# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

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

For the Quarterly Period Ended June 30, 2006

**Commission File Number 1-13165** 

# **CRYOLIFE, INC.**

(Exact name of registrant as specified in its charter)

Florida

(State or other jurisdiction of incorporation or organization)

**59-2417093** (I.R.S. Employer Identification No.)

1655 Roberts Boulevard, NW

Kennesaw, Georgia 30144 (Address of principal executive offices) (zip code)

(770) 419-3355

(Registrant's telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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

YES 🗵 NO 🗖

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (check one):

Large Accelerated filer  $\Box$  Accelerated filer  $\boxtimes$  Non-accelerated filer  $\Box$ 

Indicate by check mark whether the registrant is a shell company (as defined in the Rule 12b-2 of the Exchange Act).

YES 🗆 NO 🗵

The number of shares of common stock, par value \$0.01 per share, outstanding on July 31, 2006 was 24,824,563.

# Part I --- FINANCIAL INFORMATION

Item 1. Financial Statements

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

	Three Months Ended June 30,				nded			
	-	2006	,	2005		<u>June</u> 2006		2005
		(Unau	dited	1)		(Unau	diteo	1)
Revenues:								
Products	\$	10,569	\$	9,846	\$	20,621	\$	19,973
Human tissue preservation services		10,181		7,352		19,520		14,890
Research grants		4				62		_
Total revenues		20,754		17,198		40,203		34,863
Costs and expenses:								
Products		2,082		2,079		4,005		4,195
Human tissue preservation services (Including write-downs of \$379 for the three months and \$753 for the six months ended June 30, 2006 and \$392 for the three months and \$672 for								
the six months ended June 30, 2005)		7,034		6,070		13,797		11,969
General, administrative, and marketing		10,245		21,585		21,557		31,641
Research and development		837		929		1,746		1,850
Interest expense		188		88		335		143
Interest income		(103)		(167)		(210)		(242)
Change in valuation of derivative		11		902		67		784
Other expense, net		357		45		344		175
Total costs and expenses	_	20,651	_	31,531		41,641	_	50,515
Earnings (loss) before income taxes		103		(14,333)		(1,438)		(15,652)
Income tax (benefit) expense		(114)		46		125		84
Net income (loss)	\$	217	\$	(14,379)	\$	(1,563)	\$	(15,736)
Effect of preferred stock		(244)		(244)		(487)		(290)
Net loss applicable to common shares	\$	(27)	\$	(14,623)	\$	(2,050)	\$	(16,026)
Loss per common share:								
Basic	\$	0.00	\$	(0.61)	\$	(0.08)	\$	(0.68)
Diluted	\$	0.00	\$	(0.61)	\$	(0.08)	\$	(0.68)
Weighted average common shares outstanding:								
Basic		24,807		23,905		24,783		23,676
Diluted	_		-		-		_	
Difuiçu		24,807	_	23,905	_	24,783		23,676

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See accompanying notes to summary consolidated financial statements.

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

	June 30, 2006 (Unaudited)		De	cember 31, 2005
ASSETS	ì	,		
Current Assets:				
Cash and cash equivalents	\$	4,302	\$	6,631
Marketable securities, at market		3,480		4,968
Restricted securities		559		560
Trade receivables, net		11,881		10,153
Other receivables		1,665		1,934
Deferred preservation costs, net		17,383		13,959
Inventories		4,763		4,609
Prepaid expenses and other assets		3,838		2,387
Total current assets	_	47,871	_	45,201
	-			<u> </u>
Property and equipment, net		23,151		24,375
Patents, net		4,399		4,877
Other long-term assets		2,042		2,356
TOTAL ASSETS	\$	77,463	\$	76,809
	+	,	-	
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	\$	2,933	\$	2,239
Accrued expenses and other current liabilities		8,003		8,578
Accrued compensation		1,769		1,467
Accrued procurement fees		3,937		3,797
Notes payable		1,638		—
Derivative liability		181		114
Line of credit		4,500		4,530
Current maturities of capital lease obligations		273		554
Total current liabilities	_	23,234		21,279
				<u> </u>
Other long-term liabilities		4,549		4,909
Deferred income taxes		248		
Total liabilities		28,031		26,188
			_	
Shareholders' Equity:				
Preferred stock (325 issued shares in 2006 and 2005)		3		3
Common stock (25,713 issued shares in 2006 and 25,582 in 2005)		257		256
Additional paid-in capital		114,437		113,507
Retained deficit		(60,619)		(58,569)
Accumulated other comprehensive income		103		123
Treasury stock at cost (904 shares in 2006 and 892 in 2005)		(4,749)		(4,699)
Total shareholders' equity		49,432		50.621
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$	77,463	¢	76,809
TOTAL LIADILITIES AND SHAREHULDERS EQUILI	Ф	//,403	\$	/0,809

See accompanying notes to summary consolidated financial statements.

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

		Aonths Ended June 30,
	2006	2005
Net cash from operating activities:	(1	Jnaudited)
Net loss	\$ (1,50	53) \$ (15,736
Adjustments to reconcile net loss to net cash from operating activities:	φ (1,50	(15,750)
Loss on sale of assets	38	30 151
Depreciation and amortization	2.40	
Provision for doubtful accounts	, ,	18 <u>2,571</u>
Write-down of deferred preservation costs		53 672
Other non-cash adjustments		16 (48 <sup>°</sup>
Non-cash employee compensation	68	()
Change in valuation of derivative		57 784
Changes in operating assets and liabilities:	,	70 70 70 7
Receivables	(1.82	26) (2,415)
Income taxes	(1,02	
Deferred preservation costs and inventories	(4,33	
Prepaid expenses and other assets		
Accounts payable, accrued expenses, and other liabilities	(1,23	, ,
Net cash used in operating activities		
Net cash used in operating activities	(3,89	(7,046)
Net cash from investing activities:		
Capital expenditures	(99	(490)
Net proceeds from sale of assets		(490)
Other assets		15 <u>(114</u>
Purchases of marketable securities	(9,46	
Sales and maturities of marketable securities	11,00	, , ,
Net cash provided by (used in) investing activities	56	
Net eash provided by (used in) investing activities		14,000
Net cash from financing activities:		
Proceeds from debt issuance	25	51 265
Principal payments of debt	(28	(265)
Payment of obligations under capital leases	(28	31) (384
Proceeds from financing of insurance policies	2,34	
Principal payments on short-term notes payable	(71	/
Proceeds from exercise of stock options and issuance of common stock	(	14 235
Payment of preferred stock dividends	(48	
Proceeds from equity offerings	-	- 19,098
Purchase of treasury stock	(*	50) —
Net cash provided by financing activities	1,03	
Decrease in cash and cash equivalents	(2,29	/
Effect of exchange rate changes on cash	(3	33) (149)
Cash and cash equivalents, beginning of period	6,63	
Cash and cash equivalents, end of period	<u>\$ 4,30</u>	<u>\$ 4,189</u>

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 cash flow line items have been reclassified to conform to current year presentation. Operating results for the six months ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. 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, 2005.

The Company expects that the following will continue to have an adverse impact on earnings and cash flows during 2006:

- The anticipated lower preservation services revenues as compared to preservation revenues prior to the August 13, 2002 U.S. Food and Drug Administration ("FDA") Order, subsequent FDA activities, and related events (discussed in Note 2),
- The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and decreased yields of implantable tissue per donor,
- An expected use of cash related to the defense and resolution of lawsuits and claims, and
- The legal and professional costs related to ongoing FDA compliance.

The Company believes the following should continue to have a favorable impact on cash flow from operations during the remainder of 2006, although there can be no assurance that these events will occur as and when currently anticipated:

- Expected increases in revenues due to increases in BioGlue® Surgical Adhesive ("BioGlue") list prices implemented in January and July 2006,
- Expected increases in the preservation service revenues for cardiovascular, vascular, and orthopaedic tissues due to fee increases implemented in January and July 2006, to reflect the higher cost of processing these tissues,
- Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2005 through process changes and process directives,
- Expected increases in procurement of human tissues for processing over the levels experienced in 2005, and
- Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2005.

The Company believes that the Company's existing cash, cash equivalents, marketable securities, and availability under the Credit Agreement (as defined in Note 6) will enable the Company to meet its liquidity needs through at least June 30, 2007.

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

- The success of BioGlue and other products using related technology,
- The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,
- The Company's ability to reestablish sufficient margins on its tissue preservation services, in the face of increased processing costs, by improving yields and increasing prices,
- The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- The timing and cost of resolving product liability lawsuits and other claims (see Note 13), and
- To a lesser degree, the Company's success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft® technology.

If the Company is unable to address these issues and continues to experience negative operating cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond June 30, 2007. Additional funds may not be available when needed or on terms acceptable to the Company, which could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows.

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

## FDA Order

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

The FDA allowed non-valved cardiac and vascular tissues covered by the recall to be distributed beginning in late September 2002, subject to specified conditions. The Company changed its processing procedures and took other actions intended to address the FDA's concerns, and now processes non-valved cardiac, vascular, and orthopaedic tissues.

# **Other FDA Correspondence and Notices**

#### July 2005 483

An FDA Form 483 Notice of Observations ("483") was issued in August 2005 in connection with the FDA inspections of the Company's facilities in July 2005 ("July 2005 483"). The Company responded to the July 2005 483 in August 2005, in September 2005, and in October 2005. In April 2006 the FDA responded on the adequacy of the Company's responses. The Company responded to the FDA in June 2006. In response to the July 2005 483 the Company has implemented new and revised existing systems and procedures. The FDA may require the Company to implement additional corrective actions, perform additional validation testing, or supply additional information related to the inspections, and has the authority to take other actions, which may be more burdensome. The

Company has cooperated and will continue to cooperate with the FDA to review process improvements and address any outstanding observations.

#### **SynerGraft**

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 SynerGraft processed human cardiac tissues ("CryoValve® SG") and that premarket approval marketing authorization should be obtained for the Company's SynerGraft processed human vascular tissues ("CryoVein® SG") when marketed or labeled as an arteriovenous ("A-V") access graft. The agency's position is that use of the SynerGraft technology in the processing of allograft heart valves represents a modification to the Company's legally marketed CryoValve allograft and that vascular allografts labeled for use as A-V access grafts are medical devices that require premarket approval.

On November 3, 2003 the Company filed a 510(k) premarket notification with the FDA for the CryoValve SG. On February 4, 2004 the Company received a letter from the FDA requesting additional information. On August 24, 2004 the Company submitted an amendment to its original 510(k) submission providing clarification and additional information. The FDA requested further additional information in November 2004. On June 8, 2005 CryoLife responded to some of these additional requests. CryoLife also has initiated an appeal of other requests through administrative procedures. The FDA requested further additional information in January 2006. Since March 2006 the Company has had discussions with the FDA to address the outstanding requests for additional information and seek clearance for the CryoValve SG pulmonary valve. On July 21, 2006 the Company submitted an amendment to its 510(k) application addressing information requested by the FDA. The Company is currently undertaking further clinical and preclinical evaluations in response to requests by the FDA that will be included in an additional 510(k) amendment. The FDA may still require that additional studies be undertaken. Clearance of the 510(k) premarket notification with the FDA will be required before the Company can resume distribution of SynerGraft processed CryoValve SG.

On December 8, 2003 the Company received a letter from the FDA stating that it was the agency's position that cardiovascular tissues processed with the SynerGraft technology should be regulated as medical devices. On September 14, 2004 the Company met with the FDA to discuss the data to be used to support a formal Request for Designation ("RFD") filing for SynerGraft processed non-valved cardiac and vascular tissue, including the CryoVein SG. An RFD submission establishes the regulatory status of the tissue. The Company submitted the RFD on October 5, 2004. The FDA affirmed its original decision in letters received in December 2004. That decision was subject to an administrative appeal. On October 20, 2005 CryoLife was informed that the FDA had denied the appeal and that CryoLife will be unable to distribute CryoVein tissues with the SynerGraft technology until further submissions and FDA clearances are granted. The Company is evaluating whether it will file and seek a premarket approval for CryoVein SG or discontinue the CryoVein SG.

In 2003 the Company suspended the use of the SynerGraft technology in the processing of allograft tissue and the distribution of tissues on hand previously processed with the SynerGraft technology until the regulatory issues associated with these tissues are resolved. Additionally, the Company discontinued labeling its vascular grafts for use as A-V access grafts. Until such time as the issues surrounding SynerGraft are resolved, the Company is employing its traditional processing methods on these tissues. As of June 30, 2006 the Company had no deferred preservation costs related to SynerGraft processed tissues on its Summary Consolidated Balance Sheets.

# Note 3 — Cash Equivalents and Marketable Securities

The Company maintains cash equivalents and investments in several large, well-capitalized financial institutions, and the Company's policy excludes investment in any securities rated less than "investment-grade" by national rating services. Management determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designations quarterly.

Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are stated at amortized cost. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Trading securities are stated at their fair values, with the realized and unrealized gains and losses, interest, and dividends included in



investment income. Debt securities not classified as held-to-maturity or trading and marketable equity securities not classified as trading are classified as available-for-sale. Available-for-sale securities are stated at their fair values, with the unrealized gains and losses, net of applicable taxes, reported in a separate component of shareholders' equity. Interest, 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.

As of June 30, 2006 \$3.5 million of marketable securities were designated as available-for-sale and \$559,000 were designated as held-to-maturity. As of December 31, 2005 \$5.0 million of marketable securities were designated as available-for-sale and \$560,000 were designated as held-to-maturity. The held-to-maturity securities were designated as such due to a contractual commitment to hold the securities as pledged collateral relating to one of the Company's product liability insurance policies, and, therefore, they are reported as restricted securities on the June 30, 2006 and December 31, 2005 Summary Consolidated Balance Sheets.

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

1 - 20 2007	<u></u> C(	ost Basis	H	nrealized Iolding Gains Losses)	I	timated Jarket Value
June 30, 2006						
Cash equivalents:						
Money market funds	\$	3,193	\$		\$	3,193
Marketable securities: Government entity sponsored debt securities US Treasury debt securities Total marketable securities	\$ \$	2,481 999 3,480	\$ \$		\$ \$	2,481 999 3,480
Restricted securities:						
Government entity sponsored debt securities	\$	559	\$		\$	559

	Co	ost Basis	]	nrealized Holding Gains (Losses)	N	timated Aarket Value
December 31, 2005						
Cash equivalents:						
Money market funds	\$	5,595	\$	—	\$	5,595
Marketable securities:						
Government entity sponsored debt securities	\$	2,980	\$	(2)	\$	2,978
US Treasury debt securities		1,990		_		1,990
Total marketable securities	\$	4,970	\$	(2)	\$	4,968
Restricted securities:						
Government entity sponsored debt securities	\$	560	\$	—	\$	560

There were no gross realized gains or losses on sales of available-for-sale securities for both the three and six months ended June 30, 2006 and 2005. Differences between cost and market listed above, consisting of a net unrealized holding loss of \$2,000 less deferred taxes of zero at December 31, 2005, are included as a separate component of other comprehensive income in the shareholders' equity section of the Summary Consolidated Balance Sheets.

At June 30, 2006 and December 31, 2005 all of the Company's marketable securities had a maturity date within 90 days.

### Note 4 — Inventories

Inventories are comprised of the following (in thousands):

	 une 30, 2006 audited)	Dec	cember 31, 2005
Raw materials	\$ 2,871	\$	3,083
Work-in-process	439		415
Finished goods	1,453		1,111
Total inventories	\$ 4,763	\$	4,609

### Note 5 — Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses. These write-downs, accruals, and losses reflect reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activities, and related events. The Company continued to generate deferred tax assets for the six months ended June 30, 2006 primarily as a result of operating losses. The Company assesses the recoverability of its deferred tax assets, on an annual basis and on an interim basis, as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance when, as a result of this analysis, management believes it is more likely than not that its deferred tax assets will not be realized. In assessing the recoverability of its deferred tax assets at December 31, 2005 the Company reviewed its historical operating results, including the reasons for its operating losses, uncertainties regarding projected future operating results, and the uncertainty of the outcome of litigation. Based on the results of this analysis, at December 31, 2005 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, as of December 31, 2005 the Company had a total of \$26.4 million in valuation allowances against deferred tax assets and a net deferred tax asset balance of Zero.

For the six months ended June 30, 2006 the Company did not experience any changes that would materially affect the Company's determination of the recoverability of its deferred tax assets. As of June 30, 2006 the Company had a total of \$27.1 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$248,000 related to taxes in a foreign jurisdiction. The realizability of the Company's deferred tax assets could be limited in future periods as mandated by Internal Revenue Service Section 382.

As of June 30, 2006 the Company had income tax receivables related to federal income tax losses from the years ended December 31, 2005 and 2004 that can be carried back to prior years to offset income taxes paid and should result in approximately \$453,000 in refunds to the Company during 2006.

#### Note 6 — Debt

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. as lender (the "Credit Agreement"). The Credit Agreement provides for a revolving credit facility in an aggregate amount equal to the lesser of \$15.0 million (including a letter of credit subfacility of up to an aggregate of \$2.0 million) or a borrowing base determined in accordance with the terms of the Credit Agreement. Generally, the borrowing base is 20% of the appraised value of the business of CryoLife, reduced by specified lender reserves. The Credit Agreement places limitations on the amount that the Company may borrow, and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife either (i) maintain quarterly a minimum aggregate borrowing availability under the Credit Agreement, less certain payables incurred outside the Company's historical practices, plus unrestricted cash and cash equivalents, as defined ("Availability"), of at least \$12.5 million or (ii) achieve as of each quarter end a minimum level of earnings before extraordinary gains, interest, taxes, depreciation,

and amortization ("EBITDA"), BioGlue gross margins of at least 70% for the preceding twelve months, as well as Availability of at least \$5.0 million. While the Company currently expects that its aggregate borrowing capacity under the Credit Agreement will equal \$15.0 million, there can be no assurance that the capacity will remain at this level. The Credit Agreement also includes customary conditions on incurring new indebtedness and limitations on cash dividends. Cash dividends on any class of capital stock are prohibited, provided that cash dividends on preferred stock may be paid so long as the Company maintains \$7.5 million, in the aggregate, of cash, cash equivalents, and borrowing capacity, as defined. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The Credit Agreement expires on February 7, 2008, at which time the outstanding principal balance will be due. Due to the terms of the Credit Agreement and due to the net losses and negative cash flows experienced by the Company since the FDA Order, the Company has classified amounts due under the Credit Agreement as short-term debt on the June 30, 2006 and December 31, 2005 Summary Consolidated Balance Sheets in accordance with the provisions of FASB Technical Bulletin No. 79-3 (As Amended).

Amounts borrowed under the Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest at the bank's prime rate plus 1%, which was 9.25% as of June 30, 2006. As of June 30, 2006 the outstanding balance of the Credit Agreement was \$4.5 million and the remaining borrowing availability was \$10.5 million.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In the quarter ended June 30, 2005 the Company entered into two agreements to finance approximately \$1.7 million and \$761,000 in insurance premiums associated with the yearly renewal of certain Company insurance policies. The amounts financed accrued interest at 4.98% and 5.01%, respectively, and were payable in equal monthly payments over a nine month period and an eight month period, respectively. As of June 30, 2006 the outstanding balance under the agreements was zero.

In the second quarter of 2006 the Company entered into two agreements to finance approximately \$1.6 million and \$715,000 in insurance premiums associated with the yearly renewal of certain of the Company's insurance policies. The amounts financed accrue interest at 6.71% and 6.7%, respectively, and are payable in equal monthly payments over a nine month and an eight month period, respectively. As of June 30, 2006 the aggregate outstanding balance under the agreements was \$1.6 million.

## Note 7 — Convertible Preferred Stock

On December 17, 2004 the Company announced that it had filed a shelf registration statement on Form S-3 with the SEC covering the sale from time to time of up to \$50 million of its common stock, preferred stock, depositary shares, or any combination of these securities for its own account in one or more offerings.

On March 18 and April 19, 2005 the Company completed a public offering of 417,000 shares of 6% convertible preferred stock (the "Preferred Stock") at a price to the public of \$50.00 per share. Net proceeds from the offering, after deducting underwriting discounts and offering-related expenses, totaled approximately \$19.1 million.

Dividends on the Preferred Stock are cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of January, April, July, and October, commencing July 1, 2005. Any dividends must be declared by the Company's board of directors and must come from funds that are legally available for dividend payments. On June 7, 2006 the Company declared a dividend of \$0.75 per share on its Preferred Stock. The dividend of approximately \$244,000 was paid on July 3, 2006 to shareholders of record on June 23, 2006.

The Preferred Stock is convertible at the option of the holder at any time into the Company's common stock at a conversion rate of approximately 6.2189 shares of common stock for each share of Preferred Stock, based on an initial conversion price of \$8.04. The initial conversion price is subject to adjustment in certain events. The Company reserved 4,600,000 shares of common stock for issuance upon conversion. Through June 30, 2006 holders had voluntarily converted 92,000 shares of Preferred Stock into 575,000 shares of common stock.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company's common stock has exceeded \$12.06, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock, the "Dividend Make-Whole Payment". The Dividend Make-Whole Payment is payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. Through June 30, 2006 the Company had issued 119,000 shares of common stock to converting holders in satisfaction of this additional payment.

The Preferred Stock has a liquidation preference of \$50.00 per share, plus accrued and unpaid dividends. The liquidation preference of the Preferred Stock was approximately \$16.5 million as of June 30, 2006, before the payment of the July 2006 dividend.

The Company may elect to redeem the Preferred Stock, in whole or in part, at declining redemption prices on or after April 7, 2008.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances and as required by law.

#### Note 8 — Derivative

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), the Company is required to separate and account for the Dividend Make-Whole Payment feature of its Preferred Stock as an embedded derivative, (the "Derivative"). As an embedded derivative instrument, the Dividend Make-Whole Payment feature must be measured at fair value and reflected as a current liability on the Company's Summary Consolidated Balance Sheets. Changes in the fair value of the Derivative are recognized in the line item change in valuation of derivative as a non-operating income/expense on the Company's Summary Consolidated Statements of Operations. The Company determined the fair value of the Derivative to be \$1.0 million on March 18, 2005, the date of issuance. The Company determined the fair value of the Derivative related to the issuance of additional Preferred Stock upon exercise of the underwriter's over allotment option to be \$32,000 on April 19, 2005, the date of issuance. The proceeds from the Preferred Stock as recorded on the Summary Consolidated Balance Sheets were reduced by these amounts, which were allocated to the derivative liability.

Due to the quarterly revaluation of the derivative liability, the Company recorded other expense of \$11,000 and \$67,000 for the three and six months ended June 30, 2006, respectively. At June 30, 2006 the derivative liability was valued at \$181,000.

# Note 9 — Comprehensive Income (Loss)

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

	 Three Months Ended June 30,					Six Months Ended June 30,		
	 2006		2005	2006			2005	
	 (Unau	dited)			(Unau	dited	)	
Net income (loss)	\$ 217	\$	(14,379)	\$	(1,563)	\$	(15,736)	
Unrealized (loss) gain on investments	(1)		(15)		2		(24)	
Translation adjustment	 (25)		(75)		(22)		(149)	
Comprehensive income (loss)	\$ 191	\$	(14,469)	\$	(1,583)	\$	(15,909)	

The tax effect on the change in unrealized gain/loss on investments is zero for both the three months ended June 30, 2006 and 2005. The tax effect on the change in unrealized gain/loss on investments is zero and \$11,000 for the six months ended June 30, 2006 and 2005, respectively. The tax effect on the translation adjustment is zero for each period presented.

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

	2	ne 30, <u>006</u> udited)	December 31, 2005		
Unrealized loss on investments	\$		\$	(2)	
Translation adjustment		103		125	
Total accumulated other comprehensive income	\$	103	\$	123	

# Note 10 — Loss per Common Share

The following table sets forth the computation of basic and diluted loss per common share (in thousands, except per share data). The net income (loss) for the three and six months ended June 30, 2006 and 2005 is adjusted by the effect of the Company's cumulative, convertible Preferred Stock to arrive at net loss applicable to common shares in accordance with SFAS No. 128, "Earnings Per Share" ("SFAS 128"). The Company also considers the effect of its Preferred Stock, as discussed in Note 7, the Derivative, as discussed in Note 8, and common stock options, as discussed in Note 11, in the calculation of diluted weighted-average shares below.

	_	Three Months Ended June 30, 2006 2005 (Unaudited)			_	Six Mont June 2006 (Unau	e 30,	2005
Numerator for basic loss per common share:								
Net income (loss)	\$	217	\$	(14,379)	\$	(1,563)	\$	(15,736)
Effect of preferred stock <sup>a</sup>		(244)		(244)		(487)		(290)
Net loss applicable to common shares	\$	(27)	\$	(14,623)	\$	(2,050)	\$	(16,026)
Denominator for basic loss per common share								
Basic weighted-average shares		24,807		23,905		24,783		23,676
Basic loss per common share	\$	0.00	\$	(0.61)	\$	(0.08)	\$	(0.68)



	Three Months Ended June 30,			Six Months June 3			ded
	 2006 2005			2006		2005	
	(Unau	dited	1)		(Unau	dited	)
Numerator for diluted loss per common share:							
Net income (loss)	\$ 217	\$	(14,379)	\$	(1,563)	\$	(15,736)
Effect of preferred stock <sup>b</sup>	(244)		(244)		(487)		(290)
Effect of stock options <sup>c</sup>	_		_		_		_
Net loss applicable to common shares	\$ (27)	\$	(14,623)	\$	(2,050)	\$	(16,026)
Denominator for diluted loss per common share:							
Basic weighted-average shares	 24,807		23,905		24,783		23,676
Effect of dilutive convertible preferred stock <sup>b</sup>	 _		_		_		_
Effect of dilutive stock options <sup>c</sup>							
Adjusted weighted-average shares	 24,807		23,905		24,783		23,676
Diluted loss per common share	\$ 0.00	\$	(0.61)	\$	(0.08)	\$	(0.68)

<sup>a</sup> The amount of the accumulated dividend on Preferred Stock offset the Company's net income and increased the net loss applicable to common shares with a total unfavorable effect of \$244,000 for the three months ended June 30, 2006 and increased the net loss applicable to common shares by \$487,000 for the six months ended June 30, 2006. The amount of the accumulated dividend on Preferred Stock increased the net loss applicable to common shares by \$244,000 and \$290,000 for the three and six months ended June 30, 2005, respectively.

<sup>b</sup> The amount of the accumulated dividend on the Preferred Stock offset the Company's net income and increased the net loss applicable to common shares with a total unfavorable effect of \$244,000 for the three months ended June 30, 2006 and increased the net loss applicable to common shares by \$487,000 for the six months ended June 30, 2006. The adjustment for the quarterly revaluation of the derivative liability, would have instead decreased the net loss applicable to common shareholders by \$11,000 and \$67,000 for the three and six months ended June 30, 2006, respectively, and the common shares that would be issued to shareholders upon conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 2.3 million for both the three and six months ended June 30, 2006. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

The amount of the accumulated dividend on the Preferred Stock increased the net loss applicable to common shares by \$244,000 and \$290,000 for the three and six months ended June 30, 2005, respectively. The adjustment for the Dividend Make-Whole Payment on preferred shares converted during the period and the quarterly revaluation of the derivative liability would have instead decreased the net loss applicable to common shareholders by \$902,000 and \$784,000 for the three and six months ended June 30, 2005, respectively, and the common shares that would be issued to shareholders upon conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 2.6 million and 1.6 million for the three and six months ended June 30, 2005, respectively. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

<sup>c</sup> Outstanding options to purchase the Company's common stock that would have resulted in additional dilutive common shares of 200,000 and 195,000 for the three and six months ended June 30, 2006 were excluded from the calculation, as this item was anti-dilutive pursuant to the provisions of SFAS 128.

Outstanding options to purchase the Company's common stock that would have resulted in additional dilutive common shares of 353,000 and 377,000 for the three and six months ended June 30, 2005, respectively, were excluded from the calculation, as these items were anti-dilutive pursuant to the provisions of SFAS 128.

In future periods the basic and diluted earnings (loss) per common share are expected to be affected by the declaration of dividends on Preferred Stock, the conversion of Preferred Stock, fluctuations in the fair value of the Company's common stock, issuance of additional stock options, and changes in the valuation of the derivative.

# Note 11 — Stock Compensation

In February 2006 the Company's Board of Directors authorized the grant of stock to recognize the performance of certain Company executives. The stock grants totaled 34,000 shares of common stock, which were valued at \$145,000 based on the stock price of \$4.25 on the date of grant. The Company purchased \$50,000 of Company stock from employees, based on the closing price on the New York Stock Exchange on the day the stock was transferred to the Company, to pay employee federal and state withholding taxes related to these stock grants. The Company recorded \$145,000 in compensation expense related to these stock grants during the first quarter of 2006.

The Company has stock option and stock incentive plans that provide for grants of shares to employees and grants of options to employees and directors to purchase shares of the Company's common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company maintains a shareholder approved Employee Stock Purchase Plan (the "ESPP") for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a quarterly basis at the lower of 85% of the market price at the beginning or end of each three-month offering period. Pursuant to the adoption of SFAS 123 Revised "Share-Based Payment" ("SFAS 123R") both the Company's 15% discount on ESPP stock purchases and the lookback portion of ESPP stock purchases are considered components of stock compensation and must be expensed in the Company's financial statements. The lookback portion of the Company's ESPP constitutes an option and, as such, the expense is determined by performing a valuation as discussed below.

The Company adopted SFAS 123R as amended by SEC Rule 2005-57 "Commission Amends Compliance Dates For FASB Statement No. 123R on Employee Stock Options" for the period beginning October 1, 2005. SFAS 123R requires companies to recognize the cost of all share-based payments in the financial statements using a fair-value based measurement method. SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the implementation date, as well as to the unvested portion of awards outstanding as of the implementation date. The Company uses the Black-Scholes model to value its stock option grants under SFAS 123R and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company's ESPP options is also determined using the Black-Scholes model and is expensed quarterly at the end of the purchase period, as the option is fully vested at that time. The fair value of stock options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk free interest rate. The term assumption is primarily based on the contractual term of the option and historic data related to exercise and post-vesting cancellation history experienced by the Company, adjusted based on management's expectations of future results. The expected term is determined separately for options issued to the Company's directors and to employees. The Company's anticipated volatility level is primarily based on the historic volatility of the Company's common stock, adjusted to remove the effects of certain periods of unusual volatility not expected to recur, and adjusted based on management's expectations of future volatility, for the life of the option or option group. The Company's model includes a zero dividend yield assumption, as the Company has not historically paid nor does it anticipate paying dividends on its common stock. The risk free interest rate is based on recent U.S. Treasury note auction results with a similar life to that of the option. The Company's model does not include a discount for post-vesting restrictions, as the Company has not issued awards with such restrictions. The period expense is then determined based on the valuation of the options, and at that time an estimated forfeiture rate is used to reduce the expense recorded. The Company's estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company, and is adjusted to reflect actual forfeitures at each vesting date.

The following weighted-average assumptions were used to determine the fair value of options under SFAS 123R:

	Three Montl June 30,		Six Months June 30, 2	
	Stock Options	ESPP Options	Stock Options	ESPP Options
	(Unaudi	ited)	(Unaudit	ea)
Expected dividend yield	0%	0%	0%	0%
Expected stock price volatility	.650	.420	.650	.473
Risk-free interest rate	5.00%	4.66%	4.75%	4.25%
Expected life of options	4.3 Years	.24 Years	4.1 Years	.24 Years

The Company's expense for stock options and the Company's ESPP was approximately \$424,000 and \$542,000, for the three and six months ended June 30, 2006, respectively, of which approximately \$21,000 and \$40,000, respectively, was capitalized into the Company's deferred preservation and inventory costs. These amounts were recorded as compensation expense and were subject to the Company's normal allocation of expenses to inventory and deferred preservation costs. The Company did not recognize a tax benefit, or a related operating cash outflow and financing cash inflow, related to the additional compensation expense recorded in the three months and six months ended June 30, 2006, as the Company is currently maintaining a full valuation allowance on its deferred tax assets. See Note 5 for additional discussions of the Company's income tax valuation.

As of June 30, 2006 there was approximately \$1.9 million in total unrecognized compensation costs related to nonvested share-based compensation arrangements, before considering the effect of expected forfeitures. This expense is expected to be recognized over a weighted average period of 2.2 years.

In periods prior to October 1, 2005 the Company 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. Under APB 25, because the exercise price of the Company's employee stock options equaled the market price of the underlying stock on the date of the grant, no compensation expense was recognized. In accordance with APB 25 the compensation recorded for employee stock grants was equal to the value of the grant on the measurement date, the date of the grant, as determined by the closing price of the Company's common stock on that date. Some employee stock grants vested in future periods based on a requirement of continued service to the Company. For these stock grants the amount of the stock grant was recorded as deferred compensation in the equity section of the Company's Summary Consolidated Balance Sheets, and was expensed on a straight-line basis over the vesting period.

Pro forma information regarding net loss and loss per share was required by SFAS 123 "Accounting for Stock-Based Compensation" ("SFAS 123") for options accounted for under ABP 25. SFAS 123 required that option valuation information be disclosed as if the Company 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.

The following weighted-average assumptions were used:

	Three Months Ended June 30, 2005 (Unaudited)	Six Months Ended June 30, 2005 (Unaudited)
Expected dividend yield	0%	0%
Expected stock price volatility	.546	.576
Risk-free interest rate	3.56%	3.66%
Expected life of options	3.7 Years	4.3 Years

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

	_	Three Mon June 3 Basic (Unau	0, 2	Diluted	_	Six Mont June 3 Basic (Unau	), 20	05 Diluted
Basic net loss applicable to common shares — as reported	\$	(14,623)	\$	· · · · · · · · · · · · · · · · · · ·	\$	(16,026)	\$	(16,026)
Stock-based employee compensation:								
Add expense included in net loss		55		55		115		115
Deduct expense determined under the fair value based method for all awards		783		783		1,295		1,295
Basic net loss applicable to common shares — pro forma	\$	(15,351)	\$	(15,351)	\$	(17,206)	\$	(17,206)
Basic weighted-average shares	_	23,905	=	23,905	=	23,676	_	23,676
Basic loss per common share:								
As reported	\$	(0.61)	\$	(0.61)	\$	(0.68)	\$	(0.68)
Pro forma	\$	(0.64)	\$	(0.64)	\$	(0.73)	\$	(0.73)

# Note 12 — Segment Information

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

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

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

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

		Three Mon June		Inded		ded		
	2006 2005 (Unaudited)					2006	1. 1	2005
Revenue:	(Unaudited)					(Unau	idited	)
Implantable medical devices	\$	10,569	\$	9,846	\$	20.621	\$	19,973
Human tissue preservation services	-	10,181	*	7,352	-	19,520		14,890
All other <sup>a</sup>		4				62		
		20,754		17,198		40,203		34,863
Cost of Products and Preservation Services:								
Implantable medical devices		2,082		2,079		4,005		4,195
Human tissue preservation services		7,034		6,070		13,797		11,969
All other <sup>a</sup>								
	-	9,116		8,149		17,802		16,164
Gross Margin:								
Implantable medical devices		8,487		7,767		16,616		15,778
Human tissue preservation services		3,147		1,282		5,723		2,921
All other <sup>a</sup>		4				62		
	\$	11,638	\$	9,049	\$	22,401	\$	18,699

<sup>a</sup> The "All other" designation includes grant revenue.

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

		Three Mon Jun	nths Ei e 30,	nded		ded		
	_	2006 (Unau	2005	2	2005			
Products:		(0.1	unceu)			(Unau	, and a	,
BioGlue	\$	10,333	\$	9,552	\$ 2	20,090	\$	19,423
Bioprosthetic devices		236		294		531		550
Total products		10,569		9,846	2	20,621		19,973
Human tissue preservation services:								
Cardiovascular tissue		3,788		3,518		7,361		7,268
Vascular tissue		4,554		2,740		8,598		5,456
Orthopaedic tissue		1,839		1,094		3,561		2,166
Total preservation services		10,181	_	7,352		19,520		14,890
Research grants		4		_		62		_
	\$	20,754	\$	17,198	\$ 4	40,203	\$	34,863
			_		-		_	

# Note 13 — Commitments and Contingencies

# **Product Liability Claims**

In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. As of August 1, 2006 the Company was aware of three pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, one alleges product liability claims arising out of the Company's orthopaedic tissue services and two allege product liability claims arising out of the Company's orthopaedic tissue services and two allege product liability claims arising out of the Company's allograft heart valve tissue services.



The three outstanding product liability lawsuits against the Company are not covered by insurance policies, as the claimed loss date was prior to the effective coverage date for the insurance policy. Additional uninsured claims may be filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits as of August 1, 2006. The Company is monitoring these claims.

The Company performed an analysis as of June 30, 2006 of the settled but unpaid claims and the pending product liability claims based on settlement negotiations to date and advice from counsel. As of June 30, 2006 the Company had accrued a total of approximately \$611,000 for settled but unpaid claims and pending product liability claims. The \$611,000 accrual is included as a component of accrued expenses and other current liabilities on the June 30, 2006 Summary Consolidated Balance Sheet. This amount represents the Company's estimate of the probable loss related to two settled but unpaid claims and one of the three pending product liability claims. The Company has not recorded an accrual for the remaining two product liability claims or any asserted claims that have not resulted in a lawsuit because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time. As of December 31, 2005 the Company had accrued a total of approximately \$1.5 million for settled but unpaid claims and pending product liability claims and recorded \$244,000 representing amounts to be recovered from the Company's insurance carriers. The \$1.5 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2005 the Company had accrued be the December 31, 2005 the Company had accrued that because the settled but unpaid claims and pending product liability claims and recorded \$244,000 representing amounts to be recovered from the Company's insurance carriers. The \$1.5 million accrual is included as a component of accrued expenses and other current liabilities on the December 31, 2005 the Company had accrued be a component of accrued expenses and other current liabilities on the December 31, 2005 the Company had accrued be a component of accrued expenses and other current liabilities on the December 31, 2005 the Company had accrued be a component of accrue

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available liquid assets. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2006 the Company bound coverage for the 2006/2007 insurance policy year. This policy is a four-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2007 and reported during the period April 1, 2006 through March 31, 2007 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2006 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2006. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- A ceiling of \$5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5.0 million,
- The future claim reporting lag time would be a blend of the Company's experiences and industry data,

- The frequency of unreported claims for accident years 2001 through 2006 would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical claim frequency prior to the 2002/2003 policy year,
- The average cost per claim would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical cost per claim prior to the 2002/2003 policy year,
- The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and
- The number of BioGlue claims per million dollars of BioGlue revenue would be 35% lower than non-BioGlue claims per million dollars of revenue. The 35% factor was selected based on BioGlue claims experience to-date and consultation with the actuary.

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

Based on the actuarial valuation performed in July 2006 as of June 30, 2006, the Company estimated that its liability for unreported product liability claims was \$6.7 million. The \$6.7 million balance is included as a component of accrued expenses and other current liabilities of \$3.4 million and other long-term liabilities of \$3.3 million on the June 30, 2006 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$12.4 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of June 30, 2006, \$2.3 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.3 million insurance recoverable is included as a component of other receivables of \$1.0 million and other long-term assets of \$1.3 million on the June 30, 2006 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to June 30, 2006. Actual results may differ from this estimate.

As of December 31, 2005 the Company accrued \$7.5 million for unreported product liability claims and recorded a receivable of \$2.5 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. The \$7.5 million balance is included as a component of accrued expenses and other current liabilities of \$3.8 million and other long-term liabilities of \$3.7 million on the December 31, 2005 Summary Consolidated Balance Sheet. The \$2.5 million insurance recoverable is included as a component of other receivables of \$1.1 million and other long-term assets of \$1.4 million on the December 31, 2005 Summary Consolidated Balance Sheet.

# Insurance Coverage Dispute

The Company is involved in an insurance coverage dispute with two of its former insurance carriers. The dispute involves losses stemming from approximately \$11.25 million paid in 2005 by the Company in excess of underlying insurance policy limits to settle a securities class action lawsuit. The dispute alleges that the loss resulted from the carriers' bad faith failure to settle. There can be no assurance that the dispute will be resolved in the Company's favor. The Company will not record a gain related to this dispute prior to final resolution.

# SEC Investigation

On August 19, 2002 the Company issued a press release announcing that on August 17, 2002, the Company received a letter from the Atlanta District Office of the SEC inquiring about certain matters relating to the Company's August 14, 2002 announcement of the FDA Order. The SEC notified the Company in July 2003 that the inquiry became a formal investigation in June 2003. CryoLife cooperated with this investigation both before and after the issuance of the formal order of investigation in June 2003 and intends to continue doing so. CryoLife voluntarily reported the names of six employees and former employees to the SEC in December 2002 after discovering they had apparently sold CryoLife

shares on August 14, 2002, before trading was halted pending CryoLife's press release reporting the FDA Order. These individuals were not and are not executive officers of CryoLife. The formal order of investigation indicates that the SEC's scope includes whether, during 2002, among other things, CryoLife or others may have traded while in possession of material nonpublic information, made (or caused to be made) false or misleading statements or omissions in press releases and SEC filings, and failed to maintain accurate records and adequate controls. The investigation could also encompass matters not specifically identified in the formal order. On September 15, 2005 the SEC announced that it had commenced proceedings in federal district court against certain of the above-referenced former and current employees (and certain of their spouses) for alleged illegal insider trading arising out of their August 14, 2002 trading activities. Those proceedings resulted in settlements with the SEC. As of the date hereof, the SEC has had no discussions with CryoLife as to whether the SEC will seek relief against CryoLife, or the nature of any relief that may be sought. At present, CryoLife is unable to predict the ultimate focus or outcome of the investigation, or when it will be completed. An unfavorable outcome could have a material adverse effect on CryoLife's reputation, business, financial position, results of operations, and cash flows.

## PART I - FINANCIAL INFORMATION

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

## Overview

The reported net income for CryoLife, Inc. ("CryoLife" or the "Company") of \$217,000 during the quarter ended June 30, 2006 is the first time the Company has achieved profitability in any quarter since the quarter ended March 31, 2002. The quarter ended June 30, 2006 was also a period of record BioGlue revenues, lead by strong international sales, and strengthening in the tissue preservation business, led by a double-digit increase in vascular revenues over the first quarter of 2006. Preservation service revenues were positively affected by strong procurement levels, improvements in processing yields, and the filling of most of the Company's vacant sales territories by the end of the first quarter. See the "Results of Operations" section below for additional analysis of the second quarter results.

# FDA Order and Subsequent FDA Activity

Pursuant to an FDA Order received on August 13, 2002, the Company quarantined tissue subject to that order, recalled the portion of the covered tissues that had been distributed but not implanted, and ceased processing them. The Company changed its processing and testing procedures and took other actions intended to address the FDA's concerns, and now processes and distributes those tissues. The FDA has inspected the Company's facilities several times since the FDA Order and issued Form 483 Notices of Observations, to which the Company has submitted responses. The process is ongoing.

In 2003 the Company received two letters from the FDA regarding its SynerGraft processed human tissues. The first letter stated that a 510(k) premarket notification was required for SynerGraft processed human cardiac tissues, known as CryoValve SG. The second stated that SynerGraft processed non-valved cardiac and vascular tissues (CryoVein SG) should be regulated as medical devices. The Company no longer processes these tissues using the SynerGraft technology. It has filed a 510(k) notification for CryoValve SG, but has not yet determined whether to file and seek premarket approval for CryoVein SG.

See Note 2 to the Company's summary consolidated financial statements at Part I, Item 1 to this Form 10-Q for additional details on the FDA Order and other FDA activity.

# **Critical Accounting Policies**

A summary of the Company's significant accounting policies is included in Part II, Item 8, "Note 1 of the Notes to Summary Consolidated Financial Statements," contained in the Company's Form 10-K for the fiscal year ended December 31, 2005. 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 summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States for interim financial information, which require the Company to make estimates and assumptions. The following are accounting policies that management believes are most important to the portrayal of the Company's financial condition and results and may involve a higher degree of judgment and complexity.

**Product Liability Claims:** In the normal course of business as a medical device and services company, the Company has product liability complaints filed against it. As of August 1, 2006 the Company was aware of three pending product liability lawsuits. The lawsuits are currently in the pre-discovery or discovery stages. Of these lawsuits, one alleges product liability claims arising out of the Company's orthopaedic tissue services and two allege product liability claims arising out of the Company's orthopaedic tissue services and two allege product liability claims arising out of the Company's allograft heart valve tissue services.

The three outstanding product liability lawsuits against the Company are not covered by insurance policies, as the claimed loss date was prior to the effective coverage date for the insurance policy. Additional uninsured claims may be

filed in the future. Other product liability claims have been asserted against the Company that have not resulted in lawsuits as of August 1, 2006. The Company is monitoring these claims.

The Company performed an analysis as of June 30, 2006 of the settled but unpaid claims and the pending product liability claims based on settlement negotiations to date and advice from counsel. As of June 30, 2006 the Company had accrued a total of approximately \$611,000 for settled but unpaid claims and pending product liability claims. The \$611,000 accrual is included as a component of accrued expenses and other current liabilities on the June 30, 2006 Summary Consolidated Balance Sheet. This amount represents the Company's estimate of the probable loss related to two settled but unpaid claims and one of the three pending product liability claims. The Company has not recorded an accrual for the remaining two product liability claims or any asserted claims that have not resulted in a lawsuit because management has concluded that either a loss is remote or that, although a loss is reasonably possible or probable, a reasonable estimate of that loss or the range of losses cannot be made at this time.

The Company's product liability insurance policies do not include coverage for any punitive damages, which may be assessed at trial. The Company does not have a reasonable method for estimating the amount of compensatory or punitive damages that could be assessed by a trial jury. Additionally, if the Company is unable to settle the outstanding claims for amounts within its ability to pay or one or more of the product liability claims in which the Company is a defendant should be tried with a substantial verdict rendered in favor of the plaintiff(s), there can be no assurance that such verdict(s) would not exceed the Company's available liquid assets. Failure by the Company to meet required future cash payments to resolve the outstanding product liability claims would have a material adverse effect on the financial position, results of operations, and cash flows of the Company.

On April 1, 2006 the Company bound coverage for the 2006/2007 insurance policy year. This policy is a four-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2007 and reported during the period April 1, 2006 through March 31, 2007 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. The Company periodically evaluates its exposure to unreported product liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2006 the Company retained an independent actuarial firm to perform revised estimates of the unreported claims as of June 30, 2006. The independent firm estimated the unreported product loss liability using a frequency-severity approach, whereby projected losses were calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims were calculated based on the reported claim development method and the Bornhuetter- Ferguson method using a blend of the Company's historical claim experience and industry data. The estimated cost per claim was calculated using a lognormal claims model blending the Company's historical average cost per claim with industry claims data. The independent actuarial firm used a number of assumptions in order to estimate the unreported product loss liability including:

- A ceiling of \$5.0 million was selected for actuarial purposes in determining the liability per claim given the uncertainty in projecting claim losses in excess of \$5.0 million,
- The future claim reporting lag time would be a blend of the Company's experiences and industry data,
- The frequency of unreported claims for accident years 2001 through 2006 would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical claim frequency prior to the 2002/2003 policy year,
- The average cost per claim would be lower than the Company's experience since the 2002/2003 policy year, but higher than the Company's historical cost per claim prior to the 2002/2003 policy year,
- The average cost per BioGlue claim would be consistent with the Company's overall historical exposures until adequate historical data is available on this product line, and

• The number of BioGlue claims per million dollars of BioGlue revenue would be 35% lower than non-BioGlue claims per million dollars of revenue. The 35% factor was selected based on BioGlue claims experience to-date and consultation with the actuary.

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

Based on the actuarial valuation performed in July 2006 as of June 30, 2006, the Company estimated that its liability for unreported product liability claims was \$6.7 million. The \$6.7 million balance is included as a component of accrued expenses and other current liabilities of \$3.4 million and other long-term liabilities of \$3.3 million on the June 30, 2006 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$12.4 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. Based on the actuarial valuation, the Company estimated that as of June 30, 2006, \$2.3 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$2.3 million insurance recoverable is included as a component of other receivables of \$1.0 million and other long-term assets of \$1.3 million on the June 30, 2006 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported product liability claims related to services performed and products sold prior to June 30, 2006. Actual results may differ from this estimate.

**Deferred Preservation Costs:** By federal law, human tissues cannot be bought or sold. Therefore, the tissues the Company preserves and further processes cannot be held as inventory. 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 consist primarily of direct labor and materials (including laboratory expenses, tissue procurement fees, freight-in charges and fringe benefits) and indirect costs (including allocations of costs from departments that support processing activities and facility allocations). Although the Company cannot own human tissue, the preservation process is a manufacturing process that is accounted for in accordance with Accounting Research Bulletin #43 ("ARB 43") Chapter 4, Inventory Pricing. Preservation costs are stated at the lower of cost or market on a first-in, first-out basis and are deferred until revenue is recognized upon shipment of the tissue to the implanting facilities.

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

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company recorded \$379,000 and \$753,000, respectively, in the three and

six months ended June 30, 2006 and \$392,000 and \$672,000, respectively, in the three and six months ended June 30, 2005 as an increase to cost of preservation services to write-down the value of certain deferred tissue preservation costs that exceeded market value. The amount of these write-downs are primarily due to excess current period tissue processing costs that exceeded market value based on recent average service fees. Actual results may differ from these estimates.

As of June 30, 2006 deferred preservation costs consisted of \$4.0 million for allograft heart valve tissues, \$812,000 for non-valved cardiac tissues, \$7.9 million for vascular tissues, and \$4.6 million for orthopaedic tissues.

**Deferred Income Taxes:** Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets beginning in 2002 primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses, reflecting reductions in revenues and additional professional fees, as a result of the FDA Order, subsequent FDA activities, and related events. The Company continued to generate deferred tax assets for the six months ended June 30, 2006 primarily as a result of operating losses. The Company periodically assesses the recoverability of its 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. In assessing the recoverability of its deferred future operating results due to the effects of the FDA Order and subsequent FDA activity, and the uncertainty of the outcome of litigation. Based on the results of this analysis, at December 31, 2005 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized.

For the six months ended June 30, 2006 the Company did not experience any changes that would materially affect the Company's determination of the recoverability of its deferred tax assets. As of June 30, 2006 the Company had a total of \$27.1 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$248,000 related to taxes in a foreign jurisdiction. The realizability of the Company's deferred tax assets could be limited in future periods as mandated by Internal Revenue Service Section 382.

*Valuation of Long-lived and Intangible Assets:* The Company assesses the impairment of its long-lived, identifiable intangible assets annually and whenever events or changes in circumstances indicate that the carrying value may 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,
- Significant negative industry or economic trends,
- Significant decline in the Company's stock price for a sustained period, and
- Significant decline in the Company's market capitalization relative to net book value.

Statement of Financial Accounting Standards ("SFAS") 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 groups. 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 undiscounted future cash flows related to these asset groups exceeded their carrying values as of December 31, 2005 and, therefore, management concluded that there was not an impairment of the Company's long-lived intangible assets and tangible assets or medical device business.

However, depending on the Company's ability to rebuild demand for its tissue preservation services and the future effects of events surrounding the FDA Order, these assets may become impaired. Management will continue to evaluate the recoverability of these assets in accordance with SFAS 144. For the six months ended June 30, 2006 the Company did not experience any changes that would materially affect the Company's analysis of and recoverability of its long-lived assets.

SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"), requires that goodwill resulting from business acquisitions and other intangible assets be subject to periodic impairment testing. The Company's intangible assets consist of patent costs, which are amortized over the expected useful lives of the patents (primarily 17 years) using the straight-line method, and trademarks, which are non-amortizing. As of December 31, 2005 the Company did not believe that an impairment existed related to the other intangible assets that were assessed in accordance with SFAS 144.

*Derivative Instruments:* The terms of the Company's first quarter of 2005 6% convertible Preferred Stock offering included a Dividend Make-Whole Payment. If the Company elects to automatically convert, or the holder elects to voluntarily convert, some or all of the Preferred Stock into common stock prior to April 1, 2008, the Company will make an additional payment on the Preferred Stock equal to the aggregate amount of dividends that would have been payable on the Preferred Stock through and including April 1, 2008, less any dividends already paid on the Preferred Stock. The Dividend Make-Whole Payment is payable in cash or, at the Company's option, in shares of the Company's common stock, or a combination of cash and shares of common stock. In accordance with SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), the Company is required to separate and account for, as an embedded derivative, the Dividend Make-Whole Payment feature of the Preferred Stock (the "Derivative"). As an embedded derivative instrument, the Dividend Make-Whole Payment feature must be measured at fair value and reflected as a current liability on the Company's Summary Consolidated Balance Sheets. Changes in the fair value of the Derivative are recognized as the line item change in valuation of derivative as non-operating income/expense on the Company's Summary Consolidated Statements of Operations.

The accounting for derivatives is complex, and requires significant judgments and estimates in determining the fair value in the absence of quoted market values. These estimates are based on valuation methodologies and assumptions deemed appropriate in the circumstances. The fair value of the Dividend Make-Whole Payment feature is based on various assumptions, including the estimated market volatility and discount rates. The use of different assumptions may have a material effect on the estimated fair value amount, which is reflected in the Company's results of operations and financial position.

# **New Accounting Pronouncements**

The Company does not anticipate the adoption of any accounting pronouncements in the near future that would have a material impact on its results of operations or financial position.

#### **Results of Operations**

#### Revenues (Tables in thousands)

	Three Months Ended June 30,					Six Mont Jun	nded	
	2006 2005			2006			2005	
Revenues	\$	20,754	\$	17,198	\$	40,203	\$	34,863

Revenues increased 21% for the three months ended June 30, 2006 as compared to the three months ended June 30, 2005. This increase was primarily due to an increase in vascular preservation service revenues, as well as increases in BioGlue revenues, orthopaedic preservation service revenues, and cardiovascular preservation service revenues as compared to the prior year period.

Revenues increased 15% for the six months ended June 30, 2006 as compared to the six months ended June 30, 2005. This increase was primarily due to an increase in vascular preservation service revenues, as well as increases in orthopaedic preservation service revenues, BioGlue revenues, and cardiovascular preservation service revenues as compared to the prior year period.

A detailed discussion of the change in BioGlue revenues and in preservation service revenues for each of the three major tissue types processed by the Company is presented below.

#### **BioGlue**

		Three Months Ended June 30,				Six Months Ended June 30,				
	_	2006		2005	_	2006		2005		
Revenues	\$	10,333	\$	9,552	\$	20,090	\$	19,423		
BioGlue revenues as a percentage of total revenue		50% 56%		50%			56%			

Revenues from the sale of BioGlue increased 8% for the three months ended June 30, 2006 as compared to the three months ended June 30, 2005. The increase in revenues for the three months ended June 30, 2006 was due to an increase in BioGlue sales volume, which increased revenues by 4% and an increase in average service fees, which increased revenues by 4%.

Revenues from the sale of BioGlue increased 3% for the six months ended June 30, 2006 as compared to the six months ended June 30, 2005. The increase in revenues for the six months ended June 30, 2006 was primarily due to an increase in average service fees, which increased revenues by 3%.

The increase in average selling prices for the three and six months ended June 30, 2006 was primarily due to list price increases that went into effect on January 1, 2006 domestically and in certain international markets. The increase in volume for the three months ended June 30, 2006 was primarily due to higher unit sales of BioGlue in international markets as compared to the prior year periods. The increase in volume was experienced in the newer BioGlue syringe product line, as acceptance of these products increased, partially offset by decreases in the BioGlue cartridge product line and in lower accessory sales. The decline in accessory sales is expected to continue, as the BioGlue syringe product does not utilize a separate delivery device or require the purchase of separate applicator tips (a variety of optional applicator tips are available for the BioGlue syringe). BioGlue sales volume for the year to date period was flat.

Domestic revenues accounted for 72% and 74% of total BioGlue revenues for the three and six months ended June 30, 2006, respectively, and 74% and 76% of total BioGlue revenues for the three and six months ended June 30, 2005, respectively.

The Company anticipates that BioGlue revenues for the remainder of 2006 will increase as compared to the second half of 2005 due to the domestic price increase that went into effect on January 1, 2006, and an additional increase that went into effect on July 1, 2006 for certain BioGlue products, continued projected improvements in domestic BioGlue sales following the Company's successfully filling most vacant domestic sales territories as of March 31, 2006, and continued projected unit growth of BioGlue in international markets.

#### **Cardiovascular Preservation Services**

	Three Months Ended June 30,				ded		
	 2006 2005 20			2006	6 2005		
Revenues	\$ 3,788	\$	3,518	\$	7,361	\$	7,268
Cardiovascular revenues as a percentage of total revenue	18%	18% 20%		6 18%			21%

Revenues from cardiovascular preservation services increased 8% for the three months ended June 30, 2006 as compared to the three months ended June 30, 2005. The 8% increase in revenues for the three months ended June 30, 2006 was due to an increase in average service fees, which increased revenues by 8%, while cardiovascular volume remained flat.

Revenues from cardiovascular preservation services increased 1% for the six months ended June 30, 2006 as compared to the six months ended June 30, 2005. The 1% increase in revenues for the six months ended June 30, 2006 was due to an increase in average service fees, which increased revenues by 4%, partially offset by a decrease in cardiovascular volume, which reduced revenues by 3%.

The increase in average service fees for the three and six months ended June 30, 2006 was primarily due to the fee increases that went into effect in January 2006 on all cardiac tissues. Cardiovascular volume for the three months ended June 30, 2006 was consistent with prior year volume, which shows an improvement over the volume losses experienced in the first quarter of 2006. This improvement is primarily a result of the filling of vacant sales territories at the end of the first quarter of 2006. The decrease in cardiovascular volume for the six months ended June 30, 2006 was primarily due to a reduction in shipments of pulmonary valves, which decreased revenues by 3% and a reduced level of aortic valve shipments, which decreased revenues by 3%, largely as a result of vacant sales territories and experienced salesperson turnover during 2005. This decrease was partially offset by a 35% increase in unit shipments of non-valved cardiac tissues, which increased revenues by 3%. The increase in non-valved cardiac shipments reflects the Company's improving penetration into the pediatric cardiac market. The net effect of these changes was a 4% increase in cardiovascular tissue unit shipments in the six months ended June 30, 2006.

The Company's procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, increased 1% during the three months ended June 30, 2006 as compared to the three months ended March 31, 2006. The Company's procurement of cardiac tissues increased 16% for the three months ended June 30, 2006 as compared to the three months ended June 30, 2005.

The Company anticipates that cardiovascular service revenues for the remainder of 2006 will increase as compared to the second half of 2005 due to the domestic fee increase that went into effect on January 1, 2006, and an additional fee increase that went into effect on July 1, 2006 for certain non-valved cardiovascular tissues, and due to continued projected growth in cardiovascular tissue shipments following the Company's successfully filling most vacant domestic sales territories as of March 31, 2006. Cardiovascular revenues are also expected to increase in the second half of 2006 compared to 2005 if and to the extent tissues available for implantation increase due to expected improvements in procurement and in the Company's tissue processing yields. Process changes were implemented during 2005 and additional process changes were implemented in January 2006, which are expected to have a continuing favorable impact on the Company's tissue processing yields during the second half of 2006 as compared to 2005.



#### Vascular Preservation Services

	Three Mon June	Ended		nded			
	2006	2005		2006			2005
Revenues	\$ 4,554	\$	2,740	\$	8,598	\$	5,456
Vascular revenues as a percentage of total revenue	22% 16%		<u>6</u> 21%			16%	

Revenues from vascular preservation services increased 66% for the three months ended June 30, 2006 as compared to the three months ended June 30, 2005. The 66% increase in revenues for the three months ended June 30, 2006 was primarily due to a 44% increase in unit shipments of vascular tissues, which increased revenues by 55%, and an increase in average service fees, which increased revenues by 11%.

Revenues from vascular preservation services increased 58% for the six months ended June 30, 2006 as compared to the six months ended June 30, 2005. The 58% increase in revenues for the six months ended June 30, 2006 was primarily due to a 39% increase in unit shipments of vascular tissues, which increased revenues by 49%, and an increase in average service fees, which increased revenues by 9%.

The increase in vascular volume for the three and six months ended June 30, 2006 is primarily due to increases in shipments of saphenous veins, due in part to increased availability of tissues as a result of improvements in procurement levels in the second half of 2005 and in 2006, coupled with a strong demand for these tissues, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations. The increase in shipments of saphenous veins is a continuation of the favorable trend that began in the fourth quarter of 2005. The increase in average service fees reflects the fee increases that went into effect in January 2006 on all vascular tissues.

The Company's procurement of vascular tissues increased 11% during the three months ended June 30, 2006 as compared to the three months ended March 31, 2006. The Company's procurement of vascular tissues increased 40% for the three months ended June 30, 2006 as compared to the three months ended June 30, 2005.

The Company anticipates that vascular service revenues for the remainder of 2006 will increase as compared to the second half of 2005 due in part to the domestic fee increase that went into effect on January 1, 2006 and due to projected growth in vascular tissue shipments during 2006, due to improvements in the procurement of vascular tissues and projected continuing demand. Additionally, vascular revenues are expected to increase in the second half of 2006 compared to 2005 if and to the extent tissues available for implantation increase due to expected improvements in the Company's tissue processing yields. Process changes were implemented during 2005 and additional process changes were implemented in January 2006, which are expected to have a continuing favorable impact on the Company's tissue processing yields during the second half of 2006 as compared to 2005.

#### **Orthopaedic Preservation Services**

	Three Months Ended June 30,				Six Months Ended June 30,				
	 2006	2005		2006		_	2005		
Revenues	\$ 1,839	\$	1,094	\$	3,561	\$	2,166		
Orthopaedic revenues as a percentage of total revenue	9%		6%	,	9%		6%		

Revenues from orthopaedic preservation services increased 68% for the three months ended June 30, 2006 as compared to the three months ended June 30, 2005. The 68% increase in revenues for the three months ended June 30, 2006 was due to a 40% increase in unit shipments of orthopaedic tissues, which increased revenues by 56% and an increase in average service fees, which increased revenues by 12%. The increase in average service fees reflected the fee increases that went into effect in January 2006 on all orthopaedic tissues.

Revenues from orthopaedic preservation services increased 64% for the six months ended June 30, 2006 as compared to the six months ended June 30, 2005. The 64% increase in revenues for the six months ended June 30, 2006 was due to a 36% increase in unit shipments of orthopaedic tissues, which increased revenues by 55% and an increase in average service fees, which increased revenues by 9%. The increase in average service fees reflected the fee increases that went into effect in January 2006 on all orthopaedic tissues.

The increase in orthopaedic volume for the three and six months ended June 30, 2006 was primarily due to an increase in shipments of osteochondral grafts, with smaller increases in boned and non-boned tendons and menisci. The increase in orthopaedic tissue shipments was directly related to an increase in demand for the Company's orthopaedic tissues through the introduction of the new cryopreserved osteochondral graft in the first quarter of 2005, the reestablishment of the Company's presence in the orthopaedic tissue business, and the rebuilding of the Company's supply of tissues available for shipment. The growth of the Company's orthopaedic tissue business is illustrated by the trend of positive quarter over quarter orthopaedic revenue growth that began in the second quarter of 2005 and continues through the second quarter of 2006.

The Company procures orthopaedic tissues, which include knees, from which osteochondral grafts, menisci, and boned tendons are processed, and individual tendons, which are primarily non-boned. The Company's procurement of all orthopaedic tissues decreased 13% during the three months ended June 30, 2006 as compared to the three months ended March 31, 2006 and increased 9% for the three months ended June 30, 2006 as compared to the three months ended of knees decreased 30% during the three months ended June 30, 2006 as compared to the three months ended March 31, 2006 and increased 30% during the three months ended June 30, 2006 as compared to the three months ended June 30, 2006 as compared to the three months ended June 30, 2006 as compared to the three months ended June 30, 2006 as compared to the three months ended June 30, 2005.

The Company anticipates that orthopaedic service revenues for the remainder of 2006 will increase significantly over the second half of 2005 due to projected growth in orthopaedic tissue shipments during 2006, driven by projected continuing demand. Additionally, orthopaedic revenues are expected to increase if and to the extent tissues available for implantation increase due to expected improvements in procurement and in the Company's tissue processing yields. Process changes were implemented during 2005 and additional process changes were implemented in January 2006, which are expected to have a continuing favorable impact on the Company's tissue processing yields during the second half of 2006 as compared to 2005. Additional increases in service revenues are expected due to the domestic fee increase that went into effect on January 1, 2006, and an additional fee increase that went into effect on July 1, 2006 for certain orthopaedic tissues.

# Grant Revenues

Grant revenues were \$4,000 and zero, respectively, for the three months ended June 30, 2006 and 2005 and \$62,000 and zero, respectively, for the six months ended June 30, 2006 and 2005. Grant revenues for the three and six months ended June 30, 2006 are related to funding received under the 2005 Defense Appropriations Conference Report, the ("2005 DOD Grant"), which included \$926,000 for the development of BioFoam<sup>TM</sup>. The Company began receiving advances under the grant during the second half of 2005 and began recognizing revenues for expenses incurred related to this grant during the fourth quarter of 2005. The Company is currently involved in animal trials with the U.S. Army's Institute for Surgical Research.

The 2006 Defense Appropriations Conference Report included approximately \$2.3 million for the continued development of protein hydrogel. CryoLife applied for funding under this bill in July 2006. The Company anticipates that grant revenues will continue to be higher in 2006 than in the corresponding periods of 2005 due to the 2005 and possibly the 2006 Department of Defense funding.

## **Costs and Expenses**

#### Cost of Products

Cost of products was \$2.1 million for the three months ended June 30, 2006 and June 30, 2005, representing 20% and 21%, respectively, of total product revenues during such periods. Cost of products as a percentage of total product revenues decreased slightly, primarily due to modest improvements in BioGlue margins from period to



period. These margin improvements were largely due to improvements in BioGlue average selling prices due to the price increase which went into effect in January of 2006 and greater manufacturing throughput, which reduces the per unit cost to produce BioGlue.

Cost of products was \$4.0 million and \$4.2 million for the six months ended June 30, 2006 and 2005, respectively, representing 19% and 21%, respectively, of total product revenues during such periods. Cost of products and cost of products as a percentage of total product revenues decreased slightly, primarily due to modest improvements in BioGlue margins from period to period. These margin improvements were due to improvements in BioGlue average selling prices due to the price increase which went into effect in January of 2006 and greater manufacturing throughput, which reduces the per unit cost to produce BioGlue.

The Company anticipates that cost of products will increase for the remainder of 2006 over the corresponding periods in 2005 to reflect volume increases.

#### Cost of Human Tissue Preservation Services

Cost of human tissue preservation services was \$7.0 million for the three months ended June 30, 2006 as compared to \$6.1 million for the three months ended June 30, 2005, representing 69% and 83%, respectively, of total tissue preservation service revenues during such periods. Cost of human tissue preservation services for the three months ended June 30, 2006 and 2005 includes the write-down of \$379,000 and \$392,000, respectively, of certain deferred preservation costs that exceeded market value.

Cost of human tissue preservation services was \$13.8 million for the six months ended June 30, 2006 as compared to \$12.0 million for the six months ended June 30, 2005, representing 71% and 80%, respectively, of total tissue preservation service revenues during such periods. Cost of human tissue preservation services for the six months ended June 30, 2006 and 2005 includes the write-down of \$753,000 and \$672,000, respectively, of certain deferred preservation costs that exceeded market value.

The write-down of deferred tissue preservation costs in both years was primarily related to the Company's non-valved cardiac tissues and certain orthopaedic tissues. The Company implemented a fee increase effective July 1, 2006, in part to address these tissues, which have had costs in excess of the average service fees.

The increase in cost of human tissue preservation services for the three and six months ended June 30, 2006 is primarily due to increased tissue preservation service volume as compared to the same period in 2005. The decrease in cost of tissue preservation services as a percentage of total tissue preservation service revenues is primarily due to improvements in tissue preservation margins as a result of improvements in the Company's tissue processing yields, an increase in average service fees due to fee increases in 2006, and to a lesser extent an increase in the amount of tissues processed.

The Company anticipates that aggregate cost of human tissue preservation services for the remainder of 2006 will continue to increase over 2005 due to expected volume increases in 2006. The Company anticipates that cost of human tissue preservation services as a percentage of tissue preservation service revenues will decrease in 2006 as compared to 2005 as a result of increases in yields of implantable tissue per donor, increases in average service fees due to fee increases implemented in 2006, and increases in the amount of tissues expected to be processed due to increased procurement.

## General, Administrative, and Marketing Expenses

General, administrative, and marketing expenses decreased 53% to \$10.2 million for the three months ended June 30, 2006, compared to \$21.6 million for the three months ended June 30, 2005, representing 49% and 126%, respectively, of total revenues during such periods. General, administrative, and marketing expenses for the three months ended June 30, 2006 includes a favorable adjustment to unreported product liability accruals of \$800,000 and an unfavorable charge for stock based compensation expenses of approximately \$403,000. General, administrative, and

marketing expenses for the three months ended June 30, 2005 includes \$11.8 million in expense related to the settlement of the shareholder class action lawsuit and a favorable adjustment to unreported product liability accruals of approximately \$800,000. General, administrative, and marketing expenses for the three months ended June 30, 2006 was also impacted by lower insurance and professional fees and an increase in marketing commissions to support revenue growth.

General, administrative, and marketing expenses decreased 32% to \$21.6 million for the six months ended June 30, 2006, compared to \$31.6 million for the six months ended June 30, 2005, representing 54% and 91%, respectively, of total revenues during such periods. General, administrative, and marketing expenses for the six months ended June 30, 2006 includes a favorable adjustment for unreported product liability accruals of \$670,000 and an unfavorable charge for stock based compensation expenses of approximately \$647,000. General, administrative, and marketing expenses for the three months ended June 30, 2005 includes \$11.8 million in expense related to the settlement of the shareholder class action lawsuit and a favorable adjustment to product liability and other legal accruals of approximately \$1.1 million. Excluding these items, the remaining increase in general, administrative, and marketing expenses was primarily due to an increase in marketing commissions to support revenue growth, partially offset by lower insurance and professional fees.

Although several important components are difficult to estimate or control, the Company anticipates that general, administrative, and marketing expenses will be lower in the full year 2006 than in the full year 2005, due to the expense recorded in 2005 related to the resolution of the Company's class action and derivative lawsuits. The Company will continue to evaluate the level of accruals for product liability claims and make adjustments as required based on periodic actuarial analyses and product liability claim status. Adjustments to these accruals may be required during the second half of 2006, and the effect of these adjustments may be favorable or unfavorable to general, administrative, and marketing expenses.

## **Research and Development Expenses**

Research and development expenses were \$837,000 for the three months ended June 30, 2006, compared to \$929,000 for the three months ended June 30, 2005, representing 4% and 5%, respectively, of total revenues during each such period. Research and development expenses were \$1.7 million for the six months ended June 30, 2005, representing 4% and 5%, respectively, of total revenues during each such period. The decrease in research and development expenses in both the three and six month periods ended June 30, 2006 was due to timing delays for planned external research studies. Research and development spending in 2006 and 2005 was primarily focused on the Company's tissue preservation, SynerGraft, which includes allograft and xenograft heart valves, vascular grafts and surgical mesh, and Protein Hydrogel Technologies ("PHT"), which include BioGlue, BioFoam, BioDisc™, and related products.

The Company anticipates that research and development expenses will increase during the second half of 2006 when compared to 2005, due to increased spending on research related to PHT, which is used in BioGlue, BioFoam, and BioDisc, and due to increased spending on research related to SynerGraft vascular graft and tissue preservation. The BioFoam spending increase will be due in part to the 2005 DOD Grant and possibly due to any additional grants under the 2006 Defense Appropriation Conference Report. These items are discussed in "Revenues - Grant Revenues" above.

#### **Other Costs and Expenses**

Interest expense increased to \$188,000 for the three months ended June 30, 2006, compared to \$88,000 for the three months ended June 30, 2005. Interest expense increased to \$335,000 for the six months ended June 30, 2006, compared to \$143,000 for the six months ended June 30, 2005. The increase in interest expense for the three and six months ended June 30, 2006 is primarily due to higher borrowings under the Credit Agreement as compared to the same period in 2005 and higher interest rates on these borrowings as the bank's prime lending rate has increased since the prior year period. Interest expense for the three and six months ended 2005 included interest incurred related to the Credit Agreement, notes payable, and capital leases.

Interest income decreased to \$103,000 for the three months ended June 30, 2006, compared to \$167,000 for the three months ended June 30, 2005. Interest income decreased to \$210,000 for the six months ended June 30, 2006, compared to \$242,000 for the six months ended June 30, 2005. Interest income for the three and six months ended June 30, 2006 and 2005 was primarily due to interest earned on the Company's cash, cash equivalents, and marketable securities.



The change in valuation of the Derivative was an expense of \$11,000 for the three months ended June 30, 2006 as compared to \$902,000 for the three months ended June 30, 2005. The change in valuation of the Derivative was an expense of \$67,000 for the six months ended June 30, 2006 as compared to \$784,000 for the six months ended June 30, 2005. The valuation of the Derivative in these periods was a function of several variables including the price and expected volatility of the Company's common stock, the number of shares of Preferred Stock outstanding, and the general level of US interest rates. The change in valuation of Derivative in the three and six months ended June 30, 2005 also includes the amount of the Dividend Make-Whole Payment on preferred shares converted during the period.

The Company is unable to estimate the change in valuation of derivative for the remainder of 2006, as this amount is subject to several variables as discussed above. The change in valuation of derivative for the remainder of 2006 could differ significantly from the levels experienced in the corresponding periods of 2005.

The Company's income tax benefit of \$114,000 for the three months ended June 30, 2006 was primarily due to the favorable effect of adjustments to estimated foreign taxes on income of the Company's wholly owned European subsidiary. The Company's income tax expense of \$125,000 for the six months ended June 30, 2006 was primarily due to an expense of \$248,000 to record a deferred tax liability related to a foreign jurisdiction, partially offset by the favorable effect of adjustments to estimated foreign taxes on income of the Company's wholly owned European subsidiary.

The Company's income tax expense of \$46,000 and \$84,000 for the three and six months ended June 30, 2005, respectively, was related to foreign taxes on income of the Company's wholly owned European subsidiary.

#### Seasonality

The demand for BioGlue appears to be seasonal, with a flattening or slight decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to fewer surgeries being performed on adult patients in the summer months. The Company will continue to evaluate the seasonal nature of BioGlue sales.

The demand for the Company's cardiovascular tissue preservation services has historically been seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiovascular tissue preservation services is primarily due to the high number of surgeries scheduled during the summer months for school aged patients, who drive the demand for a large percentage of CryoLife's cardiovascular tissues. This seasonal trend has been obscured in recent years by the impact of the FDA Order and related events. The Company expects that this seasonal trend will be more apparent in future years.

The demand for the Company's orthopaedic tissue preservation services appears to be seasonal, with a flattening or slight decline in demand generally occurring in the summer months due to the scheduling of fewer elective orthopaedic surgeries during these months and due to the seasonal timing of certain sports that frequently result in the injuries treated by the Company's orthopaedic products. This seasonal trend has been obscured in recent years by the impact of the FDA Order and related events. The Company expects that this seasonal trend will be more apparent in future years.

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

### Liquidity and Capital Resources

#### Net Working Capital

At June 30, 2006 net working capital (current assets of \$47.9 million less current liabilities of \$23.2 million) was \$24.7 million, with a current ratio (current assets divided by current liabilities) of 2 to 1, compared to net working capital of \$23.9 million, with a current ratio of 2 to 1 at December 31, 2005. The Company's primary capital requirements historically arose out of general working capital needs, capital expenditures for facilities and



equipment, and funding of research and development projects, and the Company funded those requirements through cash generated by operations, equity offerings, and bank credit facilities.

In recent years the Company's primary requirements for capital have arisen out of working capital needs created by increasing costs of operations and settlements of litigation combined with losses incurred in the Company's tissue preservation services business. Operating results have also been negatively impacted by increases in general, administrative, and marketing costs over pre-FDA Order levels, as a result of legal and professional fees and litigation costs. For the six months ended June 30, 2006 the Company funded these requirements primarily through existing cash, cash equivalents, and marketable securities.

# **Overall Liquidity and Capital Resources**

The Company expects that the following will continue to have an adverse impact on earnings and cash flows during 2006:

- The anticipated lower preservation services revenues as compared to preservation revenues prior to the August 13, 2002 FDA Order, subsequent FDA activities, and related events (discussed in Part I, Item 1, "Note 2 of the Notes to Summary Consolidated Financial Statements"),
- The high cost of human tissue preservation services as a percent of revenue, as compared to the period prior to the FDA Order, as a result of lower tissue processing volumes and changes in processing methods, which have increased the cost of processing human tissue and decreased yields of implantable tissue per donor,
- An expected use of cash related to the defense and resolution of lawsuits and claims, and
- The legal and professional costs related to ongoing FDA compliance.

The Company believes the following should continue to have a favorable impact on cash flow from operations during the remainder of 2006, although there can be no assurance that these events will occur as and when currently anticipated:

- Expected increases in revenues due to increases in BioGlue list prices implemented in January and July 2006,
- Expected increases in the preservation service revenues for cardiovascular, vascular, and orthopaedic tissues due to fee increases implemented in January and July 2006, to reflect the higher cost of processing these tissues,
- Anticipated improvements in yields of implantable tissues per donor over the levels experienced in 2005 through process changes and process directives,
- Expected increases in procurement of human tissues for processing over the levels experienced in 2005, and
- Anticipated decreases in cash payments related to the defense and resolution of lawsuits and claims from the levels seen in 2003 through 2005.

The Company believes that the Company's existing cash, cash equivalents, marketable securities, and availability under the Credit Agreement will enable the Company to meet its liquidity needs through at least June 30, 2007.

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

• The success of BioGlue and other products using related technology,



- The Company's ability to increase the level of tissue procurement and demand for its tissue preservation services,
- The Company's ability to reestablish sufficient margins on its tissue preservation services, in the face of increased processing costs, by improving yields and increasing prices,
- The Company's spending levels on its research and development activities, including research studies, to develop and support its service and product pipeline,
- The timing and cost of resolving product liability lawsuits and other claims (as discussed in Part I, Item 1, "Note 13 of the Notes to Summary Consolidated Financial Statements"), and
- To a lesser degree, the Company's success at resolving the issues with the FDA regarding processing of human tissue using the SynerGraft technology.

If the Company is unable to address these issues and continues to experience negative operating cash flows, the Company anticipates that it may require additional financing or seek to raise additional funds through bank facilities, debt or equity offerings, or other sources of capital to meet liquidity and capital requirements beyond June 30, 2007. 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 January 2006 the Company engaged Piper Jaffray & Co. to assist the Company's management and Board of Directors in identifying and evaluating potential strategies to enhance shareholder value. This process is ongoing. No assurance can be given that this process will lead to any specific action or transaction or that any such transaction will have the anticipated effect.

# Product Liability Claims

As discussed in Part I, Item 1, "Note 13 of the Notes to Summary Consolidated Financial Statements", as of June 30, 2006 the Company had accrued a total of \$611,000 for settled but unpaid claims and pending product liability claims. The \$611,000 accrual is an estimate of the Company's portion of the costs required to resolve outstanding claims, and does not reflect actual settlement arrangements or actual judgments for all open claims, including punitive damages, which may be assessed by the courts. The \$611,000 accrual is not a cash reserve. The timing and amount of actual future payments is dependent on when and if judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, the Company's portion of these monies would have to be paid from liquid assets. The Company continues to attempt to reach resolution of these outstanding claims in order to minimize the potential cash payout.

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

As discussed in Part I, Item 1, "Note 13 of the Notes to Summary Consolidated Financial Statements", at June 30, 2006 the Company had accrued a total \$6.7 million for the estimated costs of unreported product liability claims related to services performed and products sold prior to June 30, 2006 and had recorded a receivable of \$2.3 million representing amounts to be paid by the Company's insurance carriers. Further analysis indicated that the liability could be estimated to be as high as \$12.4 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The \$6.7 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.



## Net Cash from Operating Activities

Net cash used in operating activities was \$3.9 million for the six months ended June 30, 2006. The \$3.9 million in cash used in the six months ended June 30, 2006 was primarily due to the payment of \$3.7 million in annual insurance policy premiums for the 2006/2007 policy year and the \$1.6 million net loss generated by the Company during the period. The Company's net loss is due to the Company's preservation services business, which has failed to generate margins sufficient to cover its operating expenses since the second half of 2002 as a result of the FDA Order, subsequent FDA activity, and related events, as discussed in Part 1, Item 1, "Note 2 of the Notes to Summary Consolidated Financial Statements".

The Company uses the indirect method to prepare its cash flow statement, and as such the operating cash flows are based on the Company's net loss, which is then adjusted to remove non-cash items included that generated a book gain or loss during the period and for changes in operating assets and liabilities. For the six months ended June 30, 2006 the Company's \$1.6 million net loss included significant recurring non-cash items that generated favorable and unfavorable adjustments to the net loss. For the six months ended June 30, 2006 these adjustments included a favorable \$2.5 million in depreciation and amortization, a favorable \$753,000 in write-downs for impairment of deferred preservation costs, and a favorable \$687,000 in non-cash employee compensation, primarily related to the implementation of SFAS 123R and the granting of annual stock awards to the board of directors during the second quarter. The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the six months ended June 30, 2006 these changes included an unfavorable \$1.8 million due to the timing differences between the recording of receivables and the actual receipt of cash, an unfavorable \$4.3 million due to the buildup of deferred preservation costs and inventories for which vendors and employees have already been paid, an unfavorable \$1.2 million due to timing differences between the making of cash payments and the expensing of assets, including the prepayment of insurance policy premiums as discussed above, and a favorable \$619,000 due to the timing differences between the recording of accounts payable and other accruals and the actual payment of cash.

## Net Cash from Investing Activities

Net cash provided by investing activities was \$568,000 for the six months ended June 30, 2006, as compared to cash used of \$14.0 million for the six months ended June 30, 2005. The \$568,000 in current year cash provided was primarily due to \$11.1 million in sales and maturities of marketable securities partially offset by \$9.5 million in purchases of marketable securities and \$992,000 in capital expenditures.

#### Net Cash from Financing Activities

Net cash provided by financing activities was \$1.0 million for the three months ended June 30, 2006, as compared to cash provided of \$20.7 million for the six months ended June 30, 2005. The \$1.0 million in current year cash provided was primarily due to \$2.3 million in proceeds from the financing of insurance policies, reduced by \$711,000 in principal payments on the notes payable, and by \$244,000 in proceeds from exercises of options and issuance of stock. These favorable effects were partially offset by \$487,000 in payments of Preferred Stock dividends and \$281,000 in principal payments on capital leases. Principal payments on debt of \$281,000 were largely offset by \$251,000 in borrowings on the Company's Credit Agreement.



# Scheduled Contractual Obligations and Future Payments

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

		Re	emainder of																																					
	 Total		2006	2007	2008		2008		2008		2008		2008		2008		2008		2008		2008		2008		2008		2008		2008		2008		2008		2008		 2009	 2010	Th	nereafter
Operating leases	\$ 20,363	\$	1,133	\$ 2,225	\$	2,171	\$ 2,061	\$ 2,103	\$	10,670																														
Revolving line of credit	4,500					4,500																																		
Insurance premium obligations	1,874		1,852	22																																				
Capital lease obligations	277		277																																					
Purchase commitments	685		683	1		1																																		
Other obligations	1,076		492	410		174				_																														
Total contractual obligations	\$ 28,775	\$	4,437	\$ 2,658	\$	6,846	\$ 2,061	\$ 2,103	\$	10,670																														

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

The line of credit obligation results from the Company's borrowing of funds under its Credit Agreement. The timing of the obligation in the above table is based on the February 7, 2008 Credit Agreement expiration date, at which time the outstanding principal balance will be due. Due to the terms of the Credit Agreement, and due to the net losses and negative cash flows experienced by the Company since the FDA Order, the Company has classified amounts due under the Credit Agreement as short-term debt on the June 30, 2006 Summary Consolidated Balance Sheet in accordance with the provisions of FASB Technical Bulletin No. 79-3 (As Amended). Assuming the Company's level of borrowings and the interest rate on the line of credit remain the same, the Company would have additional contractual obligations for interest expense and fees of \$243,000, \$484,000, and \$55,000 for the remainder of 2006, for 2007, and for 2008, respectively, which are not included in the table above.

The Company's insurance premium obligations are required installment payments related to payment plans and notes payable from the renewal and financing of certain Company insurance policies.

The Company's capital lease obligations result from the financing of certain of the Company's equipment and leasehold improvements primarily purchased during the renovation of the corporate headquarters and manufacturing facilities in previous years. The liability for the remainder of 2006 includes a lump sum payment due at the termination of certain of the Company's capital leases.

The Company's purchase commitments generally result from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production.

The Company's other obligations contain various items including minimum required royalty payments, payments to support research and development activities, litigation settlement obligations, and other items as appropriate.

#### Stock Repurchases

In the first quarter of 2006 the Company's Board of Directors authorized the purchase of shares of its common stock from employees to fund the payment of employee federal and state withholding taxes in association with the grant of stock to employees in February 2006. These repurchases of stock from employees totaled \$50,000. No further purchases will be made related to these employee stock grants.

#### Capital Expenditures

Capital expenditures for the six months ended June 30, 2006 were \$1.1 million. The Company expects that its capital expenditures for the full year of 2006 will be somewhat higher than its expenditures in 2005, which were approximately \$1.0 million. Planned capital expenditures for 2006 are primarily related to the upgrade of the Company's accounting software and related hardware purchases, largely procured in the first half of 2006, and routine

purchases of tissue processing, manufacturing, computer, and office equipment needed to support the Company's business. The Company expects to have the flexibility to increase or decrease the majority of its planned capital expenditures depending on its ability to generate cash flows.

## 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," "will," "would," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future," and other similar expressions generally identify forward-looking statements, including, in particular, statements regarding anticipated revenues, cost savings, insurance coverage, regulatory activity, available funds and capital resources, and pending litigation. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, which are as of their respective dates. Such forward-looking statements reflect the views of our management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under "Risks and Uncertainties" and elsewhere in this filing.

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

- The impact of recent accounting pronouncements,
- Adequacy and availability of product liability insurance to defend against lawsuits,
- The outcome of lawsuits filed and claims made against the Company,
- The expected continuing adverse impact of the FDA Order, subsequent FDA activity, and measures taken by the Company as a result, and the resolution of lawsuits and claims on anticipated future revenues, profits, and business operations,
- Factors impacting the Company's long-term liquidity,
- Anticipated continuing revenue increases,
- Possible 2006 Department of Defense funding,
- The expected continuing favorable impact of price and fee increases, anticipated processing yield and procurement improvements, and anticipated decreases in the annual cost of lawsuit and claim resolution,
- Future tissue procurement and processing yield levels and the impact of recent processing changes,
- Expected future impact of continuing demand, price and fee increases, added sales personnel, and costs on revenues and gross margins,
- Potential resolution of the issues raised by the FDA Order and the FDA's Form 483 Notice of Observation,
- Potential clearance of the 510(k) application for CryoValve SG,
- The estimates of the amounts accrued for directors' and officers' insurance policies and for product liability claims incurred but not reported and expected amounts receivable under insurance policies,
- Future costs of human tissue preservation services, including availability of tissues and tissue processing yields,
- Changes in liquidity and capital resources,
- Statements regarding the expected 2006 performance of the Company and its business segments, including increased revenues, relative to that of 2005,
- The Company's expectations regarding the adequacy of current liquidity and financing arrangements and anticipated capital expenditures,
- Product demand and market growth,
- Anticipated seasonal trends in future periods,
- The impact of future fluctuations in the value of the Dividend Make-Whole Payment feature of the Company's 6% convertible Preferred Stock, and
- Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including 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 1A of the Company's Form 10-K for the year ended December 31, 2005 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, its ability to continue as a going concern, and the trading value of its common and Preferred Stock include concerns that:

- The Company may be unable to sufficiently reduce costs of processing tissues, to obtain increased yields of implantable tissue, and to increase fees for tissue preservation services,
- If the Company is unable to address the causes of its historical operating losses and negative cash flows, it will need to raise additional capital which may not be available or may not be available on acceptable terms,
- The Company's review of potential strategies may not be productive and the outcome of this process is uncertain,
- The Company's revolving credit facility imposes restrictions on its ability to borrow, which could make it more difficult to borrow needed funds,
- The Company is significantly dependent on its revenues from BioGlue and is subject to a variety of risks affecting this product,
- The FDA Order and subsequent FDA activity continue to adversely impact CryoLife's business, including reducing demand for its services and increasing processing costs relative to pre-FDA Order levels,
- · Revenue from orthopaedic tissue preservation services may not return to acceptable levels,
- Physicians may be reluctant to implant CryoLife's preserved tissues,
- CryoLife's products and the tissues it processes allegedly have caused and may in the future cause injury to patients using its products or tissues and the Company has been and may be exposed to product liability claims and additional regulatory scrutiny as a result,
- Adverse publicity may reduce demand for products and services not affected by the FDA recall,
- CryoLife may be unable to address the concerns raised by the FDA in its Form 483 Notices of Observations,
- The FDA has notified CryoLife of its belief that marketing of CryoValve SG and CryoVein SG require additional regulatory submissions and/or approvals, and CryoLife may be unable to obtain such approvals,
- Regulatory action outside of the U.S. has affected CryoLife's business in the past and may also affect CryoLife's business in the future,
- Violation of government regulations could result in loss of revenues and customers and additional expense to attain compliance,
- CryoLife is the subject of an ongoing SEC investigation,
- CryoLife's insurance coverage has been and in the future may be either insufficient or unavailable by its terms,
- Satisfactory levels of insurance coverage may be difficult or impossible to obtain in the future and if obtained, could be very expensive,
- Intense competition affects CryoLife's ability to recover from the FDA Order,
- CryoLife may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and such
  products and services may not achieve market acceptance,
- Investments in new technologies or distribution rights may not be successful,
- SynerGraft processed tissues may not demonstrate expected benefits,
- If CryoLife is not successful in expanding its business activities in international markets, it will not be able to pursue one of its strategies for increasing its revenues,
- CryoLife is dependent on its key personnel,
- Extensive government regulation may adversely affect the ability to develop and sell products and services,
- Uncertainties related to patents and protection of proprietary technology may adversely affect the value of CryoLife's intellectual property,
- Future health care reimbursement methods and policies may affect the availability, amount and timing of revenues,
- Future grant funding will depend on a multitude of factors outside of CryoLife's control, and there can be no guarantee that it can be obtained,
- Rapid technological change could cause services and products to become obsolete,
- Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of CryoLife,

- Efforts by existing stockholders or others to gain influence or control over CryoLife may divert management's attention from the Company's operational recovery or otherwise be detrimental to the interests of its other stockholders,
- CryoLife could be left with no choice other than to engage in costly litigation if stockholders or others make inaccurate or misleading proposals or statements that are detrimental to the interests of its other stockholders,
- Common stock dividends are not likely to be paid in the foreseeable future,
- CryoLife may not be able to pay cash dividends on its capital stock due to legal and contractual restrictions and lack of liquidity, and
- Future fluctuations in the value of the Dividend Make-Whole Payment feature of the Company's 6% convertible Preferred Stock may have a material impact on the Company's results of operations.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk.

## **Interest Rate Risk**

The Company's interest income and expense are 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 \$4.3 million and the interest incurred on the line of credit balance of \$4.5 million as of June 30, 2006. The Company's short-term investments in marketable securities of \$3.5 million as of June 30, 2006 can also be affected by changing interest rates to the extent that these items contain variable interest rates or are subject to maturity or sale during a period of changing interest rates. A 10% adverse change in interest rates affecting the Company's cash equivalents and short-term investments or borrowings under the Company's Credit Agreement would not have a material impact on the Company's financial position, results of operations, or cash flows.

### **Derivative Valuation Risk**

The terms of the Company's March 18, 2005 6% convertible Preferred Stock offering include a Dividend Make-Whole Payment feature. This feature is considered an embedded derivative instrument. Due to the quarterly revaluation of the derivative liability, the Company recorded other expense of \$11,000 and \$67,000 for the three and six months ended June 30, 2006, respectively. At June 30, 2006 the derivative liability was valued at \$181,000. The fair value of this derivative is based on various factors, including the market price of the Company's common stock and discount rates used in determination of fair value. Changes in these factors could cause the fair value of this derivative to fluctuate significantly from period to period. These resulting changes in valuation may have a significant impact on the Company's results of operations.

## Item 4. Controls and Procedures.

The Company's management, including the Company's President and Chief Executive Officer ("CEO") and the Company's Executive Vice President, Chief Operating Officer, 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 or will be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake.

Based upon the Company's most recent disclosure controls evaluation as of June 30, 2006, 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.

During the quarter ended June 30, 2006 there were no changes in the Company's internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company's internal control over financial reporting.

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# Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

See "Note 13 of Notes to Summary Consolidated Financial Statements" at Part I, Item 1, "Financial Statements", which is incorporated herein by reference.

Item 1A. Risk Factors.

The Company's most recent Form 10-K was filed February 23, 2006. There have been no material changes from the risk factors previously disclosed in the Company's Form 10-K in response to Part I, Item 1A of Form 10-K.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

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

(a) The Annual Meeting of Shareholders was held on May 4, 2006.

(b) Management's nominees for director were elected at the meeting by the holders of common stock. The election was uncontested.

The following table shows the results of voting in the election of Directors:

	Shares Voted For	Authority Withheld	Abstained	Broker Non-Votes
Steven G. Anderson	20,569,487	2,910,575	_	
Thomas F. Ackerman	20,689,787	2,790,275	_	
James S. Benson	20,694,837	2,785,225		
Daniel J. Bevevino	20,599,375	2,880,687		
John M. Cook	20,724,482	2,755,580		
Ronald C. Elkins, M.D.	20,711,569	2,768,493		
Virginia C. Lacy	20,567,069	2,912,993		
Ronald D. McCall, Esq.	17,724,621	5,755,441	—	_
Bruce J. Van Dyne, M.D.	20,661,741	2,818,321	_	

## Item 5. Other information.

None.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description			
3.1	Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form 10-Q for the quarter ended March 31, 2003.)			
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of CryoLife, Inc., classifying and designating Series A Junior Participating Preferred Stock. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on November 3, 2005.)			
3.3	Preferred Stock Articles of Amendment to the Articles of Incorporation of the Registrant. (Incorporated herein by reference to Exhibit 3.4 to the Registrant's Form 8-A/A filed on March 15, 2005.)			
3.4	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed December 28, 2005.)			
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 33-56388).)			
10.1	Description of CryoLife, Inc. Performance Based Bonus Plan.			
10.2	Amendment to Employment Agreement with D. Ashley Lee dated May 4, 2006.			
10.3	Option Grant Agreement with D. Ashley Lee dated May 4, 2006.			
10.4	Form of Employment Agreement entered into with Albert E. Heacox, Ph.D. and David M. Fronk on May 4, 2006 (Incorporated herein by reference to Item 1.01 of and Exhibit 10.1 to the Registrant's Report on Form 8-K filed on May 10, 2006.)			
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.			

# 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.

/s/ STEVEN G. ANDERSON STEVEN G. ANDERSON

Chairman, President, and Chief Executive Officer (Principal Executive Officer)

August 3, 2006 DATE CRYOLIFE, INC. (Registrant)

/s/ DAVID ASHLEY LEE

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

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## Description of CryoLife, Inc. Performance-Based Bonus Plan

On May 4, 2006, the Compensation Committee of the Board of Directors of CryoLife, Inc. ("CryoLife" or the "Company") recommended, and the Board of Directors adopted, a performance-based bonus plan for CryoLife's corporate officers, including its executive officers, as described below. The Company's executive officers are:

- Steven G. Anderson, Chairman, President and Chief Executive Officer;
- David M. Fronk, Vice President, Regulatory Affairs and Quality Assurance;
- D. Ashley Lee, Executive Vice President, Chief Operating Officer, and Chief Financial Officer;
- Gerald B. Seery, Senior Vice President, Sales and Marketing;
- Albert E. Heacox, Ph.D., Senior Vice President, Research and Development;

The purpose of the performance-based bonus plan is to promote the interests of CryoLife and its stockholders by providing key employees with financial awards upon achievement of specified business objectives, and to help attract and retain key employees by providing attractive compensation opportunities linked to performance.

Bonuses will be payable based on a weighted formula, as follows:

- 50%, based on the Company's net income (loss) for 2006, excluding the effect of stock compensation charges. A minimum loss threshold must be met before any bonus can be earned under this measure.
- 30%, based on the Company's annual revenues from the sale of products and services. A minimum threshold must be met before any bonus can be earned under this measure.
- 20%, based on Personal performance. In considering personal performance, the Committee will consider the recommendations of management as well as its own subjective determination.

Subject to meeting minimum performance thresholds, the executive officers may earn bonuses as follows:

- Mr. Anderson, from 36% to 87% of base salary, with the target level set at 60%;
- Mr. Fronk, from 18% to 44% of base salary, with the target level set at 30%;
- Mr. Lee, from 36% to 87% of base salary, with the target level set at 60%;
- Mr. Seery, from 15% to 59% of base salary, with the target level set at 35%; and
- Mr. Heacox, from 21% to 51% of base salary, with the target level set at 35%.

If minimum performance thresholds are not met, no bonuses will be paid.

Additional performance bonuses of up to 15% of the participant's base salary will be earned if specified net loss/income targets are reached which reflect performance improvements beyond that contemplated in the primary bonus plan.

## FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to Employment Agreement (the "Amendment") dated as of the 4th day of May, 2006 (the "Effective Date"), is by and between CryoLife, Inc., a Florida corporation ("CryoLife") and D. Ashley Lee (the "Employee").

## WITNESSETH:

WHEREAS, CryoLife and Employee are party to an Employment Agreement dated September 5, 2005 (the "Agreement") which they desire to amend in certain particulars.

NOW, THEREFORE, in consideration of the premises, employee's continued employment by CryoLife, the promises hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby amend the Agreement by removing <u>Exhibit A</u> to the Agreement in its entirety and replacing it with the <u>Exhibit A</u> attached to this Amendment.

IN WITNESS WHEREOF, the Employee has hereunder set the Employee's hand and, pursuant to the authorization from its Board, CryoLife has caused these presents to be executed in its name on its behalf, all as of the day and year first above written.

D. Ashley Lee

CRYOLIFE, INC.

By:

Steven G. Anderson Chairman, President and CEO

## Exhibit A

#### Duties and Responsibilities of D. Ashley Lee:

All duties of Executive Vice President, Chief Operating Officer, Chief Financial Officer and Treasurer and duties not inconsistent with such duties that are assigned by the President.

## Compensation:

Salary of \$340,000 and bonus set by the Compensation Committee. Salary & Bonus subject to yearly review by the Compensation Committee of the Board of Directors.

#### Options:

Long-term incentive options under the 2004 Employee Stock Incentive Plan (the "Plan") to purchase 250,000 shares of CryoLife's common stock to be granted to Employee on May 4, 2006. The options will be governed by the Plan and a separate option or option grant agreement (either, the "Option Agreement"). The Option Agreement will provide in part that the options will become exercisable subject to Employee remaining continuously employed by CryoLife as follows: 50,000 shares will become subject to exercise on the first anniversary of the option grant and 50,000 more shares will become subject to exercise on each subsequent anniversary thereof until all 250,000 shares (100% of the option) is subject to exercise (on the fifth anniversary, assuming continuous employment). The option will have a term of 66 months but the option may terminate earlier as stated in the option document. The right to exercise will accelerate for all shares subject to the Option Agreement if, during the Employment Period and during Employee's continuous employment, (i) CryoLife terminates the Employee's employment other than for Cause, Death or Disability, or (ii) Employee becomes entitled to receive a Retention Payment under Section 4.

## Vacation and Employee Benefits:

See attached CryoLife vacation plan, standard CryoLife medical plan and contributory

401K plan.

## CryoLife Business:

The development, marketing, sale and distribution of tissue preservation services and biomedical and medical products including cardiac, vascular or orthopedic tissue processing business and biological glues.

## CryoLife, Inc. 1655 Roberts Boulevard N.W. Kennesaw, Georgia 30144

May 4, 2006

#### Re: Grant of Incentive Stock Option

Dear Ashley:

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

1. <u>Grant of Option</u>. Subject to the terms set forth below, the Company hereby grants to Employee the right, privilege, and option to purchase up to 250,000 shares (of Common Stock the "Option Shares") at the purchase price of \$5.03 per share. The date of grant ("Grant Date") of the option is May 4, 2006 This option is intended to be and shall be treated as an "Incentive Stock Option," as that term is defined in Section 422 of the Internal Revenue Code of 1986, as amended ("Section 422"). Provided, however, that to the extent that the option fails for any reasons to comply with the provisions of Section 422, it shall be treated as a "Non-Qualified Stock Option" (as defined in the Plan). The Company shall have no liability whatsoever to Employee in the event the option fails for any reason to satisfy the requirements for Incentive Stock Options set forth in Section 422. This option is granted pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive ((the "Plan").

## 2. <u>Time of Exercise of Option</u>.

(a) Prior to its termination as set forth in Section 5 below, this option shall vest, and the Employee may exercise the option granted herein on the following dates, or thereafter provided the option is exercised prior to its termination:

Exercise Date	Number of Option Shares Exercisable	Cumulative Percentage of Option Shares Exercisable
First Anniversary of Grant Date (05/04/07)	50,000 shares	20 percent
Second Anniversary of Grant Date (05/04/08)	100,000 shares	40 percent
Third Anniversary of Grant Date (05/04/09)	150,000 shares	60 percent
Fourth Anniversary of Grant Date (05/04/10)	200,000 shares	80 percent
Fifth Anniversary of Grant Date (05/04/11)	250,000 shares	100 percent

(b) As described in the First Amendment to Employment Agreement dated as of May 4, 2006, executed by the Company and you, and amending the Employment Agreement between the Company and you dated September 5, 2005, all shares subject to this option agreement shall vest and become immediately exercisable if, during the Employment Period and

during your continuous employment, (i) CryoLife terminates your employment other than for Cause, Death or Disability, or (ii) you become entitled to receive a Retention Payment under Section 4 of the amended Employment Agreement. The defined terms in this Section 2(b) shall have the meanings ascribed to them in the amended Employment Agreement.

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

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

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

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

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

(c) <u>Retirement</u>. In the event Employee's employment with the Company terminates by reason of normal or early retirement, any option held by such Employee may be

exercised by the Employee for a period of 36 months from the date of such termination; provided, however, that if the Employee dies within such 36 month period any unexercised option held by Employee shall thereafter be exercisable in accordance with the provisions of and shall terminate upon the first to occur of the events described in Section 5(b) and (d); or

(d) <u>Other</u>. Upon the earlier to occur of (i) 66 months following the Grant Date, or (ii) upon the expiration of ten (10) business days after termination of Employee's employment by the Company (except if such termination be by reason of death, disability, or normal or early retirement). Notwithstanding the foregoing, if the shares subject to this option become fully vested and immediately exercisable pursuant to Section 2(b), then the right to exercise this option shall terminate on the first to occur of sixty-six (66) months following the Effective Date, or 24 months from the date of acceleration pursuant to Section 2(b). It is in Compensation Committee's sole discretion to determine whether the Employee's employment with the Company terminates by reason of disability, normal or early retirement.

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

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

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

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

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

(b) Employee resides at the following address:

3802 Wieuca Trace Atlanta, Georgia 30342

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

inherent in accepting the option and has received satisfactory and complete information concerning the business and financial condition of the Company in response to all inquiries in respect thereof.

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

10. <u>Tax Matters</u>. The Employee hereby agrees to comply with any applicable federal, state, and local income and employment tax requirements which might arise with regard to a disposition of any Option Shares and to inform the Company of any such disposition which occurs prior to the expiration of (i) two years from the date of grant of the option, and (ii) one

year from the date of transfer to him of Option Shares. No later than the date as of which an amount first becomes includable in the gross income of the Employee for federal income tax purposes with respect to the exercise of any option under the Plan, Employee shall pay to the Company, or make arrangements satisfactory to the Committee regarding the payment of, any federal, state, or local taxes of any kind required by law to be withheld with respect to such amount. The obligations of the Company under the Plan are conditional on such payment or arrangements and the Company shall have the right to deduct any such taxes from any payment of any kind otherwise due to Employee.

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

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

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

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

Thank you for your good work and service.

Sincerely,

# (SEAL) THE COMPANY:

# CRYOLIFE, INC.

Suzanne K. Gabbert, Secretary for the Company

Attest:

Steven G. Anderson, President and CEO

# **EMPLOYEE:**

D. Ashley Lee

Social Security No .:

## **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(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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 functions):

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 control over financial reporting.

Date: August 3, 2006

/s/ STEVEN G. ANDERSON

Chairman, President, and Chief Executive Officer I, David Ashley Lee, Executive Vice President, Chief Operating Officer, and Chief Financial Officer, certify that:

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

2. Based on my knowledge, this 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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 functions):

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 control over financial reporting.

Date: August 3, 2006

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

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

In connection with the Quarterly Report of CryoLife Inc. (the "Company") on Form 10-Q for the quarter ending June 30, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Steven G. Anderson, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

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

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

/s/ STEVEN G. ANDERSON STEVEN G. ANDERSON Chairman, President, and Chief Executive Officer August 3, 2006 /s/ DAVID ASHLEY LEE DAVID ASHLEY LEE Executive Vice President, Chief Operating Officer, and Chief Financial Officer August 3, 2006