three and nine months ended September 30, 2002 were adversely affected by the estimated effect of the return of tissues subject to recall by the FDA Order, which resulted in an estimated decrease of $28,000 and $408,000, respectively, in service revenues.

Adjusted revenues from orthopaedic preservation services decreased 83% and 94%, respectively, for the three and nine months ended September 30, 2003 as compared to the three and nine months ended September 30, 2002. The 83% decrease in adjusted revenues for the three months ended September 30, 2003 was due to a decrease in orthopaedic volume primarily resulting from the restrictions on shipments of certain orthopaedic tissues subject to the FDA Order, the delay in the resumption of processing of orthopaedic tissue until late February 2003, and a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, which reduced revenues by 79% and a decrease in orthopaedic average service fees which reduced revenues by 4%. The 94% decrease in adjusted revenues for the nine months ended September 30, 2003 was due to a decrease in orthopaedic volume primarily due to the restrictions on shipments of certain orthopaedic tissues subject to the FDA Order, cessation of processing of orthopaedic tissue until late February 2003, and a decline in demand related to the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, which reduced revenues by 93% and a decrease in orthopaedic average service fees which reduced revenues by 1%.

The Company resumed limited processing of orthopaedic tissues in late February 2003 following the FDA inspection of the Company's operations as discussed in Note 2 to the Summary Consolidated Financial Statements. The Company began shipments of these orthopaedic tissues processed since February 2003 with the shipment of non-boned orthopaedic tissues in May 2003 and boned orthopaedic tissues in August 2003. The Company has not shipped boned orthopaedic tissues since September 2003. The Company is in the process of conducting a further review of the systems in place to process and release boned orthopaedic tissues. The Company expects to have its review completed over the next couple of months and is optimistic that it will resume shipping boned orthopaedic tissues at the completion of its review. The majority of orthopaedic revenues for the three and nine months ended September 30, 2003 have been from shipments of orthopaedic tissues that were processed since February 2003. The Company's procurement of knees decreased approximately 14% and 61%, respectively, for the three and nine months ended September 30, 2003, as compared to the three and nine months ended September 30, 2002. The Company's third quarter 2003 procurement of knees increased 8% from second quarter of 2003. The Company's procurement of orthopaedic tendons decreased approximately 68% and 86%, respectively, for the three and nine months ended September 30, 2003, as compared to the three and nine months ended September 30, 2002. The Company's third quarter 2003 procurement of orthopaedic tendons increased 14% from second quarter of 2003.

Implantable Medical Devices

Revenues from implantable medical devices decreased 22% to $133,000 for the three months ended September 30, 2003 from $171,000 for the three months ended September 30, 2002, representing 1% of total revenues as reported during such periods. Revenues from implantable medical devices decreased 47% to $313,000 for the nine months ended September 30, 2003 from $584,000 for the nine months ended September 30, 2002, representing 1% of total revenues as reported during such periods.

Distribution and Grant Revenues

Grant revenues increased to $169,000 and $526,000, respectively, for the three and nine months ended September 30, 2003 from $77,000 and $208,000 for the three and nine months ended September 30, 2002. Grant revenues in 2003 and 2002 were attributable to the Activation Control Technology ("ACT") research and development programs through AuraZyme Pharmaceuticals, Inc. ("AuraZyme") and the SynerGraft research and development programs. In February 2001 the Company formed the wholly owned subsidiary AuraZyme to foster the commercial development of ACT, a reversible linker technology that has potential uses in the areas of cancer therapy, fibrinolysis (blood clot dissolving), and other drug delivery applications.

Distribution revenues decreased to zero for the three and nine months ended September 30, 2003 from $158,000 and $450,000, respectively, for the three and nine months ended September 30, 2002. Distribution revenues consisted of commissions received for the distribution of orthopaedic tissues for another processor. The Company does not currently anticipate receiving distribution revenues from any third party processors in 2003.

Cost of Human Tissue Preservation Services

Cost of human tissue preservation services decreased to $7.5 million and $15.1 million, respectively, for the three and nine months ended September 30, 2003 as compared to $28.0 million and $53.2 million, respectively, for the three and nine months ended September 30, 2002. Cost of human tissue preservation services as a percentage of human tissue preservation service revenues was 92% and 58%, respectively, for the three and nine months ended September 30, 2003 as compared to 248% and 108%, respectively, for the three and nine months ended September 30, 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. The cost of human tissue preservation services for the three and nine months ended September 30, 2002 includes $22.7

million and $32.7 million, respectively, in write-downs of deferred preservation costs for tissues subject to the FDA Order. Additional factors negatively impacting the cost of human tissue preservation services on a dollar basis for the three and nine months ended September 30, 2003 and as a percentage of human tissue preservation service revenues for those periods as compared to the prior year periods, were higher overhead cost allocations associated with the decreased volume of tissues processed, changes in processing methods resulting from the FDA Order, and a decrease in tissue shipments of valves treated with the SynerGraft process as compared to traditional processing. Cost of human tissue preservation services on a dollar basis for the nine months ended September 30, 2003 as compared to the prior year period were positively impacted by a decrease in unit shipments.

The Company anticipates cost of human tissue preservation services will show a significant decrease for the full year 2003 compared to 2002, due to the deferred preservation cost write-downs in the second and third quarters of 2002 as discussed in Note 2 to the Summary Consolidated Financial Statements. The cost of human tissue preservation services as a percentage of revenue will continue to be high compared to pre-FDA Order levels as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue. The cost of human tissue preservation services may be minimally favorably affected, depending on the future level of tissue shipments related to previously written-down deferred preservation costs, because the write-down creates a new cost basis, which cannot be written back up if these tissues are shipped or become available for shipment. As of September 30, 2003, nominal amounts of tissues processed prior to October 3, 2001, the start date of the FDA order time period, which were previously written-down, remain available for shipment. Additionally, the Company believes that once the issues with the FDA are resolved, cost of human tissue preservation as a percentage of revenues will decrease as compared to current levels.

Cost of Products

Cost of products aggregated $1.8 million for the three months ended September 30, 2003 compared to $4.7 million for the three months ended September 30, 2002, representing 26% and 89%, respectively, of total product revenues as reported during such periods. Cost of products aggregated $5.4 million for the nine months ended September 30, 2003 compared to $8.8 million for the nine months ended September 30, 2002, representing 27% and 55%, respectively, of total product revenues as reported during such periods. The decrease in cost of products for the three and nine months ended September 30, 2003 was primarily due to a $3.1 million write-down of bioprosthetic valves, including SynerGraft and non-SynerGraft treated porcine valves, in the third quarter of 2002 due to the Company's decision to stop future expenditures on the development and marketing of these valves and to maintain its focus on its preservation services business and its BioGlue and SynerGraft vascular graft product lines. Additionally the decrease in cost of products as a percentage of total product revenues as reported for the three and nine months ended September 30, 2003 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, partially offset by the write-downs.

General, Administrative, and Marketing Expenses

General, administrative, and marketing expenses decreased 6% to $10.6 million for the three months ended September 30, 2003, compared to $11.2 million for the three months ended September 30, 2002, representing 70% and 66%, respectively, of total revenues during such periods. General, administrative, and marketing expenses increased 42% to $45.7 million for the nine months ended September 30, 2003, compared to $32.1 million for the nine months ended September 30, 2002, representing 98% and 49%, respectively, of total revenues during such periods. The decrease in expenses for the three months ended September 30, 2003 was primarily due to a $1.3 million decrease in marketing expenses, including personnel costs and sales commissions, partially offset by an increase of $213,000 in estimated costs for unreported product liability claims related to services performed and products sold during the quarter ended September 30, 2003, $282,000 in increased insurance costs, and $132,000 in increased professional fees (legal, consulting, and accounting). The increase in expenses for the nine months ended September 30, 2003 was primarily due to an accrual of $9.0 million for the estimated expense to resolve ongoing product liability claims in excess of insurance coverage, $4.1 million for estimated unreported product liability claims related to services performed and products sold prior to September 30, 2003, and $150,000 for required insurance retention payments for the Company's product liability insurance policies related to prior policy years, partially offset by a $575,000 reversal of previous retention accruals for which the Company has already fulfilled its payment obligations. (See Legal Proceedings at Part II Item 1 for further discussion of these items.) Additional increases in costs for the nine month period ending September 30, 2003 were due to an increase of approximately $3.4 million in professional fees (legal, consulting, and accounting) due to increased litigation, litigation settlement costs, and issues surrounding the FDA Order, and an increase of approximately $770,000 in insurance premiums, partially offset by a $3.9 million decrease in marketing expenses, including personnel costs and sales commissions.

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

Research and Development Expenses

Research and development expenses decreased 39% to $823,000 for the three months ended September 30, 2003, compared to $1.3 million for the three months ended September 30, 2002, representing 5% and 8%, respectively, of total revenues during such periods. Research and development expenses decreased 23% to $2.8 million for the nine months ended September 30, 2003, compared to $3.7 million for the nine months ended September 30, 2002, representing 6% of total revenues during such periods. The decrease in research and development spending for the three and nine months ended September 30, 2003 was primarily due to a delay in the timing of several external research studies, which are expected to take place in future periods, due to the Company's focus on process improvements and addressing FDA compliance requirements. Research and development spending in 2003 was primarily focused on the Company's core tissue cryopreservation, SynerGraft, and Protein Hydrogel Technologies. Research and development spending in 2002 was primarily focused on the Company's SynerGraft and Protein Hydrogel Technologies.

Other Costs and Expenses

Goodwill impairment of $1.4 million for the three and nine months ended September 30, 2002 consists of a write-down for impairment of goodwill related to the Company's tissue processing reporting unit recorded in the third quarter of 2002 as discussed above in Critical Accounting Policies.

Interest income, net of interest expense, was $14,000 for the three months ended September 30, 2003, as compared to $33,000 for the three months ended September 30, 2002. Interest expense, net of interest income, was $18,000 for the nine months ended September 30, 2003, as compared to $182,000, of interest income, net of interest expense, for the nine months ended September 30, 2002. The decrease in net interest income for the three and nine months ended September 30, 2003 was due to reduced investments earning interest in 2003 as compared to 2002, lower investment interest rates in 2003, and

additional interest payments due to the financing of 2003 insurance premiums, partially offset by a reduction in the principal debt amount outstanding due to principal payments.

Other income was $94,000 for the three months ended September 30, 2003, as compared to other expense of $35,000 for the three months ended September 30, 2002. Other expense was $46,000 for the nine months ended September 30, 2003 as compared to other income of $37,000 for the nine months ended September 30, 2002. Other income for the three months ended September 30, 2003 largely consisted of $80,000 in gains on the sale of land in the third quarter of 2003. Other expense for the nine months ended September 30, 2003 was primarily due to an expense of $222,000 to reclass the unamortized portion of the other comprehensive loss on the Company's interest rate swap to other expense/income, partially offset by a gain on the sale of land.

The Company's income tax benefit of $761,000, net of valuation allowance, for the three months ended September 30, 2003 was primarily due to the current quarter income tax benefit of $1.8 million, recorded at an effective income tax rate of 33%, and the recording of approximately $800,000 in additional income taxes receivable, partially offset by the establishment of an additional valuation allowance against the Company's deferred tax assets of $1.9 million. The Company's income tax expense of $2.7 million for the nine months ended September 30, 2003 was primarily due to the expense related to the establishment of a valuation allowance against its deferred tax assets of $11.0 million, partially offset by an income tax benefit of $7.4 million, recorded at an effective income tax rate of 33%, and the recording of approximately $800,000 in additional income tax receivables. The effective income tax rate was 34% for the three and nine months ended September 30, 2002.

Seasonality

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

Liquidity and Capital Resources

Overall Trend in Liquidity and Capital Resources

The Company expects its liquidity to continue to decrease significantly over the next twelve months due to 1) the anticipated decrease in preservation revenues as compared to preservation revenues prior to the FDA Order as a result of reported tissue infections, the FDA Order, and associated adverse publicity, 2) the increase in cost of human tissue preservation services as a percent of revenue as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue, 3) an expected use of cash due to the increased costs relating to the defense and resolution of lawsuits (discussed in Note 13), and 4) the legal and professional costs relating to the ongoing FDA compliance. The Company believes that anticipated revenue generation, expense management, tax refunds expected to be approximately $3.0 to $3.5 million, savings resulting from the reduction in the number of employees in September 2002 necessitated by the reduction in revenues, and the Company's existing cash and marketable securities will enable the Company to meet its liquidity needs through September 30, 2004.

The Company's long term liquidity and capital requirements will depend upon numerous factors, including the Company's ability to return to the level of demand for its tissue services that existed prior to the FDA Order, the outcome of litigation against the Company (discussed in Note 13), the timing of the resolution of and the amount required to resolve the product liability claims (discussed in Note 13), the ability to arrange and fund settlements of outstanding claims for amounts substantially below the amount of the accrual (discussed in Note 13), and the Company's ability to find suitable financing. The Company may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond September 30, 2004. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows. These are factors that indicate that the Company may be unable to continue operations beyond September 30, 2004.

In addition, as discussed in Note 13, the Company has recorded $9.0 million related to the estimated expense of resolving current product liability claims in excess of insurance coverage. The $9.0 million accrual is reflective of estimated settlement costs related to outstanding claims, and does not reflect actual settlement arrangements or judgments, including punitive damages, which may be assessed by the courts. The $9.0 million accrual is not a cash reserve. Should payments related to the accrual be required, the expenses would have to be paid from insurance proceeds and other liquid assets, if available. The Company continues to attempt to reach settlements of the outstanding claims in order to minimize the potential cash payout. See discussion in Note 13 regarding certain insurance carriers' tender of their remaining limits to the Company for use in settling all cases outstanding in the relevant policy period. As of November 10, 2003 the Company has entered into settlement agreements or agreements in principle to pay approximately $11.3 million which will be funded by the $13.2 million made available by the insurance carriers. If the Company is unable to settle these product liability claims for an amount substantially below the amount accrued, there may not be sufficient insurance coverage and liquid assets to meet these obligations. Furthermore, if the Company is unable to settle the outstanding claims for amounts within its ability to pay and one or more of the product liability lawsuits in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. The Company's product liability insurance policies do not include coverage for any punitive damages that may be assessed at trial. There is a possibility that significant punitive damages could be assessed in one or more lawsuits which would have to be paid out of the liquid assets of the Company, if available.

In addition, as discussed in Note 13, the Company has recorded $7.7 million for estimated costs of unreported product liability claims related to services performed and products sold prior to September 30, 2003. The $7.7 million accrual is not a cash reserve. The timing of the actual payment of the expense related to the accrual is dependent on when and if claims are asserted. Should payments related to the accrual be required, the expenses would have to be paid from insurance proceeds and liquid assets, if available. Since amounts expensed are estimates, the actual amounts required could vary significantly.

The Company previously announced a proposed buyback of certain employee stock options. After further deliberation the Company's Board of Directors decided in October 2003 not to pursue the employee stock option buyback at this time.

Net Working Capital

At September 30, 2003 net working capital (current assets of $46.4 million less current liabilities of $26.2 million) was $20.2 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of $37.6 million, with a current ratio of 3 to 1 at December 31, 2002.

The Company's primary capital requirements historically arose from general working capital needs, capital expenditures for facilities and equipment, and funding of research and development projects. The Company has historically funded these requirements through bank credit facilities, cash generated by operations, and equity offerings. Based on the decrease in revenues resulting from the adverse publicity surrounding the FDA Order, FDA Warning Letter, and reported tissue infections, and the anticipated costs to be paid by the Company in resolving pending litigation, the Company expects that its cash used in operating activities will continue to be high and will increase to the extent funds are needed to defend and resolve litigation, and that net working capital will significantly decrease.

Net Cash from Operating Activities

Net cash used by operating activities was $345,000 for the nine months ended September 30, 2003, as compared to net cash provided of $636,000 for the nine months ended September 30, 2002. Current year net cash used of $345,000 is primarily due to the year to date net loss excluding the effect of non-cash items, partially offset by the receipt of $11.4 million in federal income tax returns through a carry back of operating losses and write-downs of deferred preservation costs and estimated tax payments for 2002. The non-cash items which favorably affect the net loss for the nine months ended September 30, 2003 include an increase in accounts payable, accrued expenses, and current liabilities of $10.9 million, largely due to accruals of legal fees and settlement costs expected to be paid out in future periods as discussed in the Results of Operations section above, valuation on deferred tax assets net of current year deferred tax benefit of $5.7 million, depreciation and amortization of $4.1 million, write-down of deferred preservation costs of $3.2 million and a net decrease in prepaid and other assets of $1.4 million which excludes the effect of $2.4 million in non-cash financing of insurance premiums. These favorable non-cash items are partially offset by an $8.5 million increase in deferred preservation costs.

Net Cash from Investing Activities

Net cash provided by investing activities was $5.5 million and $5.2 million in the nine months ended September 30, 2003 and 2002, respectively. The $5.5 million in current year net cash provided was primarily due to $4.7 million in cash from sales and maturities of marketable debt securities and $1.1 million in cash received from sale of land, partially offset by $456,000 in capital expenditures.

Net Cash from Financing Activities

Net cash used in financing activities was $7.3 million and $1.0 million in the nine months ended September 30, 2003 and 2002, respectively. The $7.3 million in current year net cash used was primarily due to $5.6 million in principal payments on the Term Loan, including $4.5 million used to pay off the remaining balance of the loan during the third quarter of 2003. The remaining cash used was due to $1.6 million in principal payments on short term notes payable for the financing of insurance premiums, and $485,000 in payments on capital leases, partially offset by a $475,000 increase in cash due to proceeds from the issuance of stock in connection with the exercise of stock options and the Company's employee stock purchase plan.

Scheduled Contractual Obligations and Future Payments

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

	Total	Remainder of 2003	2004	2005	Thereafter
Note Payable	$ 806	$ 806	$ --	$ --	$ --
Capital Lease Obligations	3,005	211	843	843	1,108
Operating Leases	25,541	556	2,115	2,091	20,779
Purchase Commitments	493	92	401	--	--
Total Contractual Obligations	$ 29,845	$ 1,665	$ 3,359	$ 2,934	$ 21,887

In the quarter ended June 30, 2003 the Company entered into two agreements to finance $2.9 million in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. The amount financed accrues interest at a 3.75% rate and is payable in equal monthly payments through December 2003. As of October 31, 2003 the outstanding balance of the agreements was $535,000.

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. Therefore, all amounts due under these capital leases are reflected as a current liability on the Summary Consolidated Balance Sheets as of September 30, 2003.

Interest Rate Swap Agreement

The Company's Term Loan, which was paid in full on August 15, 2003, accrued interest computed at Adjusted LIBOR plus 1.5%, and exposed the Company to changes in interest rates going forward. On March 16, 2000 the Company entered into a $4.0 million notional amount forward-starting interest swap agreement, which took effect on June 1, 2001 and expired in 2006. This swap agreement was designated as a cash flow hedge to effectively convert a portion of the Term Loan balance to a fixed rate basis, thus reducing the impact of interest rate changes on future income. This agreement involved the receipt of floating rate amounts in exchange for fixed rate interest payments over the life of the agreement, without an exchange of the underlying principal amounts. The differential to be paid or received was recognized in the period in which it accrued as an adjustment to interest expense on the Term Loan.

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

During the quarter ended June 30, 2003 the Company became aware of the lender's intention to accelerate the payment of the Term Loan, as discussed in Note 6 above. Therefore, the Company recorded an expense of $222,000, to reclass the unamortized portion of the other comprehensive loss to other expense/income on the Summary Consolidated Statements of Operations. In conjunction with the payoff of the outstanding balance of the Term Loan, the Company paid $199,000 to terminate the swap agreement. This $199,000 payment represents the estimated fair value of the interest rate swap, as estimated by the bank based on its internal valuation models, as of the day of the termination of the agreement. For the three months ended September 30, 2003 the Company recorded a benefit of $39,000 on the interest rate swap, and for the nine months ended September 30, 2003 the Company recorded a total expense of $168,000 on the interest rate swap.

Stock Repurchase

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

Capital Expenditures

The Company expects that its full year capital expenditures in 2003, which were $456,000 through September 30, 2003, will be substantially less than its expenditures in 2002, which were approximately $4.1 million. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to resume normal operating levels once it has fully evaluated the demand for the tissues it processes. The Company does not currently anticipate any major purchase of equipment as a result of the FDA inspections.

FORWARD-LOOKING STATEMENTS

This Form 10-Q contains forward-looking statements and information made or provided by the Company that are based on the beliefs of its management as well as estimates and assumptions made by and information currently available to management. The words "could," "may," "might," "will," "would," "shall," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future" and other similar expressions generally identify forward-looking statements, including, in particular, statements regarding anticipated revenues, cost savings, insurance coverage, regulatory activity, available funds and capital resources, and pending litigation. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates.

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

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

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risks set forth under "Risk Factors" in Part I, Item 1 of the Company's Form 10-K for the year ended December 31, 2002 and other factors, many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q 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 which might impact the forward-looking statements and the Company, and its ability to continue as a going concern, include concerns that:

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company's interest income and expense are most sensitive to changes in the general level of United States interest rates. In this regard, changes in United States interest rates affect the interest earned on the Company's cash and cash equivalents of $8.2 million and short-term investments in municipal obligations of $9.7 million as of September 30, 2003. 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 interest income for 2003.

Item 4. Controls and Procedures.

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

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

Based upon the Company's most recent Disclosure Controls evaluation as of September 30, 2003, including an analysis of the reasons underlying the error regarding the tax refund available to the Company in the second quarter, the CEO and CFO have concluded that 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 United States Securities and Exchange Commission's rules and forms. The CEO and CFO have determined that no changes in the Company's Disclosure Controls or internal control over financial reporting were required as a result of the error regarding the tax refund available to the Company in the second quarter.

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

Part II — OTHER INFORMATION

Item 1. Legal Proceedings.

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. Following the FDA Order, a greater number of lawsuits than has historically been the case have been filed. As of November 12, 2003 the Company was aware of approximately 13 pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, eight 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, and one alleges product liability claims arising out of the non-tissue products made by Ideas for Medicine, when it was a subsidiary of the Company.

Included in these lawsuits is the complaint filed against the Company in the Superior Court of Cobb County, Georgia, on October 8, 2002 by Jeffrey Andronaco and Christina Andronaco. This complaint alleges strict liability, negligence, professional negligence, and breach of warranties related to cardiac tissue implanted in October 2000. The plaintiff seeks unspecified compensatory and punitive damages in the filed complaint.

Included in these lawsuits is the complaint filed against the Company in the Third District Court Salt Lake City, Utah, on January 31, 2003 by Jolene and Robert Moulton, husband and wife, on behalf of Hayley Moulton, their minor child. This complaint alleges strict liability, negligence, professional negligence, and breach of implied and express warranties related to cardiac tissue implanted in July 2001. The plaintiff seeks unspecified compensatory and punitive damages in the filed complaint.

Of the 13 open lawsuits, two lawsuits were filed in the 2000/2001 insurance policy year, two were filed in the 2001/2002 insurance policy year, eight were filed in the 2002/2003 insurance policy year and one was filed in the 2003/2004 policy year. For the 2000/2001 and 2001/2002 insurance policy years, the Company maintained claims-made insurance policies, which the Company believes to be adequate to defend against the suits filed during this period. For the 2002/2003 insurance policy year, the Company maintained claims-made insurance policies with three carriers. The first $10 million layer of coverage and approximately $1.8 million of the second layer of coverage has been used in the settlement and defense of lawsuits. The insurance carriers with the second and third layers of coverage totaling $15 million have tendered their remaining limits of approximately $13.2 million to the Company and made the funds available to settle all claims outstanding in the relevant policy period. As of November 10, 2003 approximately $13.2 million remains of the 2002/2003 insurance limits. The Company continues to attempt to reach settlements of the outstanding litigation. Of the eight open lawsuits filed in the 2002/2003 insurance policy year, four have agreed in principle to the settlement offers.

Based on an analysis of the product liability claims now pending against the Company, settlement negotiations to date, and advice from counsel, the Company has recorded a liability of $9.0 million in the accrued expenses and other current liabilities line of the Summary Consolidated Balance Sheet and a related expense of $9.0 million in general, administrative, and marketing expenses which represents the Company's best estimate of the costs and expenses related to resolving these claims and reflecting the uninsured portion of the estimated liability. The amounts recorded are reflective of estimated legal fees and settlement costs related to these claims, and do not reflect actual settlement arrangements or final judgments, which could include punitive damages.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. If the Company is unsuccessful in arranging settlements of product liability claims for an amount substantially below the amount accrued, there may not be sufficient insurance coverage and liquid assets to meet these obligations, even if the Company satisfactorily resolves the restrictions on the upper layer excess insurance coverage. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay and one or more of the product liability lawsuits in which the Company is a defendant should be tried and a substantial verdict rendered in favor of the plaintiffs(s), there can be no assurance that such verdict(s) would not exceed the Company's available insurance coverage and liquid assets. If the Company is unable to meet required future cash payments to resolve the outstanding product liability claims, it will have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims, and records accruals as necessary for the estimated cost of unreported claims related to services performed and products sold. As of December 31, 2002 the Company had accrued $3.6 million for estimated costs for unreported product claims. On May 2, 2003 the insurance carrier for the 2003/2004 policy altered the policy effective April 1, 2003 to be a first year claims made policy, i.e. only claims incurred and reported during the policy period April 1, 2003 through March 31, 2004 are covered by this policy. During the second quarter of 2003 the Company engaged an independent actuarial firm to update the analysis of the unreported product claims as of June 30, 2003. As a result of the actuarial valuation, the Company accrued an additional $3.9 million for estimated costs for unreported product liability claims related to services performed and products sold prior to June 30, 2003. The $3.9 million expense was recorded in the second quarter of 2003 in general, administrative, and marketing expenses. During the third quarter of 2003 the Company recorded an additional $213,000 in estimated costs for unreported product liability claims related to services performed and products sold during the quarter ended September 30, 2003 to increase the total accrual to $7.7 million. The $7.7 million balance is included as a component of accrued expenses and other current liabilities of $4.4 million and other long-term liabilities of $3.3 million on the Summary Consolidated Balance Sheets. As of September 30, 2003 there were no other changes in the amounts accrued for unreported product liability claims as the underlying assumptions used to calculate the liability for unreported product liability claims did not materially change during the third quarter of 2003.

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

Several putative class action lawsuits were filed in July through September 2002 against the Company and certain officers of the Company, alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 based on a series of purportedly materially false and misleading statements to the market. The suits were consolidated, and a consolidated amended complaint filed, which principally alleges that the Company failed to disclose its alleged lack of compliance with certain FDA regulations regarding the handling and processing of certain tissues and other product safety matters. The consolidated complaint seeks certification of a class of purchasers between April 2, 2001 and August 14, 2002, compensatory damages, and other expenses of litigation. The Company and the other defendants filed a motion to dismiss the consolidated complaint on February 28, 2003, which motion the United States District Court for the Northern District of Georgia denied in part and granted in part on May 27, 2003. The discovery phase of the case commenced on July 16, 2003. The Company carries directors' and officers' liability insurance policies, which the Company presently believes to be adequate to defend against this action. Nonetheless, an adverse judgment in excess of the Company's insurance coverage could have a material adverse effect on the Company's financial position, results of operations, and cash flows.

On August 30, 2002 a purported shareholder derivative action was filed by Rosemary Lichtenberger against Steven G. Anderson, Albert E. Heacox, John W. Cook, Ronald C. Elkins, Virginia C. Lacy, Ronald D. McCall, Alexander C. Schwartz, and Bruce J. Van Dyne in the Superior Court of Gwinnett County, Georgia. The suit, which names the Company as a nominal defendant, alleges that the individual defendants breached their fiduciary duties to the Company by causing or allowing the Company to engage in certain inappropriate practices that caused the Company to suffer damages. The complaint was preceded by one day by a letter written on behalf of Ms. Lichtenberger demanding that the Company's Board of Directors take certain actions in response to her allegations. On January 16, 2003 another purported derivative suit alleging claims similar to those of the Lichtenberger suit was filed in the Superior Court of Fulton County by complainant Robert F. Frailey. As in the Lichtenberger suit, the filing of the complaint in the Frailey action was preceded by a 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, is currently evaluating the consolidated amended complaint.

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

Item 2. Changes in Securities.

None

Item 3. Defaults Upon Senior Securities.

See Note 6 to the Summary Consolidated Financial Statements for information regarding a notification by the Company's lender that the FDA Order and the inquiries of the SEC have had a material adverse effect on the Company, which constitutes an event of default under the Company's Term Loan, which was paid in full on August 15, 2003. The cross default provisions included in the Company's Term Loan also triggered a default of certain capital lease agreements maintained with the lender under the Term Loan.

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

None

Item 5. Other information.

None.

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

(a) The exhibit index can be found below.

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).
31.1*	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

(b) Current Reports on Form 8-K.

The Registrant filed a Current Report on Form 8-K with the Commission on July 11, 2003 with respect to the Press Release dated July 11, 2003 regarding products liability claims and related insurance coverage.

The Registrant filed a Current Report on Form 8-K with the Commission on August 5, 2003 with respect to the Press Release dated August 5, 2003 announcing the registrant's results of operations for the second quarter 2003.

The Registrant filed a Current Report on Form 8-K with the Commission on August 11, 2003 with respect to the transcript of earnings conference call held August 5, 2003 regarding the registrant's results of operations for the second quarter 2003.

The Registrant filed a Current Report on Form 8-K with the Commission on August 21, 2003 with respect to the Press Releases dated August 19, 2003 and August 20, 2003, respectively, regarding the appointment of Thomas J. Lynch, J.D., Ph.D, as Vice President of Regulatory Affairs and Quality Assurance, and Gregory Ray, M.D., as Associate Medical Director.

SIGNATURES

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

CRYOLIFE, INC.
(Registrant)

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

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

November 13, 2003
DATE

Exhibit 31.1

CERTIFICATIONS

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

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: November 13, 2003

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

Exhibit 31.2

CERTIFICATIONS

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

1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: November 13, 2003

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

Exhibit 32

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, 2003, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Steven G. Anderson, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Vice President, Treasurer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN G. ANDERSON
STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer
November 13, 2003

/s/ DAVID ASHLEY LEE
DAVID ASHLEY LEE
Vice President, Treasurer, and
Chief Financial Officer
November 13, 2003