

CRYOLIFE INC  
Form 10-Q  
July 31, 2008

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the Quarterly Period Ended June 30, 2008

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the Period from \_\_\_\_\_ to \_\_\_\_\_

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**

Edgar Filing: CRYOLIFE INC - Form 10-Q

(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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one):

Large Accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

YES  NO

The number of shares of common stock, par value \$0.01 per share, outstanding on July 25, 2008 was 28,003,750.

**Part I FINANCIAL INFORMATION****Item 1. Financial Statements.**

## CRYOLIFE, INC. AND SUBSIDIARIES

## SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
Revenues:				
Preservation services	\$ 13,725	\$ 11,711	\$ 27,149	\$ 24,672
Products	13,280	11,156	25,260	22,551
Other	150	144	314	312
<b>Total revenues</b>	<b>27,155</b>	<b>23,011</b>	<b>52,723</b>	<b>47,535</b>
Costs and expenses:				
Preservation services (Including write-downs of \$307 for the three months and \$453 for the six months ended June 30, 2007)	7,449	6,976	14,767	14,608
Products	1,840	1,881	3,832	3,829
General, administrative, and marketing	12,358	10,842	24,425	23,177
Research and development	1,307	978	2,752	2,036
Interest expense	69	187	139	340
Interest income	(71)	(105)	(193)	(202)
Change in valuation of derivative		866		821
Other expense (income), net	55	13	(27)	102
<b>Total costs and expenses</b>	<b>23,007</b>	<b>21,638</b>	<b>45,695</b>	<b>44,711</b>
Income before income taxes	4,148	1,373	7,028	2,824
Income tax expense	260	82	375	179
Net income	\$ 3,888	\$ 1,291	\$ 6,653	\$ 2,645
Effect of preferred stock dividends				(243)
Net income applicable to common shares	\$ 3,888	\$ 1,291	\$ 6,653	\$ 2,402
Income per common share:				
Basic	\$ 0.14	\$ 0.05	\$ 0.24	\$ 0.10
Diluted	\$ 0.14	\$ 0.05	\$ 0.24	\$ 0.09

Edgar Filing: CRYOLIFE INC - Form 10-Q

Weighted average common shares outstanding:

Basic	27,756	25,480	27,661	25,234
Diluted	28,381	26,333	28,211	25,969

See accompanying Notes to Summary Consolidated Financial Statements.

## Item 1. Financial Statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	June 30, 2008 (Unaudited)	December 31, 2007
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 11,719	\$ 14,460
Marketable securities, at market		2,987
Restricted marketable securities	563	
Trade receivables, net	14,040	12,311
Other receivables	1,035	1,373
Deferred preservation costs, net	31,443	26,903
Inventories	6,254	5,607
Prepaid expenses and other current assets	2,512	1,811
<b>Total current assets</b>	<b>67,566</b>	<b>65,452</b>
Property and equipment, net	17,391	18,640
Patents, net	3,779	3,906
Trademarks and other intangibles, net	3,070	3,213
Deferred income taxes	148	148
Restricted money market funds	5,000	
Other long-term assets	1,142	1,325
<b>TOTAL ASSETS</b>	<b>\$ 98,096</b>	<b>\$ 92,684</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 3,370	\$ 2,956
Accrued compensation	2,570	2,963
Accrued procurement fees	5,484	5,161
Accrued expenses	4,952	5,611
Deferred income	1,764	1,111
Line of credit		4,506
Current maturities of notes payable and capital lease obligations	926	43
Other current liabilities	2,279	2,351
<b>Total current liabilities</b>	<b>21,345</b>	<b>24,702</b>
Line of credit	315	
Notes payable and capital lease obligations, less current maturities	85	81
Other long-term liabilities	4,697	5,274
<b>Total liabilities</b>	<b>26,442</b>	<b>30,057</b>

Edgar Filing: CRYOLIFE INC - Form 10-Q

Shareholders' Equity:		
Preferred stock		
Common stock (issued shares of 28,925 in 2008 and 28,526 in 2007)	289	285
Additional paid-in capital	123,082	120,562
Retained deficit	(46,328)	(52,981)
Accumulated other comprehensive income	9	
Treasury stock at cost (shares of 945 in 2008 and 949 in 2007)	(5,398)	(5,239)
<b>Total shareholders' equity</b>	<b>71,654</b>	<b>62,627</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 98,096</b>	<b>\$ 92,684</b>

See accompanying Notes to Summary Consolidated Financial Statements.

## Item 1. Financial Statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Six Months Ended June 30, 2008      2007 (Unaudited)	
Net cash from operating activities:		
Net income	\$ 6,653	\$ 2,645
Adjustments to reconcile net income to net cash from operating activities:		
Loss on sale or disposal of assets	17	89
Depreciation and amortization	2,199	2,235
Write-down of deferred preservation costs and inventory	1,066	451
Non-cash compensation	1,434	967
Change in valuation of derivative		821
Other non-cash adjustments	75	(41)
Changes in operating assets and liabilities:		
Receivables	(1,817)	(878)
Income taxes	234	(103)
Deferred preservation costs and inventories	(6,253)	(4,559)
Prepaid expenses and other assets	(918)	(901)
Accounts payable, accrued expenses, and other liabilities	145	700
Net cash provided by operating activities	2,835	1,426
Net cash from investing activities:		
Capital expenditures	(763)	(414)
Net proceeds from sale of assets	141	9
Restricted money market funds, long-term	(5,000)	
Purchases of marketable securities	(559)	(9,415)
Sales and maturities of marketable securities	3,000	8,155
Other	(38)	(52)
Net cash used in investing activities	(3,219)	(1,717)
Net cash from financing activities:		
Proceeds from issuance of debt and notes payable	428	282
Principal payments of debt	(4,582)	(288)
Principal payments on capital leases	(21)	(20)
Proceeds from financing of insurance policies	1,300	1,912
Principal payments on short-term notes payable	(429)	(587)
Proceeds from exercise of stock options and issuance of common stock	1,090	1,333
Payment of preferred stock dividends		(486)
Purchase of treasury stock	(159)	(413)
Net cash (used in) provided by financing activities	(2,373)	1,733
(Decrease) increase in cash and cash equivalents	(2,757)	1,442
Effect of exchange rate changes on cash	16	(56)
Cash and cash equivalents, beginning of period	14,460	4,133

Edgar Filing: CRYOLIFE INC - Form 10-Q

Cash and cash equivalents, end of period

\$ 11,719    \$ 5,519

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 summary consolidated financial statements include the accounts of CryoLife, Inc., and its subsidiaries (CryoLife, the Company, we, or us). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Summary Consolidated Balance Sheet as of December 31, 2007 has been derived from audited financial statements and the accompanying unaudited summary consolidated financial statements for the periods as of and ended June 30, 2008 and 2007 and have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (of normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife's Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

**Note 2 Exchange and Service Agreement**

On December 19, 2006 the Company announced that it had entered into an exchange and service agreement with Regeneration Technologies, Inc., (RTI) and certain of its affiliates, respecting procurement, processing, and distribution activities for cardiac and vascular tissue processed and distributed by RTI and orthopaedic tissue for the knee processed and distributed by CryoLife (the RTI Agreement). In accordance with the RTI Agreement, CryoLife ceased accepting donated human orthopaedic tissue for processing commencing January 1, 2007 and began work to transition existing arrangements for recovery of human orthopaedic tissue to RTI. Likewise, on January 1, 2007 RTI ceased accepting donated human cardiac and vascular tissues for processing and began work to transition its arrangements for recovery of these tissues to CryoLife. No cash was exchanged in the transaction. CryoLife continued to distribute its existing orthopaedic tissue inventory, and RTI continued to distribute its existing cardiac and vascular tissue inventory, through June 30, 2008. After that date CryoLife became entitled to distribute RTI's remaining cardiac and vascular tissue inventory, and RTI became entitled to distribute CryoLife's remaining orthopaedic tissue inventory. CryoLife will pay RTI a commission with respect to any of CryoLife's orthopaedic tissue distributed by RTI and will receive a commission from RTI with respect to any RTI cardiac and vascular tissue distributed by CryoLife. Under the RTI Agreement, from July 1, 2008 through December 31, 2016, except as set forth above, CryoLife has agreed not to market or solicit orders for certain human orthopaedic tissues and RTI has agreed not to market or solicit orders for human cardiac and vascular tissues. The agreement also provides for a non-exclusive license of technology from CryoLife to RTI, and contains customary provisions regarding indemnification and confidentiality.

**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 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 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 income 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, 2008 \$5.0 million of the Company's money market funds were designated as long-term restricted money market funds due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation ( GE Capital ) as discussed in Note 6.

As of June 30, 2008 \$563,000 of marketable securities was 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 were reported as restricted marketable securities on the June 30, 2008 Summary Consolidated Balance Sheets.

As of December 31, 2007 \$3.0 million of marketable securities were designated as available-for-sale.

The Company's cash equivalents include advance funding received under the U.S. Congress 2005 and 2006 Defense Appropriations Conference Reports (the 2005 DOD Grant ) and (the 2006 DOD Grant ), respectively, for the continued development of protein hydrogel technology for use on the battlefield. The advance funding is accounted for as deferred income on the Summary Consolidated Balance Sheets and is recognized as other revenue as expenses are incurred related to these grants. As of June 30, 2008 \$1.8 million of cash equivalents and deferred income was related to the 2006 DOD grant. As of December 31, 2007 \$1.0 million of cash equivalents and deferred income was related to the 2005 and 2006 DOD grants.

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

	Cost Basis	Unrealized Holding Gains	Estimated Market Value
<b>June 30, 2008 (Unaudited)</b>			
Cash equivalents:			
Money market funds	\$ 9,760	\$	\$ 9,760
Restricted money market funds, long-term	\$ 5,000	\$	\$ 5,000
Marketable securities:			
Restricted government entity sponsored debt securities	\$ 563	\$	\$ 563
<b>December 31, 2007</b>			
Cash equivalents:			
Money market funds	\$ 11,724	\$	\$ 11,724
Marketable securities:			
Government entity sponsored debt securities	\$ 2,984	\$ 3	\$ 2,987

There were no gross realized gains or losses on sales of available-for-sale securities for the three and six months ended June 30, 2008 and 2007. Differences between cost and market value listed above, consisting of an unrealized holding gain of \$3,000 at December 31, 2007, are included as a component of other comprehensive income on the Company's Summary Consolidated Balance Sheets.

At June 30, 2008 and December 31, 2007 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):

	June 30, 2008 (Unaudited)	December 31, 2007
Raw materials	\$ 3,343	\$ 2,956
Work-in-process	543	650
Finished goods	2,368	2,001
Total inventories	\$ 6,254	\$ 5,607

**Note 5 Income Taxes**

The Company periodically assesses the recoverability of its deferred tax assets in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 109 Accounting for Income Taxes ( SFAS 109 ), 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, 2007 the Company reviewed its historical operating results, including the reasons for its operating losses in prior years and uncertainties regarding projected future operating results. Based on the results of this analysis, at December 31, 2007 and June 30, 2008 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, as of June 30, 2008 and December 31, 2007 the Company had a total of \$28.2 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$27,000. The Company will reverse the remaining valuation allowance, or a portion thereof, when and if its deferred tax assets meet the SFAS 109 more likely than not standard for recognition. Also, the realizability of the Company's deferred tax assets could be limited in future periods following a change in control as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, which relates to certain specified changes in control of taxpayers.

The Company adopted the provisions of FIN 48 on January 1, 2007. As a result of the adoption of FIN 48, the Company recorded \$1.7 million in liabilities for unrecognized tax benefits plus estimated interest and penalties of \$283,000. The aggregate \$2.0 million liability was accounted for as a decrease to the January 1, 2007 balance of retained earnings of \$762,000 and a reclassification of a portion of the valuation allowances against the Company's deferred tax assets of \$1.2 million to an uncertain tax liability. To the extent these unrecognized tax benefits are ultimately recognized, it would not affect the annual effective income tax rate due to the existence of the valuation allowance.

The Company recognizes interest and penalties related to uncertain tax positions in other income and expense on the Company's Summary Consolidated Statements of Operations. As of June 30, 2008 and December 31, 2007 the Company had approximately \$390,000 and \$347,000, respectively, of accrued interest and penalties related to uncertain tax positions.

The tax years 2004-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject.

**Note 6 Debt**

On March 26, 2008 CryoLife and its subsidiaries entered into a credit agreement with GE Capital as lender (the GE Credit Agreement ). The GE Credit Agreement provides for a revolving credit facility in an aggregate amount not to exceed the initial commitment of \$15.0 million (including a letter of credit subfacility of up to an aggregate of \$1.5 million). The initial commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. While the Company currently expects that its aggregate borrowing capacity under the GE Credit Agreement will equal \$15.0 million, there can be no assurance that the borrowing capacity will remain at this level. The GE 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 (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings before extraordinary gains, interest, taxes, depreciation, and amortization ( Adjusted EBITDA ) as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. Further, beginning April 15, 2008 as required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as long-term restricted money market funds on the Company's Summary Consolidated Balance Sheet. The GE Credit Agreement also includes customary conditions on incurring new indebtedness and prohibits payments of cash dividends on the Company's common stock. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The GE Credit Agreement expires on March 25, 2011, at which time the outstanding principal balance will be due. As of June 30, 2008 the Company was in compliance with the covenants of the GE Credit Agreement.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest at either LIBOR plus 3.25% or GE Capital's base rate, as defined, plus 2.25%, as applicable. As of June 30, 2008 the outstanding balance of the GE Credit Agreement was \$315,000, the aggregate interest rate was 7.25%, and the remaining availability was \$14.7 million.

On February 8, 2005 CryoLife and its subsidiaries entered into a credit agreement with Wells Fargo Foothill, Inc. ( Wells Fargo ) as lender which provided 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. The credit agreement with Wells Fargo expired on February 8, 2008 in accordance with its terms, at which time the outstanding principal balance of \$4.5 million was paid from cash on hand. In the first quarter of 2007 the Company obtained a \$500,000 letter of credit under the subfacility of this credit agreement relating to one of the Company's product liability insurance policies. Upon the February 8, 2008 expiration of the credit agreement with Wells Fargo, the Company remitted to Wells Fargo approximately \$500,000 as collateral to cover the remaining term of the letter of credit agreement, which expired on April 2, 2008. This remitted amount was refunded to the Company in the second quarter of 2008.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In April 2008 the Company entered into such an agreement to finance approximately \$1.3 million in insurance premiums. The amount financed accrues interest at a 4.632% annual rate and is payable in equal monthly payments over a nine month period. As of June 30, 2008 the aggregate outstanding balance under this agreement was \$872,000. In the second quarter of 2007 the Company entered into two such agreements to finance approximately \$1.4 million and \$478,000 in insurance premiums. The amounts financed accrued interest at 7.027% and were payable in equal monthly payments over a nine month and an eight month period, respectively. As of June 30, 2008 the aggregate outstanding balance under these agreements was zero.

#### **Note 7 Convertible Preferred Stock**

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 were cumulative from the date of original issue at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly. Any dividends were required to be declared by the Company's board of directors and to come from funds legally available for dividend payments. On March 13, 2007 the Company declared a dividend of \$0.75 per share on its Preferred Stock. The dividend of approximately \$243,000 was paid on April 2, 2007 to shareholders of record on March 22, 2007. No dividends were declared during the remainder of 2007.

The Preferred Stock was 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 Company had reserved 4.6 million shares of common stock for issuance upon conversion. Through June 4, 2007 holders had cumulatively voluntarily converted 139,000 shares of Preferred Stock into 867,000 shares of common stock.

The Preferred Stock contained provisions that allowed the Company to convert its Preferred Stock into common stock if the closing price of the Company's common stock 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. This condition was satisfied on June 4, 2007 and on that day the Company exercised its right to automatically convert the Preferred Stock into common stock. As a result, on June 25, 2007 the Company automatically converted the remaining 278,000 shares of Preferred Stock into 1.7 million shares of common stock at the conversion rate of approximately 6.2189 shares of common stock per share of Preferred Stock.

The Company was required to make additional payments for both the voluntary and automatic conversions of 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 was 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. The Dividend Make-Whole Payment is discussed further in Note 8 below.

As of June 30, 2008 and December 31, 2007 there were no outstanding shares of Preferred Stock as a result of the second quarter 2007 automatic conversion of the Preferred Stock to common stock.

#### **Note 8 Derivative**

In accordance with SFAS No. 133 Accounting for Derivative Instruments and Hedging Activities (SFAS 133), the Company was 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 was 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 were recognized in the line item change in valuation of derivative 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 recorded on the Summary Consolidated Balance Sheets were reduced by these amounts, which were allocated to the derivative liability.

As discussed in Note 7 above, on June 25, 2007 the Company automatically converted the remaining shares of the Preferred Stock into common stock, thereby, triggering the payment of the remaining Dividend Make-Whole Payment. Through June 4, 2007 the Company had issued 132,000 shares of common stock to converting holders in satisfaction of the Dividend Make-Whole Payment. The value of voluntary conversions during 2007 was \$178,000 based on the share prices on the respective dates of conversion. On June 25, 2007 the Company issued 69,000 shares of common stock to preferred shareholders to satisfy the Dividend Make-Whole Payment due to the automatic conversion. The value of the Dividend Make-Whole Payment was \$878,000 based on the share price of \$12.71 on the date of conversion.

The Company recorded other expense of \$866,000 for the three months ended June 30, 2007 related to the automatic and voluntary conversions of the Preferred Stock to common stock. The Company recorded \$821,000 for the six months ended June 30, 2007 related to the first quarter revaluation of the Derivative and the automatic and voluntary conversion of the Preferred Stock to common stock.

At June 30, 2008 and December 31, 2007 there was no remaining derivative liability as a result of the second quarter 2007 automatic conversion of the Preferred Stock to common stock.

**Note 9 Comprehensive Income**

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

	Three Months Ended June 30		Six Months Ended June 30,	
	2008 (Unaudited)	2007 (Unaudited)	2008 (Unaudited)	2007 (Unaudited)
Net income	\$ 3,888	\$ 1,291	\$ 6,653	\$ 2,645
Unrealized loss on investments		(3)	(3)	(4)
Translation adjustment	33	(30)	12	(58)
Comprehensive income	\$ 3,921	\$ 1,258	\$ 6,662	\$ 2,583

The tax effect on the change in unrealized loss on investments and the translation adjustment is zero for each period presented.

Accumulated other comprehensive income consists of the following (in thousands):

	June 30 2008 (Unaudited)	December 31, 2007
Unrealized gain on investments	\$ 3	\$ 3
Translation adjustment	9	(3)
Total accumulated other comprehensive income	\$ 9	\$

**Note 10 Income per Common Share**

The following table sets forth the computation of basic and diluted income per common share (in thousands, except per share data). The net income for the six months ended June 30, 2007 is adjusted by the effect of the Company's cumulative, convertible Preferred Stock to arrive at net income applicable to common shares in accordance with SFAS No. 128 Earnings Per Share (SFAS 128). The Company also considers, as applicable, the effect of its Preferred Stock, as discussed in Note 7, the Derivative, as discussed in Note 8, common stock options, as discussed in Note 11, contingently returnable shares, and contingent stock awards in the calculation of diluted weighted-average shares below.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008 (Unaudited)	2007 (Unaudited)	2008 (Unaudited)	2007 (Unaudited)
Basic income per common share				
Numerator:				
Net income	\$ 3,888	\$ 1,291	\$ 6,653	\$ 2,645
Effect of preferred stock <sup>a</sup>				(243)
Net income applicable to common shares	\$ 3,888	\$ 1,291	\$ 6,653	\$ 2,402
Denominator:				
Basic weighted-average common shares	27,756	25,480	27,661	25,234
Basic income per common share	\$ 0.14	\$ 0.05	\$ 0.24	\$ 0.10



Edgar Filing: CRYOLIFE INC - Form 10-Q

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008 (Unaudited)	2007 (Unaudited)	2008 (Unaudited)	2007 (Unaudited)
Diluted income per common share				
Numerator:				
Net income	\$ 3,888	\$ 1,291	\$ 6,653	\$ 2,645
Effect of preferred stock <sup>a, b</sup>				(243)
Net income applicable to common shares	\$ 3,888	\$ 1,291	\$ 6,653	\$ 2,402
Denominator:				
Basic weighted-average common shares	27,756	25,480	27,661	25,234
Effect of dilutive convertible preferred stock <sup>b</sup>				
Effect of dilutive stock options	545	853	475	735
Effect of contingently returnable shares <sup>c</sup>	55		47	
Effect of contingent stock awards <sup>d</sup>	25		28	
Adjusted weighted-average common shares	28,381	26,333	28,211	25,969
Diluted income per common share	\$ 0.14	\$ 0.05	\$ 0.24	\$ 0.09

<sup>a</sup> The amount of the accumulated dividend on Preferred Stock reduced the net income applicable to common shares for the six months ended June 30, 2007.

<sup>b</sup> The adjustment for the Dividend Make-Whole Payment for conversions during the period would have increased net income applicable to common shareholders by \$866,000 for the three months ended June 30, 2007. The common shares that would have been issued to shareholders at the beginning of the period for the conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 1.8 million for the three months ended June 30, 2007. 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 decreased the net income applicable to common shares by \$243,000 for the six months ended June 30, 2007. The adjustment for the Dividend Make-Whole Payment for conversions during the period and the adjustment for the quarterly revaluation of the derivative liability would have instead increased net income applicable to common shareholders by \$821,000 for the six months ended June 30, 2007. The common shares that would have been issued to shareholders at the beginning of the period for the conversion of the remaining Preferred Stock and in payment of the remaining Dividend Make-Whole Payment would have increased the weighted-average shares by 2.0 million for the six months ended June 30, 2007. These adjustments were excluded from the calculation above, as they were anti-dilutive pursuant to the provisions of SFAS 128.

<sup>c</sup> Contingently returnable shares include shares of common stock issued pursuant to stock grants which have not vested and are returnable to the Company upon forfeiture.

<sup>d</sup> Contingent stock awards include shares to be issued pursuant to performance based bonus plans that have been approved by the compensation committee of the Board of Directors.

In future periods basic and diluted earnings per common share are expected to be affected by the fluctuations in the fair value of the Company's common stock, the exercise and issuance of additional stock options, contingently returnable shares, and contingent stock awards.

---

**Note 11 Stock Compensation**

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of shares and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also 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 look back portion of ESPP stock purchases are considered components of stock compensation and must be expensed in the Company's financial statements. The look back portion of the Company's ESPP constitutes an option and, as such, the expense is determined by performing a valuation as discussed below.

***Stock Grants***

The Company values its stock grants based on the market value, as determined by the stock incentive plan, on the date of grant. The value of stock grants is expensed over the vesting period of the related grant, and an estimated forfeiture rate is used to reduce the expense recorded.

In February 2008 the Compensation Committee of the Company's Board of Directors approved the terms of the Company's 2008 performance-based bonus plans to recognize the performance of the Company's executives and managers. A portion of the awards to be issued under these plans will be paid in Company stock pursuant to the Company's existing stock incentive plans, if the required performance is achieved. The Company recorded an accrual of \$450,000 related to this contingent stock grant during the six months ended June 30, 2008. The Company expects to pay out cash and stock related to these bonus plans in the first quarter of 2009.

During the first half of 2008 the Compensation Committee of the Company's Board of Directors authorized grants of stock from approved stock incentive plans to non-employee Directors and certain Company executives and managers totaling 170,000 shares of common stock, which had an aggregate value of \$1.6 million. The grants of stock during the first half of 2008 include 81,000 shares of common stock valued at \$786,000 issued as part of the 2007 performance-based bonus plans for certain Company executives and managers. The Company recorded the expense related to the 2007 performance-based bonus plans during the year ended December 31, 2007. The remaining value of the stock granted will be recorded as an expense on the Company's Summary Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

During the first half of 2007 the Compensation Committee of the Company's Board of Directors authorized grants of stock from approved stock incentive plans to non-employee Directors and certain Company executives totaling 136,000 shares of common stock, which had an aggregate value of \$1.4 million. The grants of stock during the first half of 2007 included 68,000 shares of common stock valued at \$587,000 issued as part of the 2006 performance-based bonus plan for certain Company executives. The Company recorded the expense related to the 2006 performance-based bonus plan during the year ended December 31, 2006. The remaining value of the stock granted will be recorded as an expense on the Company's Summary Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

***Stock Options***

The Compensation Committee of the Company's Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company executives and employees totaling 333,000 and 273,000 shares during the first half of 2008 and 2007, respectively, with exercise prices equal to the stock prices on the respective grant dates. The value of the stock options granted will be recorded as an expense on the Company's Summary Consolidated Statements of Operations over the respective vesting periods in accordance with SFAS 123R as discussed below.

Employees purchased common stock totaling 26,000 and 25,000 shares in the first half of 2008 and 2007, respectively, through the Company's ESPP. The value of the option portion of the stock purchased was recorded as an expense on the Company's Summary Consolidated Statements of Operations in each quarterly period in accordance with SFAS 123R as discussed below.

**Stock Compensation Expense**

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 the expense recorded 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 Months Ended June 30, 2008		Six Months Ended June 30, 2008	
	Stock Options (Unaudited)	ESPP Options	Stock Options (Unaudited)	ESPP Options
Expected dividend yield	N/A	0%	0%	0%
Expected stock price volatility	N/A	.46	.60	.62
Risk-free interest rate	N/A	1.40%	2.26%	2.42%
Expected life of options	N/A	.25 Years	3.5 Years	.25 Years

	Three Months Ended June 30, 2007		Six Months Ended June 30, 2007	
	Stock Options (Unaudited)	ESPP Options	Stock Options (Unaudited)	ESPP Options
Expected dividend yield	N/A	0%	0%	0%
Expected stock price volatility	N/A	.50	.60	.44
Risk-free interest rate	N/A	5.12%	4.78%	4.97%
Expected life of options	N/A	.25 Years	3.5 Years	.25 Years

The following table summarizes stock compensation expenses (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008 (Unaudited)	2007	2008 (Unaudited)	2007
Stock grant expense	\$ 444	\$ 358	\$ 839	\$ 575
Stock option expense	335	215	595	392
<b>Total stock compensation expense</b>	<b>\$ 779</b>	<b>\$ 573</b>	<b>\$ 1,434</b>	<b>\$ 967</b>

Included in this total stock compensation expense were expenses related to common stock grants, options issued prior and subsequent to the adoption of SFAS 123R that continue to vest during the period, and compensation related to the Company's ESPP. 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 capitalized \$30,000 and \$24,000 in the three months ended June 30, 2008 and 2007, respectively, of the stock compensation



expense into its deferred preservation costs and inventory costs. The Company capitalized \$49,000 and \$44,000 in the six months ended June 30, 2008 and 2007, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs. The Company did not recognize a tax benefit, or a related operating cash outflow and financing cash inflow, related to the compensation expense recorded in the three and six months ended June 30, 2008 and 2007, as the Company is 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, 2008 and 2007 the Company had a total of \$993,000 and \$688,000, respectively, in total unrecognized compensation costs related to unvested stock grants, before considering the effect of expected forfeitures. This expense is expected to be recognized over each stock grant's vesting period. As of June 30, 2008 the Company has outstanding stock grants that complete vesting in 2008, 2010, and 2011.

As of June 30, 2008 and 2007 there was approximately \$1.9 million and \$2.0 million, respectively, in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of June 30, 2008 and 2007 this expense is expected to be recognized over a weighted average period of 1.6 years and 1.9 years, respectively.

**Note 12 Segment Information**

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

The Preservation Services segment includes external services revenues from the cryopreservation of cardiac and vascular tissues and from shipments of previously cryopreserved orthopaedic tissues. The Implantable Medical Devices segment includes external revenues from product sales of BioGlue, Hemostase MPH, CardioWrap, and bioprosthetic devices, including the CryoLife-O Brien Stentless Aortic Bioprosthesis, and SynerGraft processed bovine vascular grafts. There are no intersegment revenues.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Preservation services	\$ 13,725	\$ 11,711	\$ 27,149	\$ 24,672
Implantable medical devices	13,280	11,156	25,260	22,551
All other <sup>a</sup>	150	144	314	312
	27,155	23,011	52,723	47,535
<b>Cost of Preservation Services and Products:</b>				
Preservation services	7,449	6,976	14,767	14,608
Implantable medical devices	1,840	1,881	3,832	3,829
All other <sup>a</sup>				
	9,289	8,857	18,599	18,437
<b>Gross Margin:</b>				
Preservation services	6,276	4,735	12,382	10,064
Implantable medical devices	11,440	9,275	21,428	18,722
All other <sup>a</sup>	150	144	314	312

\$ 17,866 \$ 14,154 \$ 34,124 \$ 29,098

<sup>a</sup> The All other designation includes 1) grant revenue and 2) revenues related to the licensing of the Company's technology to a third party.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008 (Unaudited)	2007 (Unaudited)	2008 (Unaudited)	2007 (Unaudited)
<b>Preservation services:</b>				
Cardiac tissue	\$ 6,348	\$ 5,048	\$ 12,586	\$ 10,021
Vascular tissue	7,080	5,428	13,939	11,567
Orthopaedic tissue	297	1,235	624	3,084
<b>Total preservation services</b>	<b>13,725</b>	<b>11,711</b>	<b>27,149</b>	<b>24,672</b>
<b>Products:</b>				
BioGlue	12,972	10,930	24,859	22,093
Other implantable medical devices	308	226	401	458
<b>Total products</b>	<b>13,280</b>	<b>11,156</b>	<b>25,260</b>	<b>22,551</b>
Other	150	144	314	312
<b>Total revenues</b>	<b>\$ 27,155</b>	<b>\$ 23,011</b>	<b>\$ 52,723</b>	<b>\$ 47,535</b>

### Note 13 Commitments and Contingencies

#### *Product Liability Claims*

In the normal course of business as a medical device and services company, the Company has liability and tissue processing complaints filed against it. As of July 25, 2008 one liability lawsuit was pending against the Company arising out of the Company's allograft orthopaedic tissue preservation services. Management believes this lawsuit is covered by liability insurance. This lawsuit is in the discovery stage. Other parties have made complaints that may result in lawsuits in future periods.

Based on an analysis the Company performed as of June 30, 2008 of the pending tissue processing liability lawsuit, the Company accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the June 30, 2008 Summary Consolidated Balance Sheet. As of December 31, 2007 the Company had accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the December 31, 2007 Summary Consolidated Balance Sheet.

On April 1, 2008 the Company bound liability coverage for the 2008/2009 insurance policy year. This policy is a six-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product and tissue processing 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 and tissue processing liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2008 the Company retained an independent actuarial firm to perform estimates of the unreported claims as of June 30, 2008. The independent firm estimated the unreported 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 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 2008 would be lower than the Company's experience in 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 55% lower than non-BioGlue claims per million dollars of revenue. The 55% 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 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 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 2008 as of June 30, 2008, the Company estimated that its liability for unreported liability claims was \$5.0 million. The \$5.0 million balance is included as a component of accrued expenses and other current liabilities of \$2.5 million and other long-term liabilities of \$2.5 million on the June 30, 2008 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$10.0 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, 2008, \$1.6 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.6 million insurance recoverable is included as a component of other receivables of \$800,000 and other long-term assets of \$800,000 on the June 30, 2008 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported liability claims related to services performed and products sold prior to June 30, 2008. Actual results may differ from this estimate.

As of December 31, 2007 the Company accrued \$6.3 million for unreported liability claims and recorded a receivable of \$2.4 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$6.3 million accrual was included as a component of accrued expenses and other current liabilities of \$3.2 million and other long-term liabilities of \$3.1 million on the December 31, 2007 Summary Consolidated Balance Sheet. The \$2.4 million insurance recoverable was included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.3 million on the December 31, 2007 Summary Consolidated Balance Sheet.

#### **Note 14 New Accounting Pronouncements**

The Company was required to adopt SFAS No. 157 Fair Value Measurements (SFAS 157) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The adoption of SFAS 157 did not have a material effect on the Company's results of operations or financial position.



The Company was required to adopt SFAS No. 159 The Fair Value Option for Financial Assets and Liabilities ( SFAS 159 ) for the fiscal year beginning January 1, 2008. SFAS 159 provides the option to report certain financial assets and liabilities at fair value, with the intent to mitigate volatility in financial reporting that can occur when related assets and liabilities are measured differently. The Company does not expect to voluntarily implement the optional fair value measurements portions of SFAS 159 for eligible items. The adoption of SFAS 159 did not have a material effect on the Company s results of operations or financial position.

The Company will be required to adopt SFAS No. 141R Business Combinations ( SFAS 141R ) for the fiscal year beginning January 1, 2009. FAS 141R establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The Company does not expect the adoption of FAS 141R to have a material effect on its consolidated financial position, results of operations or cash flows.

## PART I - FINANCIAL INFORMATION

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

CryoLife, Inc. (CryoLife, the Company, we, or us) develops and commercializes biomaterials and implantable medical devices, and preserves and distributes human tissues for cardiac and vascular transplant applications. The Company's human tissues include the CryoValv<sup>®</sup> SG pulmonary human heart valve, processed using CryoLife's proprietary SynerGraft<sup>®</sup> Technology. The Company's biomaterials and implantable medical devices include BioGlue<sup>®</sup> Surgical Adhesive (BioGlue), CryoLife-O<sup>®</sup> Bristleless Porcine Aortic Bioprosthesis, and ProPatch<sup>®</sup> Soft Tissue Repair Matrix (ProPatch). Additionally, the Company distributes a microporous polysaccharide hemostatic agent under the private label Hemostase MPH<sup>®</sup> for Medafor, Inc. (Medafor) and CardioWrap<sup>®</sup> bioresorbable thin film sheet used in cardiac reconstruction for MAST BioSurgery, Inc. (MAST).

In the quarter ended June 30, 2008 CryoLife revenues were \$27.2 million. This represents the second consecutive quarter that CryoLife exceeded its previous record level of quarterly revenues. The \$27.2 million in revenues included preservation services revenues of \$13.7 million and BioGlue revenues of \$13.0 million. During the second quarter of 2008 CryoLife continued to focus on physician training to enhance the acceptance of its products with physicians in the cardiac and vascular surgery specialties. This effort included the appointment of William F. Northrup, III, M.D. to the newly created position of Vice President of Medical Relations and Education. The Company also held a surgeon's cardiac allograft symposium in April and announced that it will hold a Ross summit in October 2008, focusing on training and education on the Ross cardiac procedure. The Ross procedure is a cardiac surgery operation where a diseased aortic valve is replaced with the patient's own pulmonary valve and a pulmonary allograft, such as CryoLife's CryoValve or CryoValve SG pulmonary human heart valve, is implanted to replace the patient's own pulmonary valve.

In the quarter ended June 30, 2008 CryoLife announced advances in its product offerings. In April the Company announced that it had signed an exclusive three-year agreement with Minneapolis-based Medafor to distribute its microporous polysaccharide hemostatic agent under the private label name Hemostase MPH, in May the Company announced the first implant of its combination aortic-mitral allograft heart valve at the Cleveland Clinic, and in June the Company and its partner BioForm Medical, Inc. (BioForm) announced that BioGlue had received CE Mark approval for use in brow lift procedures. See Recent Events below for further discussion of certain of these items, and see Results of Operations below for further discussion of the Company's financial results during the quarter ended June 30, 2008.

**Recent Events***Medafor License Agreement*

On April 17, 2008 CryoLife signed an exclusive three-year agreement with Medafor. Under terms of the agreement CryoLife will distribute Medafor's microporous polysaccharide hemostatic agent for use in cardiac and vascular surgery in the U.S. and for cardiac, vascular, and general surgery, other than orthopaedic and ear, nose and throat surgery, internationally, with the exception of China and Japan. This product is a plant-based, flowable powder engineered to rapidly dehydrate blood, enhancing clotting on contact. The unique, absorbable powder hemostat, which received CE Mark approval in 2003 and FDA pre-market approval in September 2006, is distributed by CryoLife under the private label name Hemostase MPH. The Company is not contractually obligated to make minimum purchases under this agreement.

CryoLife began distributing Hemostase MPH in the U.S. during the second quarter of 2008. Pursuant to the terms of the agreement, Medafor will retain distribution rights to approximately 41 hospitals until no later than December 31, 2008. Medafor also retained the exclusive rights to distribute to U.S. Department of Defense hospitals. Outside of the U.S., CryoLife began distributing Hemostase MPH in the United Kingdom and Germany during the second quarter of 2008, with distribution in other markets expected to begin later in 2008 and in 2009.

---

***BioGlue Brow Lift Approval***

On June 10, 2008 CryoLife and BioForm announced that they received a CE Mark for the use of BioGlue for periosteal fixation following endoscopic browplasty, commonly called brow lift, a reconstructive plastic surgery procedure. The CE Mark approval allows the product to be marketed in the European Community (EU). BioGlue will be distributed by BioForm, for use in approved cosmetic and reconstructive plastic surgery in the EU, under the name BioGlue Aesthetic Medical Adhesive. Under the terms of the agreement, CryoLife is the exclusive supplier of BioGlue to BioForm for all cosmetic and plastic surgery applications, and BioForm is responsible for all clinical trials and regulatory filings, and for sales and marketing of BioGlue in these applications in 12 EU countries.

**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 Consolidated Financial Statements, contained in the Company's Form 10-K for the fiscal year ended December 31, 2007. 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 U.S. 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 liability and tissue processing complaints filed against it. As of July 25, 2008 one liability lawsuit was pending against the Company arising out of the Company's allograft orthopaedic tissue preservation services. Management believes this lawsuit is covered by liability insurance. This lawsuit is in the discovery stage. Other parties have made complaints that may result in lawsuits in future periods.

Based on an analysis the Company performed as of June 30, 2008 of the pending tissue processing liability lawsuit, the Company accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the June 30, 2008 Summary Consolidated Balance Sheet. As of December 31, 2007 the Company had accrued a total of approximately \$330,000 for the pending tissue processing liability lawsuit. The \$330,000 accrual was included as a component of accrued expenses and other current liabilities on the December 31, 2007 Summary Consolidated Balance Sheet.

On April 1, 2008 the Company bound liability coverage for the 2008/2009 insurance policy year. This policy is a six-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2009 and reported during the period April 1, 2008 through March 31, 2009 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured. Any punitive damage components of claims are also uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to product and tissue processing 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 and tissue processing liability claims and records accruals as necessary for the estimated cost of unreported claims related to services performed and products used. In July 2008 the Company retained an independent actuarial firm to perform estimates of the unreported claims as of June 30, 2008. The independent firm estimated the unreported 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 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 2008 would be lower than the Company's experience in 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 55% lower than non-BioGlue claims per million dollars of revenue. The 55% 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 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 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 2008 as of June 30, 2008, the Company estimated that its liability for unreported liability claims was \$5.0 million. The \$5.0 million balance is included as a component of accrued expenses and other current liabilities of \$2.5 million and other long-term liabilities of \$2.5 million on the June 30, 2008 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$10.0 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, 2008, \$1.6 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.6 million insurance recoverable is included as a component of other receivables of \$800,000 and other long-term assets of \$800,000 on the June 30, 2008 Summary Consolidated Balance Sheet. These amounts represent management's estimate of the probable losses and anticipated recoveries for unreported liability claims related to services performed and products sold prior to June 30, 2008. Actual results may differ from this estimate.

As of December 31, 2007 the Company accrued \$6.3 million for unreported liability claims and recorded a receivable of \$2.4 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$6.3 million accrual was included as a component of accrued expenses and other current liabilities of \$3.2 million and other long-term liabilities of \$3.1 million on the December 31, 2007 Summary Consolidated Balance Sheet. The \$2.4 million insurance recoverable was included as a component of other current receivables of \$1.1 million and other long-term assets of \$1.3 million on the December 31, 2007 Summary Consolidated Balance Sheet.

**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, preservation, and distribution. Preservation costs consist primarily of direct labor and materials (including salary and fringe benefits, laboratory expenses, tissue procurement fees, and freight-in charges) 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 ARB No. 43 Chapter 4 Inventory Pricing (ARB 43). 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. Cost of preservation services also includes idle facility expense, excessive spoilage, double freight, and rehandling costs and requires allocation of fixed production overheads to be based on the normal capacity of the production

Edgar Filing: CRYOLIFE INC - Form 10-Q

facilities in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 151 Inventory Costs ( SFAS 151 ).

The calculation of deferred preservation costs involves 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 experience in prior periods and reevaluates this estimate periodically. Due to the nature of this estimate and the length of the processing times experienced by the Company, actual yields could differ from the Company's estimates. A significant change in quarantine yields could materially 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 and to determine if there are any impairments to the book value of the Company's deferred preservation costs. CryoLife records a charge to cost of preservation services to write-down the amount of deferred preservation costs that are not deemed to be recoverable. These write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels when tissues are shipped or become available for shipment.

The Company recorded a write-down of \$234,000 and \$341,000 for the three and six months ended June 30, 2007 for the value of certain deferred preservation costs that exceeded market value. No write-down for deferred preservation costs that exceeded market value has been recorded in 2008. The amount of the 2007 write-down was primarily due to excess tissue processing costs incurred in that period that exceeded market value based on then recent average service fees. Actual results may differ from these estimates.

As of June 30, 2008 deferred preservation costs consisted of \$10.2 million for allograft heart valve tissues, \$2.2 million for non-valved cardiac tissues, \$19.0 million for vascular tissues and zero for orthopaedic tissues. As of December 31, 2007 deferred preservation costs consisted of \$7.6 million for allograft heart valve tissues, \$2.1 million for non-valved cardiac tissues, \$17.1 million for vascular tissues, and \$123,000 for orthopaedic tissues.

**Deferred Income Taxes:** Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets primarily as a result of write-downs of deferred preservation costs, accruals for product liability claims, and operating losses. The Company periodically assesses the recoverability of its deferred tax assets in accordance with SFAS No. 109 Accounting for Income Taxes (SFAS 109), 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, 2007 the Company reviewed its historical operating results, including the reasons for its operating losses in prior years and uncertainties regarding projected future operating results. Based on the results of this analysis, discussed further below, at December 31, 2007 and June 30, 2008 the Company determined that it was more likely than not that the Company's deferred tax assets would not be realized. Therefore, as of June 30, 2008 and December 31, 2007 the Company had a total of \$28.2 million in valuation allowances against deferred tax assets and a net deferred tax liability of \$27,000.

Based on the Company's results for the year ended December 31, 2007 and its projections for 2008, the Company anticipates that it will utilize a portion of its net operating loss carryforwards in the 2008 income tax year to offset its U.S. taxable income, as it did in the 2007 and 2006 tax years. Although CryoLife is beginning to utilize its net operating loss carryforwards, the Company currently believes that a change in its determination of the recoverability of the related deferred tax asset is not yet warranted, as in accordance with the guidance in SFAS 109, the Company's net losses in recent years constitute significant evidence against the recoverability of its deferred tax assets that is difficult to overcome.

Although the Company has concluded that a valuation allowance is still required on its deferred tax assets, if profitable operations continue the Company may reverse all or a portion of its valuation allowance in a future period. If all or a portion of the valuation allowance is reversed, the Company will record a non-cash gain at that time that is expected to have a material impact on the Company's results of operations and financial position. In periods following the reversal, the Company's effective income tax rate is expected to be significantly higher than the effective income tax rate experienced in periods prior to the reversal.

Also, the realizability of the Company's deferred tax assets could be limited in future periods following a change in control as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, which relates to certain specified changes in control of taxpayers.

The tax years 2004-2007 remain open to examination by the major taxing jurisdictions to which the Company is subject.

**Impairments of Long-Lived Assets:** The Company assesses the potential impairment of its long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors 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, or

Significant decline in the Company's market capitalization relative to net book value.

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 group. For the year ended December 31, 2007 the Company did not experience any factors that indicated an SFAS 144 impairment review was warranted.

SFAS No. 142 Goodwill and Other Intangible Assets (SFAS 142) requires that goodwill resulting from business acquisitions and other non-amortizing intangible assets be subject to annual impairment testing. The Company's non-amortizing intangible assets as of December 31, 2007 consist of trademarks and, as a result of the Company's agreement with Regeneration Technologies, Inc. (RTI) and certain of its affiliates as discussed in Item 1, Note 2 of the Notes to Summary Consolidated Financial Statements, procurement contracts and access to the procurement of cardiac and vascular human tissues previously received by RTI. In accordance with SFAS 142, the Company performed an analysis on its non-amortizing intangible assets as of December 31, 2007. Based on the results of its analysis, the Company did not believe that an impairment existed related to its non-amortizing intangible assets as of December 31, 2007. Management will continue to evaluate the recoverability of these non-amortizing intangible assets at least on an annual basis in accordance with SFAS 142.

For the six months ended June 30, 2008 the Company did not experience any changes that would materially affect the Company's analysis of and recoverability of any of its long-lived assets.

#### **New Accounting Pronouncements**

The Company was required to adopt SFAS No. 157 Fair Value Measurements (SFAS 157) for the fiscal year beginning January 1, 2008. SFAS 157 provides a single definition of fair value and a hierarchical framework for measuring it, as well as establishing additional disclosure requirements about the use of fair value to measure assets and liabilities. The adoption of SFAS 157 did not have a material effect on the Company's results of operations or financial position.



The Company was required to adopt SFAS No. 159 The Fair Value Option for Financial Assets and Liabilities ( SFAS 159 ) for the fiscal year beginning January 1, 2008. SFAS 159 provides the option to report certain financial assets and liabilities at fair value, with the intent to mitigate volatility in financial reporting that can occur when related assets and liabilities are measured differently. The Company does not expect to voluntarily implement the optional fair value measurements portions of SFAS 159 for eligible items. The adoption of SFAS 159 did not have a material effect on the Company s results of operations or financial position.

The Company will be required to adopt SFAS No. 141R Business Combinations ( SFAS 141R ) for the fiscal year beginning January 1, 2009. FAS 141R establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. The Company does not expect the adoption of FAS 141R to have a material effect on its consolidated financial position, results of operations or cash flows.

**Results of Operations**

(Tables in thousands)

**Revenues**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Total Revenues	\$ 27,155	\$ 23,011	\$ 52,723	\$ 47,535

Revenues increased 18% for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. Revenues increased 11% for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007.

The increase in the three and six months ended June 30, 2008 was primarily due to an increase in BioGlue revenues and tissue preservation services revenues, as compared to the prior year periods.

A detailed discussion of the change in preservation services revenues for each of the three major tissue types distributed by the Company and the change in BioGlue and other implantable medical device revenues is presented below.

**Cardiac Preservation Services**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues	\$ 6,348	\$ 5,048	\$ 12,586	\$ 10,021
Cardiac revenues as a percentage of total revenues	23%	22%	24%	21%

Revenues from cardiac preservation services increased 26% for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. This increase was primarily due to volume, consisting of the aggregate impact of favorable tissue mix and a 7% increase in unit shipments of cardiac tissues, which together increased revenues by 13%, and an increase in average service fees, which increased revenues by 13%.

Revenues from cardiac preservation services increased 26% for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007. This increase was primarily due to the aggregate impact of favorable tissue mix and a 16% increase in unit shipments of cardiac tissues, which increased revenues by 15%, and an increase in average service fees, which increased revenues by 11%.

The increase in cardiac volume for the three months ended June 30, 2008 was primarily due to the favorable impact of the CryoValve SG pulmonary human heart valve ( CryoValve SG ) both due to the fact that shipments of CryoValve SG command a premium fee over standard processed pulmonary valves (favorable tissue mix) and due to the net increase in valve shipments when taking into effect shipments of the CryoValve SG and the related reduction in standard processed pulmonary valves. To a lesser extent the volume increase was due to increased shipments of non-valved cardiac tissues. The increase in cardiac volume for the six months ended June 30, 2008 was primarily due to increased shipments of non-valved cardiac tissues and to a lesser extent the favorable effect of CryoValve SG.

The favorable tissue mix from CryoValve SG was due to the February 7, 2008 FDA clearance of the Company's 510(k) premarket notification for the CryoValve SG and its subsequent reintroduction in March 2008 coupled with the premium fee charged for the CryoValve SG over the standard processed CryoValve. For the three months ended June 30, 2008, the first full quarter of distributing the CryoValve SG, CryoValve SG revenues accounted for 22% of the Company's total cardiac preservation service revenues. The increase in shipments of non-valved cardiac tissues was a result of increased availability of these high demand tissues, which are primarily used in pediatric cardiac reconstructions. The increase in average service fees for the three and six months ended June 30, 2008 was primarily due to the fee increases that went into effect in January 2008 on most standard processed cardiac tissues.

The Company's procurement of cardiac tissues, from which heart valves and non-valved cardiac tissues are processed, increased 14% for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. The Company's procurement of cardiac tissues increased 14% for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007.

The Company has experienced and could continue to experience an increase in its 2008 cardiac preservation services revenues as a result of continued shipments of the CryoValve SG, which have a premium fee over the standard processed CryoValve. However, there can be no assurance that the CryoValve SG will continue to command premium fees or that shipments of the CryoValve SG will continue to occur at material levels.

#### *Vascular Preservation Services*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues	\$ 7,080	\$ 5,428	\$ 13,939	\$ 11,567
Vascular revenues as a percentage of total revenues	26%	24%	26%	24%

Revenues from vascular preservation services increased 30% for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. This increase was primarily due to a 26% increase in unit shipments of vascular tissues, which increased revenues by 24%, and an increase in average service fees, which increased revenues by 6%.

Revenues from vascular preservation services increased 21% for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007. This increase was primarily due to a 16% increase in unit shipments of vascular tissues, which increased revenues by 16%, and an increase in average service fees, which increased revenues by 5%.

The increase in vascular volume for the three and six months ended June 30, 2008 was primarily due to increases in shipments of saphenous veins, due to the strong demand for these tissues, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations. The increase in average service fees for the three and six months ended June 30, 2008 was primarily due to the fee increases that went into effect in January 2008 on most vascular tissues.

The Company's procurement of vascular tissues increased 1% for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. The Company's procurement of vascular tissues decreased 3% for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007. The Company believes that its existing vascular tissues available for shipment and current procurement levels are sufficient to support anticipated future demand for vascular tissues.

#### *Orthopaedic Preservation Services*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues	\$ 297	\$ 1,235	\$ 624	\$ 3,084
Orthopaedic revenues as a percentage of total revenues	1%	5%	1%	6%

Revenues from orthopaedic preservation services decreased 76% for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. This decrease was primarily due to a 76% decrease in unit shipments of orthopaedic tissues, which decreased revenues by 75%.

Revenues from orthopaedic preservation services decreased 80% for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007. This decrease was primarily due to an 83% decrease in unit shipments of orthopaedic tissues, which decreased revenues by 80%.

The decrease in orthopaedic volume for the three and six months ended June 30, 2008 was primarily due to decreases in unit shipments of orthopaedic tissues, as a result of the limited supply of orthopaedic tissues available for shipment, resulting from the Company's cessation of procuring and processing these tissues on January 1, 2007 and due to declining demand for the Company's orthopaedic tissues, as the Company was no longer actively marketing its orthopaedic preservation services during these periods.

Pursuant to its agreement with RTI, CryoLife ceased marketing its orthopaedic tissue services as of June 30, 2008. For a commission, RTI can market and direct CryoLife to ship the Company's remaining orthopaedic tissues through December 31, 2008. CryoLife expects that RTI's marketing efforts will generate only nominal amounts of orthopaedic tissue service revenues for the Company in the second half of 2008.

### *BioGlue*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues	\$ 12,972	\$ 10,930	\$ 24,859	\$ 22,093
BioGlue revenues as a percentage of total revenues	48%	47%	47%	46%

Revenues from the sale of BioGlue increased 19% for the three months ended June 30, 2008 as compared to the three months ended June 30, 2007. This increase was primarily due to the aggregate impact of favorable product mix and a 7% increase in the number of BioGlue milliliters shipped, which increased revenues by 15%, an increase in average selling prices, which increased revenues by 3%, and the favorable effect of foreign exchange, which increased revenues by 1%.

Revenues from the sale of BioGlue increased 13% for the six months ended June 30, 2008 as compared to the six months ended June 30, 2007. This increase was primarily due to the aggregate impact of favorable product mix and a 2% increase in the number of BioGlue milliliters shipped, which increased revenues by 9%, an increase in average selling prices, which increased revenues by 3%, and the favorable effect of foreign exchange, which increased revenues by 1%.

The favorable product mix and volume increase for the three and six months ended June 30, 2008 was primarily due to an increase in sales of BioGlue syringes in domestic and international markets, partially offset by a related decrease in BioGlue cartridge sales, resulting in an increase in the total number of milliliters sold as well as a favorable product mix as the newer syringe product commands a premium price over the older cartridge product. The increase in average selling prices for the three and six months ended June 30, 2008 was primarily due to domestic list price increases that went into effect in January 2008.

Domestic revenues accounted for 70% of total BioGlue revenues for both the three months ended June 30, 2008 and 2007. Domestic revenues accounted for 71% and 72% of total BioGlue revenues for the six months ended June 30, 2008 and 2007, respectively.

### *Other Implantable Medical Devices*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues	\$ 308	\$ 226	\$ 401	\$ 458
Other implantable medical devices revenues as a percentage of total revenues	1%	1%	1%	1%

Revenues from the sale of other implantable medical devices increased 36% and decreased 12% for the three and six months ended June 30, 2008, respectively, as compared to the three and six months ended June 30, 2007. Other implantable medical device revenues in 2008 consisted of sales of Hemostase MPH, CardioWrap, and bioprosthetic devices. Other implantable medical device revenues in 2007 consisted of sales of CardioWrap and bioprosthetic devices.

**Other Revenues**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Revenues	\$ 150	\$ 144	\$ 314	\$ 312
Other revenues as a percentage of total revenues	1%	1%	1%	1%

Other revenues for the three months ended June 30, 2008 included revenues for research grants. Other revenues for the three months ended June 30, 2007 included revenues for research grants and revenues related to the licensing of the Company's technology to a third party.

Other revenues for the six months ended June 30, 2008 and 2007 included revenues for research grants and revenues related to the licensing of the Company's technology to a third party.

In 2005 CryoLife was awarded \$930,000 in funding allocated from the U.S. Congress 2005 Defense Appropriations Conference Report (the 2005 DOD Grant) in connection with the development of BioFoam. In 2007 CryoLife was awarded \$1.9 million in funding allocated from the 2006 Defense Appropriations Conference Report, (the 2006 DOD Grant) in connection with further development of BioFoam. Grant revenues in 2008 and 2007 are related to funding under one or both of these grants. The 2007 Defense Appropriations Conference Report (the 2007 DOD Grant) included \$848,000 for the continued development of protein hydrogel technology for use on the battlefield. CryoLife applied for funding under this bill during 2007. The Company does not currently know if it will be approved to receive funding under the 2007 DOD Grant or when the decision as to that funding will be made.

Through June 30, 2008 CryoLife had received cash payments for all funds awarded under the 2005 and 2006 DOD Grants, for a total of \$2.9 million. As of June 30, 2008 CryoLife had \$1.8 million in unspent cash advances under the grants recorded as cash and deferred revenues on the Company's Summary Consolidated Balance Sheet.

**Costs and Expenses**

**Cost of Preservation Services**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Cost of preservation services	\$ 7,449	\$ 6,976	\$ 14,767	\$ 14,608
Cost of preservation services as a percentage of preservation services revenues	54%	60%	54%	59%

Cost of preservation services for the three and six months ended June 30, 2008 increased primarily due to an increase in the volume of tissue shipments. This increase was partially offset by the favorable effect of \$234,000 and \$341,000 in write-downs recorded in the three and six months ended June 30, 2007, respectively, which did not recur in 2008, related to the Company's non-valved cardiac tissue costs that exceeded market value.

Cost of preservation services as a percentage of preservation services revenues for the three and six months ended June 30, 2008 decreased when compared to the three and six months ended June 30, 2007 primarily due to increases in average service fees, and to a lesser extent the premium related to the Company's SynerGraft processed tissues and the absence of non-valved tissue write-downs that were experienced in the three and six months ended June 30, 2007.

The Company anticipates that cost of preservation services as a percentage of preservation services revenues in 2008 may continue to be favorably impacted by shipments of the CryoValve SG, as CryoValve SG currently has and is expected to continue to have a premium fee over the standard processed CryoValve. However, there can be no assurance that the CryoValve SG will continue to command premium fees or that shipments of the CryoValve SG will continue to occur at material levels.

### *Cost of Products*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Cost of products	\$ 1,840	\$ 1,881	\$ 3,832	\$ 3,829
Cost of products as a percentage of product revenues	14%	17%	15%	17%

Cost of products for the three and six months ended June 30, 2008 was comparable to the three and six months ended June 30, 2007. Cost of products as a percentage of product revenues for the three and six months ended June 30, 2008 decreased as compared to the three and six months ended June 30, 2007.

During the three and six months ended June 30, 2008 cost of products was favorably impacted due to the effect of changes in product mix, as sales volume decreased for the higher cost bioprosthetic devices and due to slightly lower per unit BioGlue costs. During the three and six months ended June 30, 2008 cost of products was negatively impacted due to increased volume of BioGlue sales and the write-down of other implantable medical device inventory. These positive and negative impacts largely offset each other during the periods presented.

Cost of products as a percentage of product revenues for the three and six months ended June 30, 2008 decreased when compared to the three and six months ended June 30, 2007 primarily due to decreases in BioGlue costs as a percentage of revenues, as a result of an increase in average selling prices and favorable product mix, partially offset by the write-down of other implantable medical device inventory. The increase in average selling prices is primarily due to price increases that went into effect on the majority of BioGlue products in January 2008.

### *General, Administrative, and Marketing Expenses*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
General, administrative, and marketing expenses	\$ 12,358	\$ 10,842	\$ 24,425	\$ 23,177
General, administrative, and marketing expenses as a percentage of total revenues	46%	47%	46%	49%

The increase in general, administrative, and marketing expenses for the three and six months ended June 30, 2008 was primarily due to increases in marketing expenses including personnel costs, corporate advertising, and promotional materials to support the Company's expanding tissue service and product offerings and revenue growth. Additionally, there were increases in stock compensation expense over the prior year periods.

General, administrative, and marketing expenses included stock based compensation expense of \$749,000 and \$1.4 million for the three and six months ended June 30, 2008 and \$549,000 and \$923,000 for the three and six months ended June 30, 2007. General, administrative, and marketing expenses included a favorable adjustment to product liability accruals of \$610,000 and \$530,000 for the three and six months ended June 30, 2008 and \$490,000 and \$505,000 for the three and six months ended June 30, 2007. General, administrative, and marketing expenses for the six months ended June 30, 2007 included \$686,000 for postemployment benefits.

**Research and Development Expenses**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Research and development expenses	\$ 1,307	\$ 978	\$ 2,752	\$ 2,036
Research and development expenses as a percentage of total revenues	5%	4%	5%	4%

Research and development spending for the three and six months ended June 30, 2008 and 2007 included research on the Company's SynerGraft products and tissues, Protein Hydrogel Technologies ( PHT ), and tissue preservation. Research and development spending in 2008 also included research on cold storage and preservation of internal organs.

SynerGraft products and tissues include the Company's allograft and xenograft heart valves, vascular grafts, and ProPatch Soft Tissue Repair Matrix. PHT includes BioGlue, BioFoam, BioDisc®, and related products.

The Company anticipates that research and development expenses for 2008 will exceed 2007, primarily due to increased spending on research related to BioFoam, BioDisc, cold storage and preservation of internal organs, and SynerGraft products and tissues.

**Other Costs and Expenses**

Interest expense was \$69,000 for the three months ended June 30, 2008, compared to \$187,000 for the three months ended June 30, 2007. Interest expense was \$139,000 for the six months ended June 30, 2008, compared to \$340,000 for the six months ended June 30, 2007. Interest expense for the three and six months ended June 30, 2008 decreased primarily due to a decrease in line of credit borrowings as a result of the February 8, 2008 expiration and payoff of the balance due on the Company's prior credit agreement with Wells Fargo Foothill, Inc. The Company has maintained lower balances on its new line of credit with GE Capital entered into in March of 2008.

Interest income was \$71,000 for the three months ended June 30, 2008, compared to \$105,000 for the three months ended June 30, 2007. Interest income was \$193,000 for the six months ended June 30, 2008, compared to \$202,000 for the six months ended June 30, 2007. Interest income for the three and six months ended June 30, 2008 and 2007 was primarily due to interest earned on the Company's cash, cash equivalents, marketable securities and restricted cash and investments.

The change in valuation of the embedded derivative feature of the Company's preferred stock was zero for the three and six months ended June 30, 2008 as compared to an expense of \$866,000 and \$821,000 for the three and six months ended June 30, 2007. The change in valuation of the Derivative for the three and six months ended June 30, 2007 was primarily due to conversions of the Preferred Stock during the second quarter of 2007 in excess of amounts previously accrued.

The Company's income tax expense was \$260,000 and \$375,000 for the three and six months ended June 30, 2008, respectively. The Company's income tax expense was \$82,000 and \$179,000 for the three and six months ended June 30, 2007, respectively. Income tax expense in the current and prior year periods, was primarily due to estimated alternative minimum tax on the Company's taxable income in each period that cannot be offset by the Company's net operating loss carryforwards and estimated foreign taxes on income of the Company's wholly owned European subsidiary.

Although the Company has concluded that a valuation allowance is still required on its deferred tax assets, if profitable operations continue the Company may reverse all or a portion of its valuation allowance in a future period. If all or a portion of the valuation allowance is reversed, the Company will record a non-cash gain at that time that is expected to have a material impact on the Company's results of operations and financial position. In periods following the reversal, the Company's effective income tax rate is expected to be significantly higher than the effective income tax rate experienced in periods prior to the reversal.

## Seasonality

The demand for the Company's cardiac preservation services has historically been seasonal, with peak demand generally occurring in the second and third quarters. Management believes this trend for cardiac 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 cardiac tissues processed by CryoLife. In recent years the growth rate of CryoLife's cardiac business has obscured the seasonal trend, but the Company expects that this seasonal trend will be more apparent in future years.

The demand for the Company's human vascular preservation services does not appear to be seasonal.

The demand for BioGlue appears to be seasonal, with a 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 the summer holiday season in Europe and fewer surgeries being performed on adult patients in the summer months in the U.S. The Company will continue to evaluate the seasonal nature of BioGlue sales.

## Liquidity and Capital Resources

### *Net Working Capital*

At June 30, 2008 net working capital (current assets of \$67.5 million less current liabilities of \$21.3 million) was \$46.2 million, with a current ratio (current assets divided by current liabilities) of 3 to 1, compared to net working capital (current assets of \$65.5 million less current liabilities of \$24.7 million) of \$40.8 million, with a current ratio (current assets divided by current liabilities) of 3 to 1 at December 31, 2007.

### *Overall Liquidity and Capital Resources*

The Company's primary cash requirements for the six months ended June 30, 2008 arose out of the reclassification of cash equivalents to long-term restricted money market funds as required under the terms of the GE Credit Agreement as discussed below, payment of the balance due under the Company's prior credit agreement which expired in February 2008, and general working capital needs, including annual payments of royalties and bonuses accrued in the prior year, capital expenditures for facilities and equipment, and funding of research and development projects. The Company funded its cash requirements primarily through its operating activities, which generated cash during the period.

In March of 2008 CryoLife entered into a credit facility with GE Capital, which provides for up to \$15 million in revolving credit for working capital, acquisitions and other corporate purposes. As of June 30, 2008 the outstanding balance under this agreement was \$315,000. As of April 15, 2008 as required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result these funds would not be available to meet the Company's liquidity needs, and as such have been recorded as the long-term asset restricted money market funds on the Company's Summary Consolidated Balance Sheet.

The Company's cash equivalents include advance funding received under the 2006 DOD Grant for the continued development of protein hydrogel technology for use on the battlefield. As of June 30, 2008 \$1.8 million of cash equivalents were recorded on the Company's Summary Consolidated Balance Sheet related to the 2006 DOD grants. These funds must be used for the specified purposes.

CryoLife is actively pursuing three key strategies designed to generate revenue and earnings growth in addition to continuing to focus on growing its business and leveraging its strengths and expertise in its core marketplaces. These three strategies are: (i) identify and evaluate acquisition opportunities of complementary product lines and companies; (ii) license Company technology to third parties for non-competing uses; and (iii) analyze and identify underperforming assets for potential sale or disposal. Management's actions related to this Board directive are ongoing and any material acquisition of complementary product lines or companies would likely require additional debt or equity financing.

The Company believes that its anticipated cash from operations, existing cash, cash equivalents, marketable securities, and borrowing availability will enable the Company to meet its operational liquidity needs for at least the next twelve months.

#### ***Product Liability Claims***

As discussed in Critical Accounting Policies above, as of June 30, 2008 the Company had a \$330,000 accrual for the pending tissue processing liability lawsuit. The timing and amount of actual future payments with respect to product and tissue processing liability claims is dependent on when and if judgments are rendered, and/or settlements are reached. Should payments 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 outstanding claims in order to minimize the potential cash payout.

As discussed in Critical Accounting Policies above, at June 30, 2008 the Company had accrued a total \$5.0 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to June 30, 2008 and had recorded a receivable of \$1.6 million representing estimated amounts to be recoverable from the Company's insurance carriers with respect to such accrued liability. Further analysis indicated that the liability could be estimated to be as high as \$10.0 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The \$5.0 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 provided by operating activities was \$2.8 million for the six months ended June 30, 2008 as compared to \$1.4 million for the six months ended June 30, 2007. The increase in cash provided by operating activities from the prior year quarter was partially due to an increase in net income generated during the period, partially offset by increases in working capital needs due to the timing of receipts and payments in the ordinary course of business.

The current year cash provided of \$2.8 million was primarily due to net income generated during the period, largely offset by the working capital needs of the Company. The Company uses the indirect method to prepare its cash flow statement, and accordingly, the operating cash flows are based on the Company's net income, which is then adjusted to remove non-cash items and for changes in operating assets and liabilities from the prior year end. For the six months ended June 30, 2008 the Company's \$6.7 million net income included non-cash items that generated favorable and unfavorable adjustments to net income. These included favorable adjustments of \$2.2 million in depreciation and amortization expense, \$1.4 million in non-cash compensation, primarily related to expense for stock options and stock awards, and \$1.1 million in write-downs for impairment of deferred preservation costs and inventory.

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, 2008 these unfavorable changes included \$6.3 million due to the increase in deferred preservation costs and inventories, \$1.8 million due to the increase in accounts receivable, and \$918,000 due to the timing difference between making cash payments and the expensing of assets, including the prepayment of insurance policy premiums.

#### ***Net Cash from Investing Activities***

Net cash used in investing activities was \$3.2 million for the six months ended June 30, 2008, as compared to \$1.7 million for the six months ended June 30, 2007. The current year cash used was primarily due to \$5.0 million in cash equivalents that was reclassified as long-term restricted money market funds as required under the terms of the GE Credit Agreement as discussed above, \$763,000 in capital expenditures and \$559,000 in purchases of marketable securities, partially offset by \$3.0 million in sales and maturities of marketable securities.

**Net Cash from Financing Activities**

Net cash used in financing activities was \$2.4 million for the six months ended June 30, 2008, as compared to net cash provided of \$1.7 million for the six months ended June 30, 2007. The current year cash used was primarily due to \$4.6 million in principal payments on debt, and \$429,000 in principal payments on notes payable, partially offset by \$1.3 million in proceeds from the financing of insurance policies, \$1.1 million in proceeds from the exercise of options and the issuance of stock, and \$428,000 in proceeds from debt issuance. The principal payments on debt were primarily due to the payoff of the balance due under the Company's prior credit agreement which expired in February 2008.

**Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of June 30, 2008 are as follows (in thousands):

	Total	Remainder of 2008	2009	2010	2011	2012	Thereafter
Operating leases	\$ 18,019	\$ 1,254	\$ 2,498	\$ 2,376	\$ 2,336	\$ 2,340	\$ 7,215
Compensation payments	3,035		1,050		993	992	
Purchase commitments	1,476	1,357	119				
Insurance premium obligations	1,445	1,445					
Royalty payments	417	417					
Line of credit	315				315		
Capital lease obligations	114	26	53	35			
Other obligations	510	391	95	10	10	4	
<b>Total contractual obligations</b>	<b>\$ 25,331</b>	<b>\$ 4,890</b>	<b>\$ 3,815</b>	<b>\$ 2,421</b>	<b>\$ 3,654</b>	<b>\$ 3,336</b>	<b>\$ 7,215</b>

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 Company's compensation payment obligations represent estimated cash payments to be made for its 2008 performance based bonus plans and estimated payments for post employment benefits for the Company's Chief Executive Officer (CEO). The timing of the post employment benefits is based on the December 2010 expiration date of the CEO's agreement. Payment of this benefit may be accelerated by a change in control or by the voluntary retirement of the CEO.

The Company's purchase commitments include obligations from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production and contractual payments for licensing computer software. The Company's insurance premium obligations represent installment payments related to payment plans and notes payable from the second quarter 2008 renewal and financing of certain of the Company's insurance policies. The Company's royalty payments are primarily related to BioGlue revenues.

The line of credit obligation results from the Company's borrowing of funds under the GE Credit Agreement. The timing of this obligation is based on the agreement's March 25, 2011 expiration date, at which time the outstanding principal balance will be due. The table above does not include interest and fees on the line of credit, as these can vary due to changes in the level of borrowings and changes in interest rates.

The Company's capital lease obligations result from the financing of certain of the Company's equipment. The Company's other obligations contain various items including payments to support research and development activities, litigation settlement obligations, and other items as appropriate.

The schedule of contractual obligations above excludes obligations for estimated product liability claims unless they are due as a result of a pending settlement agreement or other contractual obligation. The schedule does not include additional payments of up to \$1.2 million related to licensing of technology from a third party which are contingent upon the outcome of the Company's research activities. The schedule of contractual obligations does not include \$1.7 million in advance funding received under the 2006 DOD Grant for which a specific timetable of spending has not been established and for which there are no current agreements or contracts in place. The schedule of contractual obligations above excludes any estimated liability for uncertain tax positions, currently estimated to be \$2.2 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made by any taxing authorities.

From July 1, 2008 through July 25, 2008 the Company committed to orders totaling \$750,000 under a distribution agreement, which the Company expects to pay during the third quarter of 2008.

***Capital Expenditures***

Capital expenditures for the six months ended June 30, 2008 were \$763,000 compared to \$414,000 for the six months ended June 30, 2007. Planned capital expenditures for 2008 are primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment needed to support the Company's business.

### 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 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 Company's ability to increase, and methods for increasing, BioGlue and preserved tissue market penetration;

The Company's continued use of human tissue implant data;

The expected benefits of surgical adhesives and sealants;

The Company's plans to apply for further federal funding for the development of BioFoam;

The anticipated competitive advantages and potential impact on revenues of SynerGraft;

Expected increases in grant revenues;

Expectations regarding, and possible increases in the cost and retention of, future insurance coverage;

Current intentions not to pay cash dividends on our common stock;

Current intentions to retain future earnings for capital requirements;

Expectations regarding the use of net operating loss carryforwards;

Expected decreases in revenues from the distribution of orthopaedic tissue;

Expectations regarding the impact of CryoValve SG pulmonary heart valve on cost of preservation services as a percentage of preservation services revenues;

## Edgar Filing: CRYOLIFE INC - Form 10-Q

Expectations regarding capital expenditures;

Expected usage of SynerGraft technology;

Expected timing regarding availability of CryoValve SG;

Anticipated future demand for vascular tissues;

Management's beliefs that current vascular procurement levels are sufficient to support future demand;

Commercialization plans regarding ProPatch;

Potential BioGlue product line extensions;

The ability of the Company to distribute Hemostase MPH when expected;

The potential benefits of products licensed from Trophic Solutions;

Information regarding the expected SynerGraft post-clearance study;

The ability of BioGlue to minimize post-operative pain following hernia operations;

The expected outcome of lawsuits filed against the Company;

The Company's estimated future liability for existing product liability lawsuits and for product liability claims incurred but not yet reported;

The Company's competitive position, including the impact of price increases;

The receipt of governmental grants for BioFoam development;

Future increases in research and development expenses;

Competitive advantages offered by the Company's patents, trade secrets, trademarks, and technology licensing rights;

Expected impact of adoption of new accounting pronouncements;

Expected seasonality trends;

Anticipated impact of changes in interest rates and foreign currency exchange rates;

The ability to expand the Company's service and product offerings;

Those issues most likely to impact the Company's future financial performance and cash flows;

The anticipated impact of the Company's strategic plans and its ability to implement them;

The adequacy of the Company's financial resources;

The potential reversal of the valuation allowance on our deferred tax assets and subsequent changes in our effective income tax rate; 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, 2007 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 stock include concerns that:

The FDA has previously issued a recall of certain of our products and has the ability to inspect our facilities, suspend our operations, and issue a recall of our products in the future;

Key growth strategies identified as a result of our strategic review may not generate the anticipated benefits;

There are limitations on the use of our net operating loss carryforwards;

We are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product;

We are reliant on one supplier for significant components of BioGlue;

We are dependent on the availability of sufficient quantities of tissue from human donors;

Physicians have been and may continue to be reluctant to implant our preserved tissues or use our other products;

Our products and the tissues we process allegedly have caused and may in the future cause injury to patients, and we have been and may be exposed to product liability claims and additional regulatory scrutiny as a result;

We may receive a form 483 notice of observations from the FDA and we may be unable to address the concerns raised by the FDA in such form 483;

SynerGraft processed pulmonary heart valves may not continue to be accepted by the marketplace;

SynerGraft processed pulmonary heart valves must be shipped and implanted within one year or we will be required to discard them;

We may experience difficulties and delays in the manufacturing of our products or processing of our tissues

Our SynerGraft post-clearance study may not provide expected results;

Regulatory action outside of the U.S. has affected our business in the past and may also affect our business in the future;

## Edgar Filing: CRYOLIFE INC - Form 10-Q

Our failure to adequately comply with government regulations could result in loss of revenues and customers as well as additional compliance expense;

Our existing insurance policies may not be sufficient to cover our actual claims liability;

We may be unable to obtain adequate insurance at a reasonable cost, if at all;

Intense competition may affect our ability to operate profitably;

We may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and our new products and services may not achieve market acceptance;

Investments in new technologies and acquisitions of products or distribution rights may not be successful;

If we are not successful in expanding our business activities in international markets, we will not be able to pursue one of our strategies for increasing our revenues;

We are dependent on our key personnel;

Extensive government regulation may adversely affect our ability to develop and sell products and services;

Uncertainties related to patents and protection of proprietary technology may adversely affect the value of our intellectual property and, therefore, our business;

Future health care reimbursement methods and policies may affect the availability, amount, and timing of our revenues;

Rapid technological change could cause our services and products to become obsolete;

Trading prices for our securities have been, and may continue to be, volatile;

Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of CryoLife;

We are not likely to pay common stock dividends in the foreseeable future, and we may not be able to pay cash dividends on our capital stock due to legal restrictions and lack of liquidity;

We may not be able to effectively leverage our existing sales force to sell Hemostase MPH;

Surgeons may not chose to utilize Hemostase MPH;

Hemostase MPH may not perform as expected or provide all expected benefits;

Other distributors of the Hemostase MPH product may impede our ability to sell to new or existing customers;

We may not be able to maintain the required Adjusted EBITDA levels or other borrowing conditions under its credit facility;

There is no guarantee that the credit facility will provide us with sufficient resources to pursue strategic opportunities that may arise, and as a result additional financing activities may be required;

While we currently expect that our aggregate borrowing capacity under the GE Credit Agreement will equal \$15.0 million, there can be no assurance that the borrowing capacity will remain at this level; and

We expect our effective tax rate to significantly increase if we are required to reverse our valuation allowance on our deferred tax assets.

---

**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 U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents of \$11.7 million and restricted money market funds and investments of \$5.6 million and interest paid on the Company's variable rate line of credit as of June 30, 2008. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended June 30, 2008, affecting the Company's cash and cash equivalents, restricted money market funds and investments, and line of credit would not have a material impact on the Company's financial position, results of operations, or cash flows.

***Foreign Currency Exchange Rate Risk***

The Company has balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. dollar equivalent of cash or funds that the Company will receive in payment for assets or that the Company would have to pay to settle liabilities. As a result the Company could be required to record these changes as gains or losses on foreign currency translation. A 10% adverse change in foreign currency rates as compared to the rates on June 30, 2008 affecting the Company's balances denominated in foreign currencies would not have a material impact on the Company's financial position, results of operations, or cash flows.

**Item 4. Controls and Procedures.**

The Company's management, including the Company's President and Chief Executive Officer ( CEO ) and the Company's 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, 2008, the CEO and CFO have concluded that the Company's disclosure controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

During the quarter ended June 30, 2008 there were no changes in the Company's internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company's internal control over financial reporting.

**Part II - OTHER INFORMATION****Item 1. Legal Proceedings.**

There have been no material changes from the legal proceedings previously discussed in the Company's Form 10-Q for the quarter ended March 31, 2008 in response to Part II, Item 1 thereof.

**Item 1A. Risk Factors.**

The Company's most recent Form 10-K was filed February 21, 2008. 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.**

- (c) The following table provides information about purchases by the Company during the quarter ended June 30, 2008 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

## Issuer Purchases of Equity Securities

## Common Stock

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Common Shares That May Yet Be Purchased Under the Plans or Programs
04/01/08 - 04/30/08	11,510	\$ 10.12		
05/01/08 - 05/31/08	10,343	11.52		
06/01/08 - 06/30/08	1,311	11.16		
Total	23,164	\$ 10.81		

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

**Item 3. Defaults Upon Senior Securities.**

None.

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

(a) The Annual Meeting of Shareholders was held on May 1, 2008. The following table shows the results of voting:

Matter Voted Upon	Shares Voted For	Authority Withheld	Abstained	Broker Non-Votes
Election of Directors:				
Steven G. Anderson	24,197,848	874,483		
Thomas F. Ackerman	24,201,056	871,275		
James S. Benson	24,259,828	812,503		
Daniel J. Bevevino	24,266,435	805,896		
John M. Cook	24,228,576	843,755		
Ronald C. Elkins, M.D.	24,168,536	903,795		
Ronald D. McCall, Esq.	24,213,483	858,848		
Harvey Morgan	24,251,955	820,376		
Adoption of Non-Employee Directors Omnibus Stock Plan	15,988,205	1,181,384	366,648	7,536,096
Ratification of Deloitte & Touche LLP	24,791,231	150,896	130,206	

**Item 5. Other information.**

None.

**Item 6. Exhibits.**

The exhibit index can be found below.

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form 10-K for the year ended December 31, 2007.)
3.2	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.4 to the Registrant's Current Report on Form 8-K filed August 1, 2007.)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
10.1*	Agreement between CryoLife, Inc. and Medafor, Inc. dated April 18, 2008.
10.2*	CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan.

\* Filed herewith.

The Registrant has requested confidential treatment for certain portions of this Exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Edgar Filing: CRYOLIFE INC - Form 10-Q

---

- 10.3\* Form of Non-Employee Director Stock Grant Agreement pursuant to the CryoLife, Inc. 2008 Non-Employee Directors Omnibus Stock Plan.
- 31.1\* Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
- 32\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed herewith.

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)

July 31, 2008

DATE

CRYOLIFE, INC.  
(Registrant)

/s/ D. ASHLEY LEE  
D. ASHLEY LEE  
Executive Vice President,  
Chief Operating Officer, and

Chief Financial Officer

(Principal Financial and

Accounting Officer)