

CRYOLIFE INC
Form 10-Q
October 29, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2009

OR

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

For the transition period from _____ to _____

Commission file number: 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Edgar Filing: CRYOLIFE INC - Form 10-Q

Florida
(State or other jurisdiction of
incorporation or organization)

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

1655 Roberts Boulevard, NW, Kennesaw, Georgia
(Address of principal executive offices)

30144
(Zip Code)

(770) 419-3355

(Registrant's telephone number, including area code)

Not Applicable

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

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

Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

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.

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at October 23, 2009
Common Stock, \$0.01 par value per share	28,463,282 shares

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

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(Unaudited)		(Unaudited)	
Revenues:				
Preservation services	\$ 15,033	\$ 14,188	\$ 42,672	\$ 41,337
Products	12,806	12,239	39,669	37,499
Other	380	377	729	691
Total revenues	28,219	26,804	83,070	79,527
Costs of preservation services and products:				
Preservation services	8,903	7,615	24,421	22,382
Products	2,275	2,028	6,478	5,860
Total cost of preservation services and products	11,178	9,643	30,899	28,242
Gross margin	17,041	17,161	52,171	51,285
Operating expenses:				
General, administrative, and marketing	12,386	12,072	37,440	36,497
Research and development	1,461	1,186	3,854	3,938
Total operating expenses	13,847	13,258	41,294	40,435
Operating income	3,194	3,903	10,877	10,850
Interest expense	58	62	168	201
Interest income	(10)	(92)	(73)	(285)
Other expense, net	8	142	100	115
Income before income taxes	3,138	3,791	10,682	10,819
Income tax expense	1,276	235	4,369	610
Net income	\$ 1,862	\$ 3,556	\$ 6,313	\$ 10,209
Income per common share:				
Basic	\$ 0.07	\$ 0.13	\$ 0.22	\$ 0.37

Edgar Filing: CRYOLIFE INC - Form 10-Q

Diluted	\$ 0.07	\$ 0.12	\$ 0.22	\$ 0.36
Weighted average common shares outstanding:				
Basic	28,145	27,899	28,074	27,741
Diluted	28,382	28,703	28,261	28,384

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	September 30, 2009	December 31, 2008
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,046	\$ 17,201
Restricted securities		562
Receivables, net	15,293	13,999
Deferred preservation costs	36,737	34,913
Inventories	6,462	7,077
Deferred income taxes	5,322	4,896
Prepaid expenses and other current assets	2,696	1,719
Total current assets	93,556	80,367
Property and equipment, net	14,939	16,438
Patents, net	4,067	3,771
Trademarks and other intangibles, net	2,796	2,952
Deferred income taxes	12,086	16,499
Restricted money market funds	5,000	5,000
Other long-term assets	855	968
Total assets	\$ 133,299	\$ 125,995
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,848	\$ 3,270
Accrued compensation	3,312	3,850
Accrued procurement fees	3,240	4,473
Deferred income	2,559	1,592
Deferred income taxes	395	391
Accrued expenses and other current liabilities	7,214	7,421
Total current liabilities	19,568	20,997
Deferred income taxes	847	919
Line of credit	315	315
Other long-term liabilities	4,309	4,438
Total liabilities	25,039	26,669
Shareholders' equity:		
Preferred stock		
Common stock (issued shares of 29,434 in 2009 and 29,102 in 2008)	294	291
Additional paid-in capital	127,614	124,744
Retained deficit	(13,760)	(20,073)

Edgar Filing: CRYOLIFE INC - Form 10-Q

Accumulated other comprehensive loss	(50)	(80)
Treasury stock at cost (shares of 992 in 2009 and 955 in 2008)	(5,838)	(5,556)
Total shareholders equity	108,260	99,326
Total liabilities and shareholders equity	\$ 133,299	\$ 125,995

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Nine Months Ended September 30,	
	2009	2008
	(Unaudited)	
Net cash from operating activities:		
Net income	\$ 6,313	\$ 10,209
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	3,179	3,284
Write-down of deferred preservation costs and inventories	392	1,390
Deferred income taxes	3,919	111
Non-cash compensation	1,982	2,132
Other non-cash adjustments to income	154	39
Changes in operating assets and liabilities:		
Trade and other receivables	(1,428)	(1,537)
Income taxes	3	194
Deferred preservation costs and inventories	(1,601)	(8,988)
Prepaid expenses and other assets	(899)	(732)
Accounts payable, accrued expenses and other liabilities	(1,857)	567
Net cash flows provided by operating activities	10,157	6,669
Net cash from investing activities:		
Capital expenditures	(1,341)	(1,417)
Restricted money market funds, long-term		(5,000)
Purchases of marketable securities	(564)	(1,118)
Sales and maturities of marketable securities	1,130	3,565
Other	(542)	48
Net cash flows used in investing activities	(1,317)	(3,922)
Net cash from financing activities:		
Proceeds from debt issuance		428
Principal payments of debt		(4,582)
Proceeds from financing of insurance policies	1,272	1,300
Principal payments on capital leases and short-term notes payable	(886)	(897)
Proceeds from exercise of stock options and issuance of common stock	891	1,839
Purchase of treasury stock	(282)	(315)
Net cash flows provided by (used in) financing activities	995	(2,227)
Increase in cash and cash equivalents	9,835	520
Effect of exchange rate changes on cash	10	(2)
Cash and cash equivalents, beginning of period	17,201	14,460
Cash and cash equivalents, end of period	\$ 27,046	\$ 14,978

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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, 2008 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of and for the three and nine months ended September 30, 2009 and 2008 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 (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Events subsequent to September 30, 2009 have been evaluated through October 29, 2009, the date the financial statements were issued. Operating results for the three and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. 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 year ended December 31, 2008.

2. Cash Equivalents and Marketable Securities

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

	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value
<u>September 30, 2009 (Unaudited):</u>			
Cash equivalents:			
U.S. Treasury money market funds	\$ 15,276	\$	\$ 15,276
U.S. Treasury debt securities	\$ 9,749	\$	\$ 9,749
Restricted securities:			
Money market funds, long-term	\$ 5,000	\$	\$ 5,000
<u>December 31, 2008:</u>			
Cash equivalents:			
Money market funds	\$ 14,372	\$	\$ 14,372
Restricted securities:			
Government entity sponsored debt securities	\$ 562	\$	\$ 562
Money market funds, long-term	\$ 5,000	\$	\$ 5,000

There were no gross realized gains or losses on sales of securities for the three and nine months ended September 30, 2009 and 2008. As of September 30, 2009 all of the Company's restricted securities had a maturity date within 90 days. As of December 31, 2008 all of the Company's restricted securities had a maturity date between 90 days and one year.

3. Inventories

Inventories are comprised of the following (in thousands):

September 30, 2009	December 31, 2008
-----------------------	----------------------

Edgar Filing: CRYOLIFE INC - Form 10-Q

Raw materials	\$	4,147	\$	4,418
Work-in-process		440		616
Finished goods		1,875		2,043
Total inventories	\$	6,462	\$	7,077

4. 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 tissue processing and product liability claims, and operating losses.

The Company periodically assesses the recoverability of its deferred tax assets, 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 against its deferred tax assets when, as a result of this analysis, management believes it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company assessed the recoverability of its deferred tax assets and the appropriate level of its valuation allowance as of December 31, 2008. In conducting this assessment, management considered a variety of factors, including the Company's operating profits for the years ended December 31, 2008 and 2007, the reasons for the Company's operating losses in prior years, management's judgment as to the likelihood of continued profitability and expectations of future performance, as well as other factors. Based on this analysis, as of December 31, 2008 the Company determined that maintaining a full valuation allowance on its deferred tax assets was no longer appropriate.

As a result, on December 31, 2008 the Company recorded a tax benefit of \$20.1 million to reverse substantially all of the valuation allowance on its deferred tax assets and continued to maintain valuation allowances of \$2.8 million on a portion of its deferred tax assets, primarily related to state tax net operating loss carryforwards that the Company does not believe it will be able to utilize based on its projections of profitability in certain states and state carryforward rules and limitations. In future periods, the Company will assess the recoverability of its deferred tax assets as necessary when the Company experiences changes that could materially affect its prior determination of the recoverability of its deferred tax assets.

During the nine months ended September 30, 2009, the Company reversed approximately \$63,000 in valuation allowances related to tax credits that were previously expected to expire unused. The Company did not experience any other changes that caused it to reassess the recoverability of its deferred tax assets during the nine months ended September 30, 2009. As of September 30, 2009 the Company had a net deferred tax asset of \$16.2 million, including a total of \$2.7 million in valuation allowances against deferred tax assets, primarily related to state net operating loss carryforwards.

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 2005 through 2008 remain open to examination by the major taxing jurisdictions to which the Company is subject.

5. Debt

On March 26, 2008 CryoLife 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. In the second quarter of 2009, as requested by the German courts, the Company obtained a letter of credit relating to the Company's patent infringement legal proceeding against Tenaxis, Inc. in Germany, which reduced the aggregate borrowing capacity to \$14.8 million. While the Company currently expects that its aggregate borrowing capacity under the GE Credit Agreement will remain at \$14.8 million, there can be no assurance that the borrowing capacity will remain at this level. Also, if the current global financial and credit market difficulties continue, GE Capital may be unable or unwilling to lend money pursuant to this agreement.

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 minimum earnings subject to defined adjustments as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. Further, since 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 Sheets, as they are restricted for the term of the GE Credit Agreement. 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 September 30, 2009 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 September 30, 2009 the outstanding balance of the GE Credit Agreement was \$315,000, the aggregate interest rate was 5.50%, and the remaining availability was \$14.5 million. As of December 31, 2008 the outstanding balance of the GE Credit Agreement was \$315,000, the aggregate interest rate was 5.50%, 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 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.

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In April 2009 the Company entered into an agreement to finance approximately \$1.3 million in insurance premiums at a 3.695% annual interest rate, which is payable in equal monthly payments over a nine month period. In April 2008 the Company entered into an agreement to finance approximately \$1.3 million in insurance premiums at a 4.632% annual interest rate, which was payable in equal monthly payments over a nine month period. As of September 30, 2009 and December 31, 2008 the aggregate outstanding balances under these agreements were \$428,000 and zero, respectively.

6. Comprehensive Income

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income	\$ 1,862	\$ 3,556	\$ 6,313	\$ 10,209
Change in unrealized loss on investments				(3)
Translation adjustment	(16)	(31)	30	(19)
Comprehensive income	\$ 1,846	\$ 3,525	\$ 6,343	\$ 10,187

The tax effect on the change in unrealized loss on investments and the translation adjustment is zero for each period presented. The accumulated other comprehensive loss of \$50,000 and \$80,000 as of September 30, 2009 and December, 31, 2008, respectively, consisted solely of currency translation adjustments.

7. 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
<u>Basic income per common share:</u>				
Net income	\$ 1,862	\$ 3,556	\$ 6,313	\$ 10,209
Basic weighted-average common shares outstanding	28,145	27,899	28,074	27,741

Edgar Filing: CRYOLIFE INC - Form 10-Q

Basic income per common share	\$ 0.07	\$ 0.13	\$ 0.22	\$ 0.37
-------------------------------	---------	---------	---------	---------

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
<i>Diluted income per common share:</i>				
Net income	\$ 1,862	\$ 3,556	\$ 6,313	\$ 10,209
Basic weighted-average common shares outstanding	28,145	27,899	28,074	27,741
Effect of dilutive stock options	143	697	108	557
Effect of dilutive restricted stock awards	94	73	79	56
Effect of contingent stock awards ^a		34		30
Diluted weighted-average common shares outstanding	28,382	28,703	28,261	28,384
Diluted income per common share	\$ 0.07	\$ 0.12	\$ 0.22	\$ 0.36

^a Contingent stock awards in 2008 included shares that were expected to be issued pursuant to performance-based bonus plans that were approved by the Compensation Committee of the Company's Board of Directors. No contingent stock awards are expected to be issued in 2009 due to the current intent of the Company's Board of Directors to pay 2009 performance-based bonuses in cash.

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, and restricted stock awards.

8. Stock Compensation

Overview

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of restricted stock awards 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.

Stock Awards

During the nine months ended September 30, 2009 the Compensation Committee of the Company's Board of Directors authorized awards of stock from approved stock incentive plans to non-employee Directors and certain Company executives and officers totaling 160,000 shares of common stock, which had an aggregate value of \$1.1 million.

During the nine months ended September 30, 2008 the Compensation Committee of the Company's Board of Directors authorized awards of stock from approved stock incentive plans to non-employee Directors and certain Company executives, officers, and managers totaling 183,000 shares of common stock, which had an aggregate value of \$1.8 million. These stock awards included 81,000 shares of common stock valued at \$786,000 issued as part of the 2007 performance-based bonus plans for certain Company executives, officers, and managers. The Company recorded the expense related to the 2007 performance-based bonus plans during the year ended December 31, 2007.

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 438,000 and 403,000 shares during the nine months ended September 30, 2009 and 2008, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Employees purchased common stock totaling 58,000 and 38,000 shares during the nine months ended September 30, 2009 and 2008, respectively, through the Company's ESPP.

Stock Compensation Expense

Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company uses a Black-Scholes model to value its stock option grants and expenses the related compensation cost using the straight-line method over the vesting period. 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. Stock awards and stock options are valued based on

the stock price as of each grant date and are recorded as an expense on the Company's Summary Consolidated Statements of Operations over the respective vesting periods. The fair value of the Company's ESPP options is also determined using a Black-Scholes model and is expensed over the three month vesting period.

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

	Three Months Ended September 30, 2009		Nine Months Ended September 30, 2009	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	.25 Years	4.0 Years	.25 Years
Expected stock price volatility	N/A	.79	.65	.80
Risk-free interest rate	N/A	.17%	1.51%	.15%

	Three Months Ended September 30, 2008		Nine Months Ended September 30, 2008	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	3.5 Years	.25 Years	3.5 Years	.25 Years
Expected stock price volatility	.60	.57	.60	.61
Risk-free interest rate	2.72%	1.87%	2.34%	2.25%

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

	Three Months Ended September 30, 2009		Nine Months Ended September 30, 2008	
	2009	2008	2009	2008
Stock award expense	\$ 224	\$ 438	\$ 675	\$ 1,277
Stock option expense	383	260	1,307	855
Total stock compensation expense	\$ 607	\$ 698	\$ 1,982	\$ 2,132

Included in this total stock compensation expense were expenses related to common stock awards and stock options issued in the current year as well as those issued in prior years that continue to vest during the period, and compensation expense 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 \$66,000 and \$39,000 in the three months ended September 30, 2009 and 2008, respectively, and \$187,000 and \$88,000 in the nine months ended September 30, 2009 and 2008, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

As of September 30, 2009 the Company had a total of \$1.2 million in total unrecognized compensation costs related to unvested stock awards, before considering the effect of expected forfeitures. As of September 30, 2009 this expense is expected to be recognized over a weighted average period of 1.4 years. As of September 30, 2009 there was approximately \$2.0 million in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of September 30, 2009 this expense is expected to be recognized over a weighted average period of 1.7 years.

9. Segment Information

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

The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues and from shipments of previously preserved orthopaedic tissues. The Medical Devices segment includes external revenues from product sales of BioGlue® Surgical Adhesive (BioGlue) and related products, and HemoStase , as well as sales of other medical devices. BioGlue related products include BioFam Surgical Matrix, and BIOGLUE *Aesthetic* Medical Adhesive. There are no intersegment revenues.

Edgar Filing: CRYOLIFE INC - Form 10-Q

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.

Edgar Filing: CRYOLIFE INC - Form 10-Q

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		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Revenues:				
Preservation services	\$ 15,033	\$ 14,188	\$ 42,672	\$ 41,337
Medical devices	12,806	12,239	39,669	37,499
Other ^a	380	377	729	691
	28,219	26,804	83,070	79,527
Costs of preservation services and products:				
Preservation services	8,903	7,615	24,421	22,382
Medical devices	2,275	2,028	6,478	5,860
	11,178	9,643	30,899	28,242
Gross margin:				
Preservation services	6,130	6,573	18,251	18,955
Medical devices	10,531	10,211	33,191	31,639
Other ^a	380	377	729	691
	\$ 17,041	\$ 17,161	\$ 52,171	\$ 51,285

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

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Preservation services:				
Cardiac tissue	\$ 7,315	\$ 7,034	\$ 19,377	\$ 19,620
Vascular tissue	7,699	7,116	23,147	21,055
Orthopaedic tissue	19	38	148	662
Total preservation services	15,033	14,188	42,672	41,337
Products:				
BioGlue and related products	11,180	11,623	35,323	36,482
HemoStase	1,562	549	4,139	726
Other medical devices	64	67	207	291
Total products	12,806	12,239	39,669	37,499
Other ^a	380	377	729	691
Total revenues	\$ 28,219	\$ 26,804	\$ 83,070	\$ 79,527

^a For the three and nine months ended September 30, 2009 and the three months ended September 30, 2008, the Other designation includes grant revenue. For the nine months ended September 30, 2008, the Other designation includes 1) grant revenue and 2) revenues related to the licensing of the Company's technology to a third party.

10. Commitments and Contingencies

Liability Claims

In the normal course of business we are made aware of adverse events involving our tissue and products. Any adverse event could ultimately give rise to a lawsuit against us. In addition tissue processing and liability claims may be asserted against us in the future based on events we are not aware of at the present time. As of October 23, 2009 there were no pending tissue processing or product liability lawsuits filed against the Company.

On April 1, 2009 the Company bound liability coverage for the 2009/2010 insurance policy year. This policy is a seven-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2010 and reported during the period April 1, 2009 through March 31, 2010 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 uninsured.

The Company maintains claims-made insurance policies to mitigate its financial exposure to tissue processing and product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period.

The Company estimated that its liability for unreported tissue processing and product liability claims was \$3.9 million as of September 30, 2009. The \$3.9 million balance is included as a component of accrued expenses of \$1.9 million and other long-term liabilities of \$2.0 million on the September 30, 2009 Summary Consolidated Balance Sheet. Further analysis indicated that the liability could be estimated to be as high as \$8.5 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The Company estimated that as of September 30, 2009, \$1.4 million of the accrual for unreported liability claims would be recoverable under the Company's insurance policies. The \$1.4 million insurance recoverable is included as a component of receivables of \$700,000 and other long-term assets of \$700,000 on the September 30, 2009 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 September 30, 2009. Actual results may differ from this estimate.

The Company believes that the assumptions it uses to determine its unreported loss liability provide a reasonable basis for its calculation. However, the accuracy of the 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.

As of December 31, 2008 the Company accrued \$4.4 million for unreported tissue processing and product liability claims and recorded a receivable of \$1.5 million for unreported liability claims estimated to be recoverable under the Company's insurance policies. This \$4.4 million accrual was included as a component of accrued expenses and other current liabilities of \$2.2 million and other long-term liabilities of \$2.2 million on the December 31, 2008 Summary Consolidated Balance Sheet. The \$1.5 million insurance recoverable was included as a component of receivables of \$700,000 and other long-term assets of \$800,000 on the December 31, 2008 Summary Consolidated Balance Sheet.

11. New Accounting Pronouncements

The Company was required to adopt new accounting guidance related to business combinations on January 1, 2009. The new guidance 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 adoption of the new guidance did not have an effect on the financial position, profitability, or cash flows of the Company, but will affect the accounting for any future business combination.

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), incorporated in 1984 in Florida, preserves and distributes human tissues for cardiac and vascular transplant applications and develops and commercializes medical devices. The human tissue distributed by the Company includes the CryoValve[®] SG pulmonary heart valve and the CryoPatch[®] SG pulmonary cardiac patch (CryoPatch SG), both processed using CryoLife's proprietary SynerGraft[®] technology. The Company's medical devices include BioGlue[®] Surgical Adhesive (BioGlue), BioFoam[®] Surgical Matrix (BioFoam), BIOGLUE *Aesthetic* Medical Adhesive (BioGlue Aesthetic), and HemoStase, which the Company distributes for a third party, as well as other medical devices.

During the third quarter of 2009 CryoLife announced a new regulatory clearance and a new approval, further expanding the Company's service and product offerings. The Company received FDA 510(k) clearance for its CryoPatch SG. This clearance represents an extension of the line of tissues processed with the Company's proprietary SynerGraft technology. The Company also received CE Mark approval for BioFoam Surgical Matrix for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen). This approval represents the extension of the Company's successful BioGlue line of products. The Company also announced the first clinical usage of the CryoPatch SG and BioFoam during the quarter.

During the third quarter of 2009 CryoLife received a Humanitarian Use Device (HUD) designation from the Food and Drug Administration (FDA) for its CryoValve SG aortic heart valve. The HUD designation is the first step in obtaining a Humanitarian Device Exemption (HDE), which would allow the Company to market the CryoValve SG aortic heart valve in the U.S. An HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 4,000 individuals in the U.S. per year, provided that no comparable device with the same intended use is marketed with other FDA approvals. The CryoValve SG aortic heart valve is intended to be used for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic aortic valves in children from 0 to 21 years of age. The Company estimates that up to 1,500 children per year could benefit from this technology if the Company is successful in obtaining an HDE.

Also during the third quarter of 2009 CryoLife held its second annual Ross Summit, a two-day physician training conference hosted at the Company's corporate headquarters dedicated to education pertaining to the Ross Procedure. The Ross Procedure is a type of specialized aortic valve surgery in which the patient's diseased aortic valve is replaced with his or her own pulmonary valve. The pulmonary valve can then be replaced with a cryopreserved human pulmonary valve. The 2009 Ross Summit had a faculty of more than 30 world-renowned cardiovascular surgeons and cardiologists, who presented clinical data on heart reconstruction surgery at their respective clinics. The summit included two sessions of hands-on instruction in the various techniques of cardiac reconstruction and was attended by cardiac surgeons from around the world.

In the third quarter of 2009 CryoLife's revenues were \$28.2 million, a new quarterly record, increasing 5% over the prior year quarter. On a sequential quarter basis, revenues from the distribution of cardiac tissues showed a strong quarter over quarter increase, increasing 13% over the second quarter of 2009 and HemoStase revenues increased 6% from the second quarter of 2009, while BioGlue and related product revenues decreased 10% from the second quarter of 2009. See the Results of Operations section below for additional analysis of the third quarter 2009 results.

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 year ended December 31, 2008. 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 Company did not experience any significant changes during the quarter ended September 30, 2009 in its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2008.

New Accounting Pronouncements

The Company was required to adopt new accounting guidance related to business combinations on January 1, 2009. The new guidance 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 adoption of the new guidance did not have an effect on the financial position, profitability, or cash flows of the Company, but will affect the accounting for any future business combination.

Results of Operations

(Tables in thousands)

Revenues

	Revenues for the Three Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Three Months Ended September 30,	
	2009	2008	2009	2008
Preservation services:				
Cardiac tissue	\$ 7,315	\$ 7,034	26%	26%
Vascular tissue	7,699	7,116	27%	27%
Orthopaedic tissue	19	38	%	%
Total preservation services	15,033	14,188	53%	53%
Products:				
BioGlue and related products	11,180	11,623	40%	43%
HemoStase	1,562	549	6%	2%
Other medical devices	64	67	%	1%
Total products	12,806	12,239	46%	46%
Other	380	377	1%	1%
Total	\$ 28,219	\$ 26,804	100%	100%

	Revenues for the Nine Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2009	2008	2009	2008
Preservation services:				
Cardiac tissue	\$ 19,377	\$ 19,620	23%	25%
Vascular tissue	23,147	21,055	28%	26%
Orthopaedic tissue	148	662	%	1%
Total preservation services	42,672	41,337	51%	52%
Products:				

Edgar Filing: CRYOLIFE INC - Form 10-Q

BioGlue and related products	35,323	36,482	43%	46%
HemoStase	4,139	726	5%	1%
Other medical devices	207	291	%	%
Total products	39,669	37,499	48%	47%
Other	729	691	1%	1%
Total	\$ 83,070	\$ 79,527	100%	100%

Revenues increased 5% for the three months and 4% for the nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. A detailed discussion of the changes in preservation services revenues, product revenues, and other revenues for the three and nine months ended September 30, 2009 is presented below.

Preservation Services

Revenues from preservation services increased 6% for the three months and 3% for the nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. This increase was primarily due to an

increase in vascular preservation services revenues. See further discussions of cardiac and vascular preservation services revenues below.

Cardiac Preservation Services

Revenues from cardiac preservation services increased 4% for the three months ended September 30, 2009 as compared to the three months ended September 30, 2008. This increase was primarily due to the aggregate impact of volume and tissue mix, which together increased revenues by 5%, partially offset by a decrease in average service fees, which decreased revenues by 1%.

Revenues from cardiac preservation services decreased 1% for the nine months ended September 30, 2009 as compared to the nine months ended September 30, 2008. This decrease was primarily due to the aggregate impact of volume and tissue mix, which decreased revenues by 1%.

The Company's cardiac revenues consist of revenues from valved cardiac tissues, non-valved cardiac tissues, and minimally processed tissues that are distributed to a third party tissue processor.

The 5% increase in revenues from the net effect of volume and tissue mix for the three months ended September 30, 2009 was primarily due to a 7% increase in shipments of valved and non-valved cardiac tissues. The revenue increase was primarily in non-valved conduits, aortic valves, CryoValve SG pulmonary heart valves, and CryoPatch SG. These increases were partially offset by a decrease in shipments of standard processed pulmonary valves. The Company believes that the increase in shipments of cardiac tissues in the three months ended September 30, 2009 was due to the Company's physician training efforts, including the Ross Summit and monthly Aortic Allograft Workshops, which have resulted in additional physicians implanting the Company's tissues, and the efforts of the Company's new cardiac tissue focused sales force, the cardiac specialist program, which was implemented throughout the second half of 2008 and the beginning of 2009.

The 1% decrease in revenues from the net effect of volume and tissue mix for the nine months ended September 30, 2009 was primarily due to a 4% decrease in shipments of valved and non-valved cardiac tissues. The revenue decrease was primarily in standard processed pulmonary valves, and to a lesser extent, non-valved conduits. These decreases were largely offset by increases in CryoValve SG pulmonary heart valves, and to a lesser extent, aortic valves and CryoPatch SG. The Company believes that this decrease was primarily due to the first quarter impact of hospitals decreasing the number of valved cardiac tissues they keep on hand for urgent procedures as a result of the current economic conditions and their constraining effect on hospital budgets, largely offset by increases in second and third quarter tissue shipments.

The Company's procurement of cardiac tissues decreased 15% for both the three and nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. As a part of the normal course of business, CryoLife routinely adjusts its criteria for accepting incoming tissue based on certain variables. These variables include changes in demand for certain types of tissues processed by the Company, the level of tissues currently available for shipment, changes in incoming tissue availability, and the likelihood that certain tissues will pass the Company's quality controls and testing processes. The decrease in cardiac procurement for the three and nine months ended September 30, 2009 was primarily the result of changes in tissue acceptance criteria made during 2009 and 2008. The Company believes that cardiac procurement will continue at a lower level in the fourth quarter of 2009 comparable to the third quarter of 2009. The Company may continue to make changes in incoming tissue acceptance criteria, and as a result, the Company's level of procurement may continue to vary from quarter-to-quarter and year-to-year. The Company believes that its existing cardiac tissues available for shipment and current procurement levels are sufficient to support anticipated future demand for cardiac tissues for the reasonably foreseeable future.

Although cardiac tissue shipments increased for the three months ended September 30, 2009 as compared to the prior year period, the Company's cardiac tissue shipments may be negatively impacted by current economic conditions and their constraining effect on hospital budgets in the fourth quarter of 2009, and into 2010.

Vascular Preservation Services

Revenues from vascular preservation services increased 8% for the three months ended September 30, 2009 as compared to the three months ended September 30, 2008, primarily due to an 8% increase in unit shipments of vascular tissues. Revenues from vascular preservation services increased 10% for the nine months ended September 30, 2009 as compared to the nine months ended September 30, 2008, primarily due to a 10% increase in unit shipments of vascular tissues.

The increase in vascular volume for the three months ended September 30, 2009 was primarily due to increases in shipments of femoral veins and aortoiliac grafts. The increase in vascular volume for the nine months ended September 30, 2009 was due to increases in shipments of each of the types of vascular tissues processed by the Company.

The Company's procurement of vascular tissues decreased 21% for both the three and nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. As a part of the normal course of business, CryoLife routinely adjusts its criteria for accepting incoming tissue based on certain variables. These variables include changes in demand for certain types of tissues processed by the Company, the level of tissues currently available for shipment, changes in incoming tissue availability, and the likelihood that certain tissues will pass the Company's quality controls and testing processes. The decrease in vascular procurement for the three and nine months ended September 30, 2009 was primarily the result of changes in tissue acceptance criteria made during 2009 and 2008. The Company believes that vascular procurement will continue at a lower level in the fourth quarter of 2009 comparable to the third quarter of 2009. The Company may continue to make changes in incoming tissue acceptance criteria, and as a result, the Company's level of procurement may continue to vary from quarter-to-quarter and year-to-year. 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 for the reasonably foreseeable future.

Products

Revenues from products increased 5% for the three months and 6% for the nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. This increase was primarily due to an increase in HemoStase revenues, partially offset by a decrease in revenues of BioGlue and related products. See further discussions of BioGlue and related products and HemoStase revenues below.

BioGlue and Related Products

Revenues from the sale of BioGlue and related products decreased 4% for the three months ended September 30, 2009 as compared to the three months ended September 30, 2008. This decrease was primarily due to a 5% decrease in the volume of milliliters sold, which decreased revenues by 7%, and the unfavorable impact of foreign exchange, which reduced revenues by 1%, partially offset by an increase in average selling prices, which increased revenues by 4%.

Revenues from the sale of BioGlue and related products decreased 3% for the nine months ended September 30, 2009 as compared to the nine months ended September 30, 2008. This decrease was primarily due to a 3% decrease in the volume of milliliters sold, which decreased revenues by 5%, and the unfavorable impact of foreign exchange, which reduced revenues by 2%, partially offset by an increase in average selling prices, which increased revenues by 4%.

The decrease in sales volume for BioGlue and related products for the three and nine months ended September 30, 2009 was primarily due to a decrease in shipments of BioGlue in domestic markets, as a result of the current economic conditions and their constraining effect on hospital budgets. Management believes that hospitals are attempting to control costs by reducing spending on items, such as BioGlue, that are consumed during surgical procedures. Sales of BioGlue and related products for the three and nine months ended September 30, 2009 included international sales of BioFoam Surgical Matrix following receipt of the CE Mark approval during the third quarter of 2009.

The unfavorable impact of foreign exchange for the three and nine months ended September 30, 2009 was due to changes in the exchange rates between the U.S. Dollar and both the British Pound and the Euro in the three and nine months ended September 30, 2009 as compared to the respective periods in 2008. The Company's sales of BioGlue and related products through its direct sales force to United Kingdom hospitals are denominated in British Pounds and its sales to German hospitals and certain distributors are denominated in Euros.

The increase in average selling prices for the three and nine months ended September 30, 2009 was primarily due to list price increases on certain BioGlue products that went into effect during 2009 and the negotiation of pricing contracts with certain customers.

Domestic revenues accounted for 70% of total BioGlue revenues in both the three months ended September 30, 2009 and 2008. Domestic revenues accounted for 70% and 71% of total BioGlue revenues in the nine months ended September 30, 2009 and 2008, respectively.

The Company believes that domestic hospital cost cutting practices are likely to continue in the fourth quarter of 2009, and into 2010. Should these attempts to control costs continue or accelerate, BioGlue revenues could be materially adversely affected.

HemoStase

Revenues from the sale of HemoStase increased 185% for the three months and 470% for the nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. HemoStase revenues for the three

and nine months ended September 30, 2009 increased in both domestic and international markets. CryoLife began marketing and distribution of HemoStase under a multinational distribution agreement with Medafor, Inc. (Medafor) in the second quarter of 2008.

The Company believes that HemoStase revenues will increase in the fourth quarter of 2009 as compared to the fourth quarter of 2008, as this product is in an early growth phase associated with the recent launch of distribution efforts for this product. Revenues from HemoStase could be materially adversely impacted by the Company's lawsuit with Medafor or any future attempts by Medafor to terminate the Company's distribution agreement. See Part II, Item 1, Legal Proceedings.

Other Revenues

Other revenues for the three and nine months ended September 30, 2009 and the three months ended September 30, 2008 included revenues from research grants. Other revenues for the nine months ended September 30, 2008 included revenues from research grants and revenues related to the licensing of the Company's technology to a third party.

As of September 30, 2009 CryoLife has been awarded a total of \$5.4 million in funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the (DOD Grants), which includes \$1.7 million awarded in March of 2009. The DOD Grants were awarded to CryoLife for the development of protein hydrogel technology, which the Company is currently developing for use in organ sealing. Grant revenues in 2009 and 2008 are related to funding under the DOD Grants.

Through September 30, 2009 CryoLife has received cash payments totaling \$5.0 million for the DOD Grants and expects to receive the remaining \$424,000 in cash payments in the fourth quarter of 2009. The Company had \$2.6 million remaining in unspent cash advances recorded as cash and cash equivalents and deferred income on the Company's Summary Consolidated Balance Sheet as of September 30, 2009.

Cost of Preservation Services and Products

Cost of Preservation Services

	Three Months Ended September 30, 2009		Nine Months Ended September 30, 2008	
Cost of preservation services	\$ 8,903	\$ 7,615	\$ 24,421	\$ 22,382
Cost of preservation services as a percentage of preservation services revenues	59%	54%	57%	54%

Cost of preservation services increased 17% for the three months and 9% for the nine months ended September 30, 2009, as compared to the three and nine months ended September 30, 2008, respectively.

The increase in cost of preservation services in the three months ended September 30, 2009 was primarily due to an increase in the per unit costs of processing tissues and an increase in cardiac and vascular tissues shipped, as discussed above. The increase in cost of preservation services in the nine months ended September 30, 2009 was primarily due to an increase in the per unit costs of processing tissues, largely as a result of decreased processing and packaging throughput, and to a lesser extent, an increase in vascular tissues shipped, as discussed above.

The increase in cost of preservation services as a percentage of preservation services revenues for the three and nine months ended September 30, 2009 was primarily due to the increase in the per unit costs of processing tissues, and to a lesser extent, a decrease in average service fees due to pricing pressures. The Company expects this higher cost of preservation services as a percentage of preservation services revenues to continue in the fourth quarter of 2009, and into 2010.

Cost of Products

	Three Months Ended September 30, 2009		Nine Months Ended September 30, 2008	
Cost of products	\$ 2,275	\$ 2,028	\$ 6,478	\$ 5,860

Cost of products as a percentage of product revenues	18%	17%	16%	16%
--	-----	-----	-----	-----

Cost of products increased 12% for the three months and 11% for the nine months ended September 30, 2009, as compared to the three and nine months ended September 30, 2008, respectively.

The increase in cost of products in the three and nine months ended September 30, 2009 was primarily due to the increase in shipments of HemoStase, which the Company began distributing in the second quarter of 2008. To a lesser extent, the increase in cost of products was due to a slight increase in the per unit cost of BioGlue, largely offset by a decrease in the per unit cost of HemoStase. The per unit cost of HemoStase decreased due to increased distribution of HemoStase internationally, as international product has a reduced cost. Cost of products for the three and nine months ended September 30, 2008 was negatively impacted by the write-down of \$281,000 and \$1.2 million, respectively, in other medical device inventory.

Cost of products as a percentage of product revenues for the three and nine months ended September 30, 2009 was comparable to the three and nine months ended September 30, 2008, respectively.

The Company expects that cost of products and cost of products as a percentage of product revenues will continue to be impacted by an increased volume of HemoStase revenues in the fourth quarter of 2009 when compared to the prior year period.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
General, administrative, and marketing expenses	\$ 12,386	\$ 12,072	\$ 37,440	\$ 36,497
General, administrative, and marketing expenses as a percentage of total revenues	44%	45%	45%	46%

General, administrative, and marketing expenses increased 3% for both the three and nine months ended September 30, 2009, as compared to the three and nine months ended September 30, 2008.

The increase in general, administrative, and marketing expenses for the three months ended September 30, 2009 was primarily due to the marketing expenses for the 2009 Ross Summit, which took place in the third quarter of 2009 as comparable marketing expenses for the 2008 Ross Summit were included in the fourth quarter of 2008. The increase in general, administrative, and marketing expenses for the nine months ended September 30, 2009 was primarily due to increases in marketing expenses, including spending related to the 2009 Ross Summit, increased personnel costs, partially related to an increase in sales force, and other marketing expenses to support current revenue growth and the Company's efforts to increase its preservation service and product offerings.

The Company's expenses related to the grant of stock options and restricted stock awards were \$468,000 and \$532,000 for the three months ended September 30, 2009 and 2008, respectively, and \$1.6 million and \$1.8 million for the nine months ended September 30, 2009 and 2008, respectively. The Company's general, administrative, and marketing expenses included a benefit for the reduction in tissue processing and product liability accruals of \$405,000 and \$449,000 for the nine months ended September 30, 2009 and 2008, respectively.

The Company has begun and continues to undertake initiatives to evaluate its manufacturing costs and general, administrative, and marketing expenses in an attempt to increase efficiencies and reduce costs. The Company expects to implement a portion of these initiatives in the fourth quarter of 2009.

Research and Development Expenses

	Three Months Ended		Nine Months Ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Research and development expenses	\$ 1,461	\$ 1,186	\$ 3,854	\$ 3,938

Edgar Filing: CRYOLIFE INC - Form 10-Q

Research and development expenses as a percentage of total revenues	5%	4%	5%	5%
---	----	----	----	----

Research and development spending in 2009 and 2008 was primarily focused on the Company's tissue preservation, SynerGraft products and tissues, and BioGlue and related products. SynerGraft products and tissues include the Company's

CryoValve SG pulmonary and aortic heart valves, CryoPatch SG, and xenograft SynerGraft tissue products. BioGlue related products include BioGlue Aesthetic, BioFoam, and BioDisc®.

Other Income and Expenses

Interest expense was \$58,000 and \$62,000 for the three months ended September 30, 2009 and 2008, respectively, and \$168,000 and \$201,000 for the nine months ended September 30, 2009 and 2008, respectively. Interest expense for the three and nine months ended September 30, 2009 and 2008 included interest incurred related to the Company's debt as discussed in Note 5 of the Notes to Summary Consolidated Financial Statements, capital leases, and interest related to uncertain tax positions.

Interest income was \$10,000 and \$92,000 for the three months ended September 30, 2009 and 2008, respectively, and \$73,000 and \$285,000 for the nine months ended September 30, 2009 and 2008, respectively. Interest income for the three and nine months ended September 30, 2009 and 2008 was primarily due to interest earned on the Company's cash, cash equivalents, and restricted securities. The decrease in interest income in 2009 was primarily due to a decline in interest rates paid on the Company's cash and cash equivalents, partially offset by an increase in the balance in these accounts.

Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Income before income taxes	\$ 3,138	\$ 3,791	\$ 10,682	\$ 10,819
Income tax expense	1,276	235	4,369	610
Net income	\$ 1,862	\$ 3,556	\$ 6,313	\$ 10,209
Diluted income per common share	\$ 0.07	\$ 0.12	\$ 0.22	\$ 0.36

Income before income taxes decreased 17% for the three months and 1% for the nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. Income before income taxes for the three months ended September 30, 2009 decreased primarily due to the factors discussed above.

Income tax expense during 2009 was recorded at the Company's estimated combined federal, state, and foreign effective tax rate of 41%. The Company did not record income tax expense based on its effective tax rate in the first nine months of 2008 due to the valuation allowance on the Company's deferred tax assets during that time. Income tax expense during the first nine months of 2008 was primarily related to estimated alternative minimum tax on the Company's U.S. taxable income that could not be offset by the Company's net operating loss carryforwards and estimated foreign taxes on income of the Company's wholly owned European subsidiary.

As in the first nine months of 2009, the Company's income tax expense is expected to be significantly higher for the full year of 2009 as compared to 2008, due to the change in recording tax expenses, as discussed above, and the large tax benefit recorded by the Company in the fourth quarter of 2008 to reverse a significant portion of the valuation allowance on its deferred tax assets, which will not recur in 2009. Due to the Company's federal and state net operating loss carryforwards, the Company expects that cash paid for taxes will continue to be significantly less than the tax expense recorded during 2009.

Net income decreased 48% for the three months and 38% for the nine months ended September 30, 2009 as compared to the three and nine months ended September 30, 2008, respectively. Net income and diluted earnings per common share decreased in 2009 primarily due to the increase in income tax expense.

Seasonality

The demand for the Company's cardiac preservation services has historically been seasonal, with peak demand generally occurring in the third quarter. 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. Due to the deterioration in recent quarters in the U.S. and global economies, along with the Company's efforts to grow its cardiac business, the seasonal nature of the Company's cardiac preservation service business has been somewhat obscured.

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 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 is uncertain whether demand for HemoStase will be seasonal. As HemoStase is in a growth phase generally associated with a recently introduced product that has not fully penetrated the marketplace, the nature of any seasonal trends in HemoStase sales may be obscured.

Liquidity and Capital Resources

Net Working Capital

As of September 30, 2009 net working capital (current assets of \$93.6 million less current liabilities of \$19.6 million) was \$74.0 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of \$59.4 million, with a current ratio of 4 to 1 at December 31, 2008.

Overall Liquidity and Capital Resources

The Company's primary cash requirements for the nine months ended September 30, 2009 arose out of general working capital needs, including the annual payment of bonuses and royalties 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 \$15.0 million in revolving credit for working capital, acquisitions, and other corporate purposes, of which \$14.5 million is currently available for borrowing. If the current global financial and credit market difficulties continue, GE may be unable or unwilling to lend money pursuant to this agreement. As of September 30, 2009 the outstanding balance under this agreement was \$315,000. 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 will not be available to meet the Company's liquidity needs during the term of the GE Credit Agreement, 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 DOD Grants for the continued development of protein hydrogel technology. As of September 30, 2009 \$2.6 million of cash equivalents were recorded on the Company's Summary Consolidated Balance Sheet related to the DOD Grants. These funds must be used for the specified purposes.

The Company believes that its anticipated cash from operations, and existing cash, cash equivalents, and marketable securities will enable the Company to meet its operational liquidity needs for at least the next twelve months. The Company's future cash requirements may include cash for general working capital needs, to fund acquisitions, to purchase license agreements, and for other corporate purposes.

Liability Claims

As of September 30, 2009 the Company had accrued a total \$3.9 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to September 30, 2009 and had recorded a receivable of \$1.4 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 \$8.5 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques. The \$3.9 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 \$10.2 million for the nine months ended September 30, 2009 as compared to \$6.7 million for the nine months ended September 30, 2008. The current year cash provided was primarily due to net income generated during the period and the net effect of non-cash items, partially offset by increases in working capital needs due to the timing of receipts and payments in the ordinary course of business.

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 nine months ended September 30, 2009 these non-cash items included a favorable \$3.2 million in depreciation and amortization expense, \$3.9 million in deferred income taxes, and \$2.0 million in non-cash stock based compensation.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2009 these changes included an unfavorable \$1.4 million due to the increase in receivables, \$1.6 million due to increases in deferred preservation costs and inventory balances, for which vendors and employees have already been paid, \$899,000 due to the timing difference between making cash payments and the expensing of assets, including prepaid insurance policy premiums, and \$1.9 million due to the timing differences between the recording of accounts payable, accrued expenses, and other current liabilities and the actual payment of cash.

Net Cash from Investing Activities

Net cash used in investing activities was \$1.3 million for the nine months ended September 30, 2009, as compared to \$3.9 million for the nine months ended September 30, 2008. The current year cash used was primarily due to \$1.3 million in capital expenditures, and \$564,000 in purchases of restricted marketable securities, partially offset by \$1.1 million in sales and maturities of restricted marketable securities.

Net Cash from Financing Activities

Net cash provided by financing activities was \$995,000 for the nine months ended September 30, 2009, as compared to net cash used of \$2.2 million for the nine months ended September 30, 2008. The current year cash provided was primarily due to \$1.3 million in proceeds from the financing of insurance policies, and \$891,000 in proceeds from the exercise of options and the issuance of common stock under the Company's employee stock purchase plan, partially offset by \$886,000 in principal payments on capital leases and short-term notes payable.

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 September 30, 2009 are as follows (in thousands):

	Total	Remainder of					
		2009	2010	2011	2012	2013	Thereafter
Operating leases	\$ 14,834	\$ 638	\$ 2,438	\$ 2,391	\$ 2,332	\$ 2,353	\$ 4,682
Compensation payments	3,685		1,700	993	992		
Research obligations	2,913	717	849	756	591		
Purchase commitments	682	563	119				
Royalty payments	595		595				
Insurance premium obligations	523	523					
Line of credit	315			315			
Other obligations	474	395	66	10	3		
Total contractual obligations	\$ 24,021	\$ 2,836	\$ 5,767	\$ 4,465	\$ 3,918	\$ 2,353	\$ 4,682

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 2009 performance-based bonus plans and estimated payments for post employment benefits for the Company's Chief Executive Officer (CEO). The timing of the CEO's post employment benefits is based on the December 2010 expiration date of the CEO's employment agreement. Payment of this benefit may be accelerated by a change in control or by the voluntary retirement of the CEO.

The Company's research obligations represent commitments for ongoing studies and payments to support research and development activities, the majority of which will be funded by the advances received under the DOD Grants.

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 royalty payments are related to BioGlue revenues. The Company's insurance premium obligations represent the 2009 renewal of certain of the Company's insurance policies.

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 other obligations contain various items including capital lease obligations, estimated real and personal property tax payments, and other items as appropriate.

The schedule of contractual obligations above excludes (i) obligations for estimated tissue processing and product liability claims unless they are due as a result of a pending settlement agreement or other contractual obligation and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$1.2 million, because the Company could not 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.

Capital Expenditures

Capital expenditures for the nine months ended September 30, 2009 were \$1.3 million compared to \$1.4 million for the nine months ended September 30, 2008. Planned capital expenditures for 2009 are primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment and renovations to the Company's corporate headquarters 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 words identify forward-looking statements. 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:

- Expectations regarding our assessments and treatment of our deferred tax assets, including the recoverability thereof;
- The expectation that contingent stock awards will not be issued in 2009 and that 2009 performance-based bonuses will be paid in cash;
- Expectations regarding influences on basic and diluted earnings per common share in future periods;
- Expectations regarding the recognition of certain expenses related to stock compensation in future periods;
- Management's belief that future cardiac tissue shipments may be negatively impacted by current economic conditions and their constraining effect on hospital budgets;
- Management's belief that future BioGlue revenues may be negatively impacted by hospital cost cutting practices and that such practices are likely to continue in the fourth quarter of 2009, and into 2010;
- Expectations regarding future HemoStase revenues;
- Expectations that the higher cost of preservation services as a percentage of preservation services revenues will continue in the fourth quarter of 2009, and into 2010;
- Expectations that the cost of products and costs of products as a percentage of revenues will continue to be impacted by an increased volume of HemoStase revenues;
- Expectations regarding, and possible increases in the cost and retention of, future insurance coverage;
- Expectations regarding future cardiac and vascular tissue procurement levels;
- Management's belief that current cardiac and vascular tissue procurement levels are sufficient to support future demand;
- Expectations regarding the timing of payments with respect to government grants;
- Expectations regarding the Company's future income tax expense and cash outlay for taxes;
- Expectations regarding the Company's aggregate borrowing capacity under its credit agreement with GE Capital;
- The impact of the current global financial and credit market difficulties on the Company and its credit agreement with GE Capital;
- Expectations regarding capital expenditures;
- The adequacy of the Company's insurance coverage;
- The expected outcome of lawsuits filed by or against the Company and the impact of such lawsuits on the Company's relationships and future sales;
- The Company's estimated future liability for tissue processing and product liability claims incurred but not yet reported and the source of payment and timing of payment for any such claims;
- Expected seasonality trends;
- Anticipated impact of changes in interest rates and foreign currency exchange rates;
- The Company's ability to meet its operational liquidity needs during the next twelve months;
- The adequacy of the Company's financial resources; 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 Part II, Item 1A, of this Form 10-Q and the Company's Forms 10-Q for the quarters ended March 31, 2009 and June 30, 2009, and under Risk Factors in Part I, Item 1A, of the Company's Form 10-K for the year ended December 31, 2008 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 the risk factors described under Part II, Item 1A of this Form 10-Q and concerns that:

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

We may receive a Form 483 notice of observations, a warning letter, or other similar communication from the FDA, and we may be unable to address the concerns raised by the FDA in such correspondence or communication, or addressing the concerns may be costly or could materially and adversely affect our operations;

Our CryoValve SG pulmonary heart valves and other SynerGraft tissues and products may not be accepted by the marketplace;

Our CryoValve SG pulmonary heart valves have a one year shelf life;

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

Our CryoValve SG pulmonary heart valve post-clearance study may not provide expected results;

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;

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 liability claims and additional regulatory scrutiny as a result;

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

Uncertainties related to patents and protection of proprietary technology for products we distributed may adversely affect our ability to distribute those products;

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;

We may be unable to successfully market HemoStase;

The lawsuit we filed against Medafor regarding our distribution agreement with Medafor may adversely impact our relationship with Medafor and could hinder our distribution of HemoStase or prevent us from distributing HemoStase;

Our credit facility could limit our ability to pursue significant acquisitions;

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

Deflation of foreign currencies relative to the U.S. Dollar could materially and adversely impact our business;

The financial and credit liquidity crisis may adversely affect our ability to borrow money or raise capital;

Current economic conditions may impact demand for our products and tissues;

Intense competition may affect our ability to operate profitably;

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

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

Our ability to borrow under our credit facility may be limited;

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;

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

Physicians have been and may continue to be reluctant to implant our preserved tissues or use our other products;
In the past, we have experienced operating losses and negative cash flows, and we must continue to address the underlying causes in order to continue to operate profitably and generate positive cash flows;
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 be unable to increase our revenues;
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;
Extensive government regulation may adversely affect our ability to develop and sell products and services;
We are dependent on our key personnel;
Trading prices for our common stock, and for the securities of biotechnology companies in general, have been, and may continue to be, volatile;
Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of us;
We may not 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 or contractual restrictions;
Healthcare policy changes, including pending proposals to reform the U.S. healthcare system, may have a material adverse effect on us;
The current and future economic and credit crisis may adversely affect our business and financial condition; and
Demand for our tissues and products could decrease in the future, which could have a material adverse effect on our business.

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 \$27.0 million and restricted money market funds of \$5.0 million and interest paid on the Company's variable rate line of credit as of September 30, 2009. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended September 30, 2009, affecting the Company's cash and cash equivalents, restricted money market funds, and line of credit would not have a material impact on the Company's financial position, profitability, 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 denominated balances 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.

The Company has revenues and expenses that are denominated in foreign currencies. Specifically, a majority of the Company's international BioGlue revenues are denominated in British Pounds and Euros and a portion of the Company's general, administrative, and marketing expenses are denominated in British Pounds and Euros. 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 net income from transactions conducted in other currencies. As a result, the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates. In the fourth quarter of 2008 and in the first nine months of 2009 the Company experienced a decrease in revenues when compared to the respective prior year periods due to changes in exchange rates.

Changes in exchange rates which occurred during the nine months ended September 30, 2009 as well as any future material adverse fluctuations in exchange rates could have a material and adverse effect on the Company's revenues, profitability, and cash flows for the full year of 2009. An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2009 affecting the Company's balances denominated in foreign currencies would not have had a material impact on the Company's financial position or cash flows. An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2009 as compared to the weighted average exchange rates experienced by the Company for the nine months ended September 30, 2009 affecting the Company's revenue and expense transactions denominated in foreign currencies, would not have had a material impact on the Company's financial position, profitability, or cash flows.

Item 4. Controls and Procedures.

The Company maintains disclosure controls and procedures ("Disclosure Controls") as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934. These Disclosure Controls are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms, and that such information is accumulated and communicated to management, including the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosures.

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

Based upon the most recent Disclosure Controls evaluation conducted by management, with the participation of the CEO and CFO, as of September 30, 2009 the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

During the quarter ended September 30, 2009 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.

With respect to the lawsuit previously discussed in the Company's Form 10-Q for the quarter ended March 31, 2009, filed by the Company against Medafor, Inc. (Medafor) in the U.S. District Court for the Northern District of Georgia alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia Racketeer Influenced and Corrupt Organizations Act (Georgia RICO), on July 30, 2009, the Company filed an amended complaint to further clarify its claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia RICO, and Medafor filed a new motion to dismiss the Company's claims for fraud, negligent misrepresentation, and violations of the Georgia RICO. The Court has not set a date for a hearing on the motion, nor has it stated that it will hold a hearing or when it will rule on Medafor's dismissal motion. While the motion to dismiss is pending, no formal discovery can commence.

On September 18, 2009, as previously discussed in a Form 8-K filed by the Company on September 24, 2009, Medafor informed CryoLife by letter of its belief that CryoLife materially breached its duties and obligations under the distribution agreement between the parties and gave CryoLife notice of its intent to terminate the distribution agreement if the breach was not cured within 30 days. On October 12, 2009 the Company filed a motion for temporary restraining order and preliminary injunction, requesting that the Court enjoin Medafor from terminating the agreement pursuant to Medafor's September 18, 2009 letter. On October 14, 2009 the court granted the parties' Consent Temporary Restraining Order, preventing Medafor from terminating the distribution agreement pending a hearing and ruling from the Court on the Company's request for an entry of preliminary injunction. On October 21, 2009 Medafor informed CryoLife that it would not terminate the distribution agreement based on the activities described in CryoLife's motion for temporary restraining order and preliminary injunction or set forth in Medafor's September 18, 2009 letter. On October 22, 2009 CryoLife notified the court that it was withdrawing its motion for temporary restraining order and preliminary injunction.

Item 1A. Risk Factors.

Other than the risk factors included below, there have been no material changes to the Risk Factors as previously disclosed in Part I, Item 1A, Risk Factors in our Form 10-K for the year ended December 31, 2008, as updated by Part II, Item 1A, Risk Factors in our Form 10-Q for the quarters ended June 30, 2009 and March 31, 2009.

Medafor May In the Future Attempt to Terminate our Distribution Agreement Which Could Hinder Our Distribution of HemoStase or Prevent Us From Distributing HemoStase.

Medafor has previously attempted to terminate our exclusive agreement to distribute HemoStase due to an alleged material breach of the contract, which we disputed. If Medafor is successful in any future attempt to terminate the agreement, we would no longer be able to distribute HemoStase and our revenues would be adversely impacted. Also, Medafor's attempt to terminate the agreement, even though unsuccessful, may signal future attempts to terminate the agreement over other issues and our relationship with Medafor may become strained, potentially hindering our ability to effectively distribute HemoStase or prevent us from distributing HemoStase. See Part II, Item 1 for further information regarding our distribution agreement with Medafor.

CryoPatch SG Pulmonary Cardiac Patch Has a One Year Shelf Life.

We are currently using the SynerGraft technology for a portion of our cardiac pulmonary patch processing pursuant to the 510(k) clearance we received for the CryoPatch SG in the third quarter. Our CryoPatch SG pulmonary cardiac patches currently

have a one year shelf life, whereas our non-SynerGraft processed pulmonary cardiac patches have a five-year shelf life. We do not know when the shelf life of the CryoPatch SG pulmonary cardiac patches may be extended, if at all. Accordingly, if we do not implant our CryoPatch SG pulmonary cardiac patches within one year of cryopreservation, we may be required to discard these patches, and as a result we may lose more tissues than before we started processing pulmonary cardiac patches with the SynerGraft technology, which could have a material adverse effect on our revenues, financial condition, profitability, and cash flows.

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 September 30, 2009 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
07/01/09	07/31/09		\$		
08/01/09	08/31/09	27,784	7.58		
09/01/09	09/30/09	6,141	8.37		
Total		33,925	\$ 7.73		

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.

None.

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 3.1 to the Registrant's Amended Current Report on Form 8-K/A filed March 5, 2009.)
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 year ended December 31, 1997.)
4.2	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.)
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)

October 29, 2009

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)