CRYOLIFE INC
Form 10-Q
November 05, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2010

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)

Florida	**59-2417093**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1655 Roberts Boulevard, NW, Kennesaw, Georgia	**30144**
(Address of principal executive offices)	**(Zip Code)**

(770) 419-3355

(Registrant s telephone number, including area code)

Not Applicable

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

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

Yes x No ¨

Indicate by check mark whether the registrant 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 x
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 x

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 29, 2010**
Common Stock, $0.01 par value per share	28,131,665 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,	
	2010	2009	2010	2009
	(Unaudited)		(Unaudited)	
Revenues:				
Preservation services	$ 15,111	$ 15,033	$ 45,699	$ 42,672
Products	13,175	12,806	41,276	39,669
Other	157	380	448	729
Total revenues	**28,443**	**28,219**	**87,423**	**83,070**
Cost of preservation services and products:				
Preservation services	8,911	8,903	27,322	24,421
Products	4,310	2,275	9,318	6,478
Total cost of preservation services and products	**13,221**	**11,178**	**36,640**	**30,899**
Gross margin	**15,222**	**17,041**	**50,783**	**52,171**
Operating expenses:				
General, administrative, and marketing	11,376	12,386	36,863	37,440
Research and development	1,354	1,461	3,886	3,854
Write-down of acquired in-process research and development	3,749		3,749	
Total operating expenses	**16,479**	**13,847**	**44,498**	**41,294**
Operating (loss) income	**(1,257)**	**3,194**	**6,285**	**10,877**
Interest expense	29	58	145	168
Interest income	(6)	(10)	(16)	(73)
Gain on valuation of derivative	(143)		(1,345)	
Other than temporary investment impairment	3,638		3,638	
Other (income) expense, net	(187)	8	44	100
(Loss) income before income taxes	**(4,588)**	**3,138**	**3,819**	**10,682**
Income tax (benefit) expense	(1,557)	1,276	1,990	4,369
Net (loss) income	**$ (3,031)**	**$ 1,862**	**$ 1,829**	**$ 6,313**

(Loss) income per common share:				
Basic	**$ (0.11)**	**$ 0.07**	**$ 0.07**	**$ 0.22**
Diluted	**$ (0.11)**	**$ 0.07**	**$ 0.06**	**$ 0.22**
Weighted-average common shares outstanding:				
Basic	27,783	28,145	28,086	28,074
Diluted	27,783	28,382	28,356	28,261

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	September 30, 2010 (Unaudited)	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,002	$ 30,121
Restricted securities	5,316	
Receivables, net	15,217	14,636
Deferred preservation costs	32,350	36,445
Inventories	6,298	6,446
Deferred income taxes	5,694	5,694
Prepaid expenses and other current assets	2,704	2,186
Total current assets	**98,581**	**95,528**
Property and equipment, net	13,280	14,309
Investment in equity securities	2,608	3,221
Restricted securities		5,000
Patents, net	3,345	4,248
Trademarks and other intangibles, net	5,520	2,724
Deferred income taxes	8,887	8,075
Other long-term assets	2,284	754
Total assets	**$ 134,505**	**$ 133,859**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,554	$ 2,954
Accrued compensation	2,858	3,361
Accrued procurement fees	3,072	3,228
Accrued expenses and other current liabilities	6,160	6,302
Deferred income	2,198	2,646
Derivative liability		725
Notes payable	405	
Total current liabilities	**18,247**	**19,216**
Line of credit		315
Other long-term liabilities	3,880	3,882
Total liabilities	**22,127**	**23,413**
Shareholders equity:		
Preferred stock		

Common stock (issued shares of 29,945 in 2010 and 29,475 in 2009)	299	295
Additional paid-in capital	132,816	128,427
Retained deficit	(10,523)	(12,352)
Accumulated other comprehensive loss	(9)	(38)
Treasury stock at cost (shares of 1,778 in 2010 and 1,000 in 2009)	(10,205)	(5,886)
Total shareholders equity	**112,378**	**110,446**
Total liabilities and shareholders equity	**$ 134,505**	**$ 133,859**

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,	
	2010	2009
	(Unaudited)	
Net cash from operating activities:		
Net income	$ 1,829	$ 6,313
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	2,908	3,179
Deferred income taxes	(801)	3,919
Other than temporary investment impairment	3,638	
Non-cash compensation	1,938	1,795
Write-down of acquired in-process research and development	3,749	
Write-down of deferred preservation costs and inventories	1,965	392
Write-down of intangible asset	856	
Gain on valuation of derivative	(1,345)	
Other non-cash adjustments to income	(922)	154
Changes in operating assets and liabilities:		
Receivables	(738)	(1,425)
Deferred preservation costs	4,188	(2,079)
Inventories	(1,693)	665
Prepaid expenses and other assets	(2,108)	(899)
Accounts payable, accrued expenses, and other liabilities	358	(1,857)
Net cash flows provided by operating activities	**13,822**	**10,157**
Net cash from investing activities:		
Acquisition of Starch Medical intangible assets	(5,392)	
Capital expenditures	(1,475)	(1,341)
Purchases of restricted securities and investments	(2,705)	(564)
Sales and maturities of marketable securities		1,130
Other	(369)	(542)
Net cash flows used in investing activities	**(9,941)**	**(1,317)**
Net cash from financing activities:		
Principal payments on debt	(315)	
Proceeds from financing of insurance policies	1,475	1,272
Principal payments on capital leases and short-term notes payable	(1,120)	(886)
Proceeds from exercise of stock options and issuance of common stock	236	891
Purchase of treasury stock	(4,295)	(282)
Other	1,013	
Net cash flows (used in) provided by financing activities	**(3,006)**	**995**
Increase in cash and cash equivalents	**875**	**9,835**

Effect of exchange rate changes on cash	6	10
Cash and cash equivalents, beginning of period	30,121	17,201
Cash and cash equivalents, end of period	**$ 31,002**	**$ 27,046**
Supplemental disclosures of cash flow information - non-cash investing activities:		
Issuance of common stock for acquisition of Starch Medical intangible assets	$ 989	$

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, 2009 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, 2010 and 2009 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. Operating results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. 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, 2009.

2. Financial Instruments

Financial instruments measured at fair value are recorded in accordance with the fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data; and

Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available.

A summary of the Company s financial instruments measured at fair value as of September 30, 2010 is as follows (in thousands):

	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
U.S. Treasury money market funds	$	$ 1,854	$	$ 1,854
U.S. Treasury debt securities	16,548			16,548
Restricted securities:				
Money market funds		316		316
U.S. Treasury debt securities	5,000			5,000
Total assets	$ 21,548	$ 2,170	$	$ 23,718

Changes in fair value of level 3 liabilities are listed in the table below (in thousands). Refer to Note 5 for further discussion of the derivative liability.

	Derivative Liability
Balance as of December 31, 2009	$ 725
Total gains unrealized included in earnings	(1,345)
Purchases	620
Balance as of September 30, 2010	$

3. Cash Equivalents and Restricted Securities

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

	Cost Basis	Unrealized Holding Gains	Estimated Market Value
September 30, 2010			
Cash equivalents:			
U.S. Treasury money market funds	$ 1,854	$	$ 1,854
U.S. Treasury debt securities	16,548		16,548
Restricted securities:			
Money market funds	316		316
U.S. Treasury debt securities	5,000		5,000
December 31, 2009			
Cash equivalents:			
U.S. Treasury money market funds	$ 18,754	$	$ 18,754
U.S. Treasury debt securities	8,999		8,999
Restricted securities:			
U.S. Treasury money market funds, long-term	5,000		5,000

As of September 30, 2010 $316,000 of the Company s money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating to international tax obligations. As of September 30, 2010 $5.0 million of the Company s U.S. Treasury debt securities and as of December 31, 2009 $5.0 million of the Company s U.S. Treasury money market funds were designated as restricted securities due to a financial covenant requirement under the Company s credit agreement with General Electric Capital Corporation (GE Capital) as discussed in Note 9.

There were no material realized gains or losses on cash equivalents in the nine months ended September 30, 2010 and 2009. At September 30, 2010 $5.0 million of restricted securities had a maturity date within 90 days and $316,000 of restricted securities had a maturity date of between 90 days and one year. As of December 31, 2009 none of the Company s restricted securities had a maturity date.

4. Starch Medical Agreements

Overview

On September 28, 2010 CryoLife entered into a worldwide distribution agreement (the Distribution Agreement) and a license and manufacturing agreement (the License Agreement) with Starch Medical Inc. (SMI) of San Jose, California for PerClot®, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, spinal, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. Under the terms of the agreements, CryoLife received the worldwide rights, excluding China, Taiwan, Hong Kong, Macau, North Korea, Iran, and Syria, to commercialize PerClot for all approved surgical indications and a license to manufacture the PerClot product, exclusive of rights to sell PerClot with an endoscope. CryoLife also received an assignment of the PerClot trademark from SMI as part of the terms of the agreements. CryoLife plans to file an Investigational Device Exemption with the U.S. Food and Drug Administration (FDA) to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S.

The Distribution Agreement contains certain minimum purchase requirements and has a term of 15 years. CryoLife may begin manufacturing PerClot from plant starch modified by SMI under the terms of the License Agreement, which is anticipated to occur sometime in 2011 or 2012. Following the start of manufacturing and U.S. regulatory approval, CryoLife may terminate the Distribution Agreement. CryoLife will pay royalties to SMI at stated rates on net revenues of products manufactured under the License Agreement. In addition to allowing CryoLife to manufacture PerClot, the License Agreement grants CryoLife a three-year option to purchase certain remaining related technology from SMI.

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As part of the transaction, CryoLife paid SMI $6.75 million in cash, which includes $1.5 million in cash for prepaid royalties, and approximately 209,000 shares of restricted CryoLife common stock. CryoLife will pay additional contingent amounts of up to $2.75 million to SMI if certain FDA regulatory and other commercial milestones are achieved.

Accounting for the Transaction

CryoLife accounted for the agreements discussed above as an asset acquisition. The initial consideration aggregated approximately $8.0 million, including $6.75 million in cash, restricted common stock valued at approximately $1.0 million, and direct transaction costs. CryoLife recorded a non-current asset for the $1.5 million in prepaid royalties and allocated the remaining consideration to the individual intangible assets acquired based on their relative fair values as determined by a valuation study. As a result, CryoLife recorded intangible assets of $319,000 for the PerClot trademark, $2.4 million for the PerClot distribution and manufacturing rights in certain international countries, and $3.7 million for the PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This $3.7 million is considered in-process research and development as it is dependant upon regulatory approvals which have not yet been obtained. Therefore, CryoLife expensed the $3.7 million as in-process research and development upon acquisition. The PerClot trademark acquired by the Company has an indefinite useful life; therefore, that asset will not be amortized, but will instead be subject to periodic impairment testing. The $2.4 million intangible asset will be amortized over its useful life of 15 years. See additional disclosures in Note 7 below.

CryoLife expects to record future contingent payment amounts of up to $2.75 million initially as research and development expense or, after FDA approval or issuance of a patent, as acquired intangible assets. The common stock issued to SMI will be held by CryoLife until March 31, 2012, when the restricted provisions of the stock lapse.

5. Medafor Matters

Overview

CryoLife began distributing HemoStase® (HemoStase) in 2008 for Medafor, Inc. (Medafor), a privately held company incorporated in Minnesota, under a private label exclusive distribution agreement between the parties (the EDA). In November 2009 and in 2010 the Company executed stock purchase agreements to purchase a total of approximately 2.4 million shares of common stock in Medafor for $4.9 million. The carrying value of this investment as of June 30, 2010 was $6.2 million or $2.61 per share, which included the purchase price and adjustments to record certain of the stock purchase agreements embedded derivative liabilities at the fair market value on the purchase date, as discussed further below. As Medafor s common stock is not actively traded on any public stock exchange and as Medafor is a privately held company for which financial information is not readily available, the Company accounted for this investment using the cost method and recorded it as the long-term asset, investment in equity securities, on the Company s Summary Consolidated Balance Sheets.

Recent Events

On March 18, 2010 Medafor announced that it was treating the EDA as terminated and ceased shipments of HemoStase to CryoLife. CryoLife thereafter moved the U.S. District Court for the Northern District of Georgia, Atlanta Division (the Court) to preliminarily enjoin Medafor from proceeding with its termination. Shortly thereafter, Medafor informed CryoLife that, although Medafor had terminated the EDA, it would continue to act as if the EDA were in effect for a short period of time. Medafor resumed shipments of HemoStase in late June of 2010. On September 20, 2010, the Court issued an order denying CryoLife s request for the preliminary injunction. On September 27, 2010, Medafor sent CryoLife a letter stating that it was fully and finally terminating the EDA based upon CryoLife s alleged repudiation, although it had never rescinded its prior termination. This was the sixth time that Medafor notified CryoLife that it either had terminated the EDA or was going to terminate the EDA.

Based on this communication and subsequent communications CryoLife has received from Medafor, CryoLife does not believe that Medafor will make any further inventory shipments to CryoLife. CryoLife was Medafor s largest distributor in 2009 and 2008, accounting for 19% and 15% of Medafor s total revenues, respectively. See further discussion of these recent events in Legal Action below.

On September 28, 2010 CryoLife announced that it had entered into a worldwide Distribution Agreement and License Agreement with SMI for PerClot, a competing hemostatic agent used in surgery, as discussed in Note 4 above.

Investment in Medafor Common Stock

During the three months ended September 30, 2010, the Company reviewed available information, including the events described in the paragraphs above, to determine if factors indicated that a decrease in value of the investment in Medafor common stock had occurred. CryoLife determined that the available information, particularly Medafor s termination of its largest distributor, indicated that the Company should evaluate its investment in Medafor common stock for impairment.

CryoLife used a market based approach for the valuation, including comparing Medafor to a variety of comparable publicly traded companies, recent merger targets, and company groups. CryoLife considered both qualitative and quantitative factors that could effect the valuation of Medafor s common stock. Based on its analysis, the Company believes that its investment in Medafor was impaired and that this impairment was other than temporary. Therefore, CryoLife recorded a non-operating expense, other than temporary investment impairment, of $3.6 million to write-down its investment in Medafor common stock. The carrying value of the Company s 2.4 million shares of Medafor common stock after this write-down was $2.6 million or $1.09 per share as of September 30, 2010.

The Company will continue to evaluate the carrying value of this investment if changes to the factors discussed above or additional factors become known that indicate the Company should evaluate its investment in Medafor common stock for further impairment. If the Company subsequently determines that the value of its Medafor common stock has been impaired further or if the Company decides to sell its Medafor common stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in Medafor could be material.

Medafor Derivative

Per the terms of certain of the stock purchase agreements for the Medafor shares discussed above, in the event that CryoLife acquires more than 50% of the diluted outstanding stock of Medafor or merges with Medafor within a three-year period from each respective agreement date (a Triggering Event), CryoLife is required to make a future per share payment (the Purchase Price Make-Whole Payment) to such sellers. The payment would be equal to the difference between an amount calculated using the average cost of any subsequent shares purchased, as defined in each respective agreement, and the price of the shares purchased pursuant to each applicable stock purchase agreement. The Company was required to account for these Purchase Price Make-Whole Payment provisions as embedded derivatives (collectively the Medafor Derivative).

CryoLife performed a valuation of the Medafor Derivative using a Black-Scholes model to estimate the future value of the shares on the purchase date. Management s assumptions as to the likelihood of a Triggering Event occurring coupled with the valuation of the Purchase Price Make-Whole Payment were then used to calculate the derivative liability. The fair value of the Medafor Derivative was initially recorded as an increase to the investment in equity securities and a corresponding derivative liability on the Company s Summary Consolidated Balance Sheet. The Medafor Derivative is revalued quarterly, and any change in the value of the derivative subsequent to the purchase date is recorded in the Company s Summary Consolidated Statement of Operations.

As of September 30, 2010 the Company believed that the likelihood of a Triggering Event was zero. As a result, the Company recorded a gain on the change in the value of derivative on the Summary Consolidated Statement of Operations of $143,000 and $1.3 million for the three and nine months ended September 30, 2010, respectively. The non-cash gain on valuation of the Medafor Derivative was substantially due to changes during these periods in the Company s estimates of the likelihood of a Triggering Event occurring.

The gain on valuation of the Medafor Derivative was recorded as a decrease in the derivative liability on the Summary Consolidated Balance Sheet. This decrease in the liability was partially offset by an increase of $620,000 related to additional purchases of Medafor common stock during the nine months ended September 30, 2010. See also the disclosure of the change in fair value of the derivative liability in Note 2. The value of the Medafor Derivative was zero and $725,000 as of September 30, 2010 and December 31, 2009, respectively.

HemoStase Inventory

Based on Medafor s termination of the EDA in late September 2010 and the determination that Medafor would no longer be shipping HemoStase to CryoLife, the Company performed a review of its HemoStase inventory to determine if the carrying value of the inventory had been impaired.

Per its review of the EDA, the Company expects to continue to sell HemoStase for a six month period following the most recent termination of the EDA. As a result, the Company determined that the carrying value of the HemoStase inventory was

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impaired and increased its cost of products by $1.6 million to write-down related finished goods inventory in the three months ended September 30, 2010. The Company believes that the remaining value of $1.7 million of HemoStase inventory after the write-down is recoverable over the six-month selling period following the termination of the EDA.

The amount of this write-down reflects management s estimate based on information currently available. Management will continue to evaluate the recoverability of its HemoStase inventory as more information becomes available and may record additional write-downs if it becomes clear that additional impairments have occurred. The write-down creates a new cost basis which cannot be written back up if the inventory becomes saleable. The cost of products in future periods may be favorably impacted if the Company is able to sell more HemoStase than the amounts estimated as discussed above.

Legal Action

CryoLife s Lawsuit and Claims with Medafor

As previously reported in CryoLife s Annual Report on Form 10-K for the year ended December 31, 2009, and CryoLife s Forms 10-Q for the quarters ended March 31, 2010, and June 30, 2010, CryoLife filed a lawsuit against Medafor in 2009 in the Court, alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia s Racketeer Influenced and Corrupt Organizations Act (Georgia RICO). The lawsuit arises out of the EDA, which gave CryoLife the right to distribute a product manufactured by Medafor under the name HemoStase. The Court dismissed CryoLife s Georgia RICO claim on August 9, 2010. On October 20, 2010 CryoLife filed supplemental claims against Medafor for additional breaches of contract, including those related to Medafor s wrongful termination of the EDA.

CryoLife s Potential Damages

The Company seeks to recover its damages from Medafor, accompanied by preliminary and permanent injunctive relief, punitive damages, and reimbursement of its attorneys fees. In addition, the Company will seek damages related to Medafor s wrongful termination of the EDA, which will be based upon the Company s lost profits for the period of time during which the EDA would have continued in effect but for Medafor s termination of it. The amount of these damages will be determined through discovery in the lawsuit. No trial date has been set.

Medafor s Counter-claims

On September 8, 2010 Medafor answered CryoLife s complaint and filed a counter-complaint against CryoLife, alleging claims for, among other things, breach of contract, breach of the implied duty of good faith and fair dealing, violation of the Georgia trade secrets act, tortious interference with business relationships, libel, violation of the uniform deceptive trade practices act, fraud and negligent misrepresentation. In addition, Medafor requested that the Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Uniform Commercial Code.

Background on Current Status of the EDA Medafor s Decision to Terminate the EDA Due to CryoLife s Alleged Repudiation

As previously reported in CryoLife s Current Report on Form 8-K dated March 19, 2010, and CryoLife s Forms 10-Q for the quarters ended March 31, 2010 and June 30, 2010, Medafor informed CryoLife on March 18, 2010 of its contention that CryoLife had repudiated the EDA, thereby entitling Medafor to terminate the EDA. Medafor asserted that it had made a valid statutory demand, in a February 10, 2010 letter to CryoLife, for adequate assurances of CryoLife s future performance under the EDA, and that CryoLife had repudiated the EDA by failing to respond in a timely manner. On March 22, 2010 CryoLife informed Medafor that it disputed Medafor s assertions, and that Medafor had no right to terminate the EDA. CryoLife then filed a motion for preliminary injunction, asking the Court to enjoin Medafor from proceeding with its termination of the EDA.

As previously reported in CryoLife s Current Report on Form 8-K dated September 20, 2010, the Court, on September 20, 2010, issued an order denying CryoLife s request for a preliminary injunction against Medafor. Although the order denied the preliminary injunction, it did not address the merits of the parties respective positions on the underlying issues, which the Court viewed as more appropriately addressed at summary judgment.

As previously reported in CryoLife s Current Report on Form 8-K dated September 28, 2010, on September 27, 2010, Medafor sent CryoLife a letter stating that it had fully and finally terminated the EDA based upon CryoLife s alleged repudiation. This was Medafor s sixth termination or termination attempt with respect to the EDA.

Medafor s Letters to CryoLife Asserting Additional Claims

On September 29, 2010 Medafor notified CryoLife that it was Medafor s position that CryoLife s interactions with Starch Medical, Inc. had resulted in numerous breaches of the EDA by CryoLife that could not be cured. Medafor additionally informed CryoLife that Medafor believed these alleged breaches were additional bases for termination of the EDA. Finally, Medafor informed CryoLife that Medafor would promptly move to amend its counter-claim to add additional claims for breach of contract and fraud, and for conspiracy and aiding and abetting, and other undefined claims.

On October 1, 2010 Medafor notified CryoLife that it was Medafor s position that CryoLife s continued selling of HemoStase tortiously interferes with Medafor s customer relationships and violates the Lanham Act and Georgia s Deceptive Trade Practices Act. Medafor informed CryoLife that if CryoLife continued to sell HemoStase, Medafor would amend its counter-claim to add claims for violations of the Lanham Act and Georgia s Deceptive Trade Practices Act, and other undefined claims.

As of November 4, 2010 Medafor has not amended its counter-claims, although CryoLife expects Medafor to do so by November 12, 2010.

Summary of Medafor s Potential Damages Claims

Pursuant to its counter-claims to date, Medafor seeks to recover its alleged damages from CryoLife, including rescinding the EDA to restore to Medafor all of the benefits that CryoLife has received under the EDA, compensatory damages, injunctive relief, prejudgment interest, punitive damages, and attorneys fees and expenses.

Current Status of the Lawsuit

No trial date has been set. Discovery began on October 8, 2010. CryoLife has filed Rule 12(e) and (f) motions, requesting that the Court compel Medafor to make more definitive claims with regards to its counter-claims for libel, violations of the Uniform Deceptive Trade Practices Act, and rescission and to strike several of Medafor s affirmative defenses to CryoLife s claims. Medafor filed a motion in response to CryoLife s Rule 12(e) and (f) motions generally opposing CryoLife s requests. CryoLife may also file a Rule 12(c) motion for judgment on the pleadings in order to have the Court dismiss certain claims made by Medafor. CryoLife intends to vigorously prosecute the case and defend itself and contest the matter.

Contingency Related to the Lawsuit and Claims

CryoLife intends to vigorously defend itself and contest the matter. Given the early stage of this case, the Company does not believe at this time that there is a reasonable probability that a loss will occur. Due to the early stage of the case, CryoLife does not currently believe that it is possible to reasonably estimate the amount of loss or a range of losses on the current counter-claims made by Medafor or any future additional counter-claims that may be made by Medafor. The parties have not discussed settlement in any meaningful way.

6. Inventories

Inventories are comprised of the following (in thousands):

	September 30, 2010	December 31, 2009
Raw materials	$ 3,347	$ 4,144
Work-in-process	295	278
Finished goods	2,656	2,024
Total inventories	$ 6,298	$ 6,446

As discussed in Note 5 above, during the quarter ended September 30, 2010, CryoLife wrote-down $1.6 million in HemoStase finished goods inventory due to an impairment. The $2.7 million in finished goods inventory in the table above includes $1.7 million of HemoStase inventory.

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7. Intangible Assets

The Company s intangible assets consist of procurement contracts and agreements, trademarks, patents, customer lists, non-compete agreement, and distribution and manufacturing rights acquired in the SMI transaction discussed in Note 4 above.

Indefinite Lived Intangible Assets

Based on its experience with similar agreements, the Company believes that its acquired contracts and procurement agreements have an indefinite useful life, as the Company expects to continue to renew these contracts for the foreseeable future. Accordingly, the Company s indefinite lived intangible assets do not amortize, but are instead subject to periodic impairment testing. As of September 30, 2010 and December 31, 2009 the carrying values of the Company s indefinite lived intangible assets are as follows (in thousands):

	September 30, 2010	December 31, 2009
Procurement contracts and agreements	$ 2,013	$ 2,013
Trademarks	769	435

Definite Lived Intangible Assets

The Company generally amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. As of September 30, 2010 and December 31, 2009 gross carrying values, accumulated amortization, and approximate amortization periods of the Company s definite lived intangible assets are as follows (in thousands):

	Gross Carrying Value	Accumulated Amortization	Amortization Period
September 30, 2010			
Patents	$ 5,830	$ 2,485	17 Years
Customer lists	579	520	3 Years
Non-compete agreement	381	143	10 Years
Distribution and manufacturing rights	2,441		15 Years
December 31, 2009			
Patents	$ 6,403	$ 2,155	17 Years
Customer lists	574	565	3 Years
Non-compete agreement	381	114	10 Years

Amortization Expense

The following is a summary of amortization expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Amortization expense	$ 132	$ 142	$ 395	$ 413

As of September 30, 2010 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2010	2011	2012	2013	2014	2015
Amortization expense	$ 173	$ 685	$ 671	$ 583	$ 489	$ 464

8. 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, inventory, and in-process research and development; accruals for tissue processing and product liability claims; and operating losses.

As of September 30, 2010 the Company had a net deferred tax asset of $14.6 million, including a total of $1.8 million in valuation allowances against deferred tax assets. As of December 31, 2009 the Company had a net deferred tax asset of $13.8 million, including a total of $1.8 million in valuation allowances against deferred tax assets. Valuation allowances at September 30, 2010 and December 31, 2009 related to state net operating loss carryforwards that are not expected to be fully utilized prior to their expiration. 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 2006 through 2009 remain open to examination by the major taxing jurisdictions to which the Company is subject.

The Company s effective income tax rate was a benefit of 34% for the three months ended September 30, 2010 and expense of 52% for the nine months ended September 30, 2010 as compared to expense of 41% for both the three and nine months ended September 30, 2009.

9. Debt

GE Credit Agreement

On March 26, 2008 CryoLife entered into a credit agreement with GE Capital as lender, as amended (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). 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. The letter of credit had a one-year initial term and automatically renews for additional one-year periods. 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.

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings 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 has been 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 restricted securities on the Company s Summary Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined, of at least $20.0 million. The GE Credit Agreement 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 any outstanding principal balance will be due. Based on the expiration date, the Company will classify any amounts due under the GE Credit Agreement as short-term debt and has classified the related restricted securities as a current asset on the September 30, 2010 Summary Consolidated Balance Sheet. As of September 30, 2010 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 LIBOR, with a minimum rate of 3%, or GE Capital s base rate, with a minimum rate of 4% each, plus the applicable margin. During the second quarter of 2010, the outstanding principal balance of $315,000 on the GE Credit Agreement was paid from cash on hand. As of September 30, 2010 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate would be 5.50%, and the remaining availability was $14.8 million. As of December 31, 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.

Other

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In March 2010 the Company entered into an agreement to finance approximately $1.5 million in insurance premiums at a 2.707% annual interest rate, which is payable in equal monthly payments over a nine month period. 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 was payable in equal monthly payments over a nine month period. As of September 30, 2010 and December 31, 2009 the aggregate outstanding balances under these agreements were $395,000 and zero, respectively.

Total interest expense was $29,000 and $58,000 for the three months ended September 30, 2010 and 2009, respectively, and $145,000 and $168,000 for the nine months ended September 30, 2010 and 2009, respectively, which included interest on debt and uncertain tax positions.

10. Comprehensive (Loss) Income

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net (loss) income	$ (3,031)	$ 1,862	$ 1,829	$ 6,313
Change in translation adjustment	22	(16)	29	30
Comprehensive (loss) income	$ (3,009)	$ 1,846	$ 1,858	$ 6,343

The tax effect on the translation adjustment is zero for each period presented. The accumulated other comprehensive loss of $9,000 and $38,000 as of September 30, 2010 and December 31, 2009, respectively, consisted solely of currency translation adjustments.

11. (Loss) Income Per Common Share

The following is the computation of basic and diluted (loss) income per common share (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Basic (loss) income per common share:				
Net (loss) income	$ (3,031)	$ 1,862	$ 1,829	$ 6,313
Basic weighted-average common shares outstanding	27,783	28,145	28,086	28,074
Basic (loss) income per common share	$ (0.11)	$ 0.07	$ 0.07	$ 0.22

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Diluted (loss) income per common share:				
Net (loss) income	$ (3,031)	$ 1,862	$ 1,829	$ 6,313
Basic weighted-average common shares outstanding	27,783	28,145	28,086	28,074
Effect of dilutive stock options [a]		143	126	108
Effect of dilutive unvested restricted stock awards [b]		94	144	79
Diluted weighted-average common shares outstanding	27,783	28,382	28,356	28,261
Diluted (loss) income per common share	$ (0. 11)	$ 0.07	$ 0.06	$ 0.22

[a] Stock options to purchase 1.6 million and 1.2 million common shares for the three months ended September 30, 2010 and 2009, respectively, and 1.5 million and 1.3 million common shares for the nine months ended September 30, 2010 and 2009, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding, as such stock options would be antidilutive to the computation of (loss) income per common share.

[b] Unvested restricted stock awards that would have resulted in 145,000 additional dilutive common shares for the three months ended September 30, 2010, were excluded from the calculation of diluted weighted-average common shares outstanding, as such unvested restricted stock would be antidilutive to the computation of (loss) income per common share.

In future periods, basic and diluted (loss) income 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, the issuance of additional restricted stock awards, and stock repurchases as discussed in Note 12 below.

12. Stock Repurchase

On June 1, 2010 the Company publicly announced that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions on such terms as management deems appropriate, and will be dependent upon various factors, including price, regulatory requirements, and other market conditions. As of September 30, 2010 the Company had purchased 767,000 shares of its common stock for an aggregate purchase price of $4.3 million. These shares were accounted for as treasury stock, carried at cost, and reflected as a reduction of shareholders equity on the Company s Summary Consolidated Balance Sheet.

13. 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 regular basis at the lower of 85% of the market price at the beginning or end of each offering period.

Equity Grants

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 officers totaling 215,000 and 160,000 shares of common stock during the nine months ended September 30, 2010 and 2009, respectively, which had an aggregate market value of $1.3 million and $1.1 million, respectively.

The Compensation Committee of the Company s Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers and employees totaling 427,000 and 438,000 shares during the nine months ended September 30, 2010 and 2009, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Employees purchased common stock totaling 43,000 and 58,000 shares in the nine months ended September 30, 2010 and 2009, respectively, through the Company s ESPP.

Stock Compensation Expense

The Company values its stock awards based on the stock price on the date of grant and expenses the related compensation cost using the straight-line method over the vesting period. 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 fair value of the Company s ESPP options is also determined using a Black-Scholes model and is expensed over the vesting period. The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk-free interest rate. The period expense is then determined based on this valuation and, at that time, an estimated forfeiture rate is used to reduce the expense recorded. The Company s estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company and is adjusted to reflect actual forfeitures at each vesting date.

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

	Three Months Ended September 30, 2010		Nine Months Ended September 30, 2010	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	.50 Years	3.75 Years	.34 Years
Expected stock price volatility	N/A	.467	.650	.472
Risk-free interest rate	N/A	0.22%	1.29%	0.16%

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	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	4.00 Years	.25 Years
Expected stock price volatility	N/A	.790	.650	.800
Risk-free interest rate	N/A	0.17%	1.51%	0.15%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Stock grant expense	$ 139	$ 224	$ 691	$ 675
Stock option expense	424	383	1,464	1,307
Total stock compensation expense	$ 563	$ 607	$ 2,155	$ 1,982

Included in the 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 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 deferred preservation costs and inventories. The Company capitalized $80,000 and $66,000 in the three months ended September 30, 2010 and 2009, respectively, and $217,000 and $187,000 in the nine months ended September 30, 2010 and 2009, respectively, of the stock compensation expense into its deferred preservation costs and inventories.

As of September 30, 2010 the Company had a total of $1.4 million in unrecognized compensation costs related to unvested stock awards, before considering the effect of expected forfeitures. As of September 30, 2010 this expense is expected to be recognized over a weighted-average period of 1.5 years. As of September 30, 2010 there was approximately $2.3 million in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of September 30, 2010 this expense is expected to be recognized over a weighted-average period of 1.5 years.

14. 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 during 2010 and 2009 and from shipments of previously preserved orthopaedic tissues during 2009. The Medical Devices segment includes external revenues from product sales of BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and HemoStase, as well as sales of other medical devices. There are no intersegment revenues.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Preservation services	$ 15,111	$ 15,033	$ 45,699	$ 42,672
Medical devices	13,175	12,806	41,276	39,669
Other [a]	157	380	448	729
Total revenues	28,443	28,219	87,423	83,070
Cost of preservation services and products:				
Preservation services	8,911	8,903	27,322	24,421
Medical devices	4,310	2,275	9,318	6,478
Total cost of preservation services and products	13,221	11,178	36,640	30,899
Gross margin:				
Preservation services	6,200	6,130	18,377	18,251
Medical devices	8,865	10,531	31,958	33,191
Other [a]	157	380	448	729
Total gross margin	$ 15,222	$ 17,041	$ 50,783	$ 52,171

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Preservation services:				
Cardiac tissue	$ 7,189	$ 7,315	$ 20,953	$ 19,377
Vascular tissue	7,922	7,699	24,746	23,147
Orthopaedic tissue		19		148
Total preservation services	15,111	15,033	45,699	42,672
Products:				
BioGlue and BioFoam	11,046	11,180	35,219	35,323
HemoStase	2,129	1,562	6,127	4,139
Other medical devices		64	(70)	207
Total products	13,175	12,806	41,276	39,669
Other [a]	157	380	448	729

Total revenues	$ 28,443	$ 28,219	$ 87,423	$ 83,070

[a] For the three and nine months ended September 30, 2010 and 2009, the Other designation includes grant revenue.

15. Commitments and Contingencies

Liability Claims

In the normal course of business the Company is made aware of adverse events involving its tissues and products. Any adverse event could ultimately give rise to a lawsuit against the Company. In addition, tissue processing and product liability claims may be asserted against the Company in the future based on events it is not aware of at the present time. 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. Any punitive damage components of claims are uninsured.

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.

The Company accrues its estimate of unreported tissue processing and product liability claims as components of accrued expenses and other long-term liabilities and records the related recoverable insurance amounts as a component of receivables and other long-term assets. The amounts recorded represent management s estimate of the probable losses and anticipated recoveries for unreported claims related to services performed and products sold prior to the balance sheet date.

At September 30, 2010 and December 31, 2009 the short-term and long-term portions of the unreported loss liability and any related recoverable insurance amounts are as follows (in thousands):

	September 30, 2010	December 31, 2009
Short-term liability	$ 1,545	$ 1,890
Long-term liability	1,535	1,790
Total liability	3,080	3,680
Short-term recoverable	575	660
Long-term recoverable	620	680
Total recoverable	1,195	1,340
Total net unreported loss liability	$ 1,885	$ 2,340

Further analysis indicated that the liability as of September 30, 2010 could be estimated to be as high as $5.2 million, based on a higher estimate of future claims frequency.

On March 31, 2010 the Company bound liability coverage for the 2010/2011 insurance policy year. This policy is an eight-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2011 and reported during the period April 1, 2010 through March 31, 2011 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

As of November 4, 2010 there were no pending tissue processing or product liability lawsuits filed against the Company.

Lawsuit with Medafor

See Note 5 above for discussion of CryoLife s ongoing business litigation arising from a contract dispute with Medafor.

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 January 19, 1984 in Florida, preserves and distributes human tissues and develops, manufactures, and commercializes medical devices for cardiac and vascular transplant applications. The human tissue distributed by CryoLife includes the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife s proprietary SynerGraft® technology. CryoLife s medical devices consist primarily of surgical adhesives, sealants, and hemostats including BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot®, which the Company began distributing for Starch Medical Inc. (SMI) in October of 2010, and HemoStase® (HemoStase), which the Company currently distributes for Medafor, Inc. (Medafor), although CryoLife has received notice from Medafor that it has terminated its HemoStase distribution agreement with CryoLife.

In the third quarter of 2010 CryoLife announced that it had entered into an agreement to sell PerClot®, a novel polysaccharide hemostatic agent used in surgery, currently manufactured by SMI. This announcement helped to address the anticipated absence of HemoStase from CryoLife s product portfolio, due to Medafor s most recent termination of the exclusive distribution agreement (the EDA) between the parties. See further discussion of SMI and Medafor below. In early October 2010, CryoLife also announced that BioGlue has been approved in Japan for use in the repair of aortic dissections. CryoLife expects to begin selling BioGlue in Japan through its distribution partner Century Medical, Inc. in the first half of 2011.

CryoLife generated significant cash from operations of $13.8 million during the first nine months of 2010. This cash flow performance was largely due to the Company s strong sales coupled with careful management of its operating cash requirements, including a $4.2 million reduction in the Company s deferred preservation cost balances since December 31, 2009. See the Results of Operations section below for additional analysis of the three and nine months ended September 30, 2010.

Recent Events

Starch Medical

On September 28, 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI of San Jose, California for PerClot®, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, spinal, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. CryoLife plans to file an Investigational Device Exemption with the U.S. Food and Drug Administration (FDA) to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S.

Medafor

As previously reported, on March 18, 2010 Medafor announced that it was treating the EDA as terminated and ceased shipments of HemoStase to CryoLife. CryoLife thereafter moved the U.S. District Court for the Northern District of Georgia, Atlanta Division (the Court) to preliminarily enjoin Medafor from proceeding with its termination. Shortly thereafter, Medafor informed CryoLife that, although Medafor had terminated the EDA, it would continue to act as if the EDA were in effect for a short period of time. Medafor resumed shipments of HemoStase in late March of 2010. On September 20, 2010 the Court issued an order denying CryoLife s request for the preliminary injunction. On September 27, 2010 Medafor sent CryoLife a letter stating that it was fully and finally terminating the EDA based upon CryoLife s alleged repudiation, although it had never rescinded its prior termination. This was the sixth time that Medafor notified CryoLife that it either had terminated the EDA or was going to terminate the EDA.

Based on this communication and subsequent communications CryoLife has received from Medafor, CryoLife does not believe that Medafor will make any further inventory shipments to CryoLife. CryoLife was Medafor s largest distributor in 2009 and 2008, accounting for 19% and 15% of Medafor s total revenues, respectively. As of September 30, 2010 CryoLife owned approximately 2.4 million shares of Medafor common stock. See also Part I, Item 2, Risks and Uncertainties and Part II, Item 1, Legal Proceedings.

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Stock Repurchase Program

The Company announced on June 1, 2010 that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. As of September 30, 2010 the Company had repurchased approximately 767,000 shares or $4.3 million of its common stock in accordance with this plan.

Critical Accounting Policies

A summary of the Company s significant accounting policies is included in Note 1 of the Notes to Consolidated Financial Statements, contained in the Company s Form 10-K for the year ended December 31, 2009. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company s operating results and financial condition. The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require the Company to make estimates and assumptions. The Company did not experience any significant changes during the quarter ended September 30, 2010 in its Critical Accounting Policies from those contained in the Company s Form 10-K for the year ended December 31, 2009.

New Accounting Pronouncements

There were no new accounting pronouncements relevant to the Company that management anticipates adopting during the year ending December 31, 2010.

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,	
	2010	2009	2010	2009
Preservation services:				
Cardiac tissue	$ 7,189	$ 7,315	25%	26%
Vascular tissue	7,922	7,699	28%	27%
Orthopaedic tissue		19	%	%
Total preservation services	15,111	15,033	53%	53%
Products:				
BioGlue and BioFoam	11,046	11,180	39%	40%
HemoStase	2,129	1,562	7%	6%
Other medical devices		64	%	%
Total products	13,175	12,806	46%	46%
Other	157	380	1%	1%
Total	$ 28,443	$ 28,219	100%	100%

	Revenues for the Nine Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2010	2009	2010	2009
Preservation services:				
Cardiac tissue	$ 20,953	$ 19,377	24%	23%
Vascular tissue	24,746	23,147	28%	28%
Orthopaedic tissue		148	%	%
Total preservation services	45,699	42,672	52%	51%
Products:				
BioGlue and BioFoam	35,219	35,323	40%	43%
HemoStase	6,127	4,139	7%	5%
Other medical devices	(70)	207	%	%
Total products	41,276	39,669	47%	48%
Other	448	729	1%	1%

Total	$ 87,423	$ 83,070	100%	100%

Revenues increased 1% for the three months and 5% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, 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, 2010 is presented below.

Preservation Services

Revenues from preservation services increased 1% for the three months and 7% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, respectively. The increase for the three months ended September 30, 2010 was primarily due to an increase in vascular preservation service revenues. The increase for the nine months ended September 30, 2010 was due to an increase in both cardiac and vascular preservation services revenues. See further discussion of cardiac and vascular preservation services revenues below.

Cardiac Preservation Services

Revenues from cardiac preservation services (consisting of revenues from the distribution of heart valves, cardiac patch tissues, and minimally processed tissues that are distributed to a third party tissue processor) decreased 2% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009, primarily due to the impact of a 7% decrease in shipments of heart valves and cardiac patch tissues, partially offset by favorable tissue mix.

Revenues from cardiac preservation services increased 8% for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009, primarily due to the aggregate impact of favorable tissue mix and a 4% increase in shipments of heart valves and cardiac patch tissues.

The favorable tissue mix in the three and nine months ended September 30, 2010 was primarily due to the favorable impact of SynerGraft tissues including the CryoValve SGPV and CryoPatch SG, which command a premium fee over standard processed tissues.

The decrease in cardiac tissue shipments for the three months ended September 30, 2010 was primarily in traditionally processed pulmonary valves and cardiac patch tissues, partially offset by an increase in CryoValve SGPV. The increase in cardiac tissue shipments for the nine months ended September 30, 2010 was primarily in CryoValve SGPV and CryoPatch SG, partially offset by a decrease in traditionally processed cardiac patch tissues and pulmonary valves.

In both the three and nine months ended September 30, 2010, the decrease in revenues from traditionally processed pulmonary valves was more than offset by an increase in revenues related to the CryoValve SGPV, as hospitals continue to transition to the SynerGraft processed product, particularly after the shelf-life extension discussed further below. In the three months ended, and to a lesser extent in the nine months ended, September 30, 2010 the decrease in revenues from traditionally processed cardiac patch tissues was not fully offset by increases in revenues from the CryoPatch SG. The Company believes that these revenues were unfavorably impacted by increasing competitive pressures and by a reduced supply of standard processed patch tissues available for shipment during the period as the Company works to achieve an optimal balance among its offered tissues. These lost revenues were not replaced by the CryoPatch SG, which has not yet received the market penetration and acceptance of the CryoValve SGPV.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 37% and 33% of total cardiac preservation services revenues for the three and nine months ended September 30, 2010, respectively, and 26% and 24% of total cardiac preservation services revenues for the three and nine months ended September 30, 2009, respectively. Domestic revenues accounted for 93% of total cardiac preservation services revenues for both the three and nine months ended September 30, 2010 and 93% and 95% of total cardiac preservation services revenues for the three and nine months ended September 30, 2009, respectively.

In the second quarter of 2010 the Company received FDA clearance to extend the shelf-life of the CryoValve SGPV to five years. Following the announcement of the shelf-life extension, in June 2010 the Company shipped significantly more CryoValve SGPVs than in any other month since the initial FDA clearance of this valve in March 2008. The Company continued to ship higher numbers of CryoValve SGPVs in the three months ended September 30, 2010 than before the shelf-life extension, although the number of shipments did decrease during the course of the quarter. As a result, the Company believes that it may experience additional favorable tissue mix during the remainder of 2010 if the Company continues shipping a higher percentage of CryoValve SGPVs than in the corresponding prior year periods, however, this trend may not continue or may slow in future months.

Vascular Preservation Services

Revenues from vascular preservation services increased 3% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009, primarily due to an increase in average service fees, which increased revenues by 2%.

Revenues from vascular preservation services increased 7% for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009, primarily due to a 4% increase in unit shipments of vascular tissues, which increased revenues by 5% and an increase in average service fees, which increased revenues by 2%.

The increase in vascular volume for the nine months ended September 30, 2010 was primarily due to increases in shipments of saphenous veins, resulting from the strong demand for these tissues in domestic markets, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations.

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Products

Revenues from products increased 3% for the three months and 4% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, respectively. These increases were primarily due to an increase in HemoStase revenues. See further discussions of BioGlue, BioFoam, and HemoStase revenues below.

BioGlue and BioFoam

Revenues from the sale of BioGlue and BioFoam decreased 1% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009. This decrease was primarily due to a 9% decrease in the volume of milliliters sold, which decreased revenues by 5% and the unfavorable impact of foreign exchange, which decreased revenues by 1%, largely offset by an increase in average selling prices, which increased revenues by 5%.

Revenues from the sale of BioGlue and BioFoam were flat for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009. The revenues were impacted by a 6% decrease in the volume of milliliters sold, which decreased revenues by 4% and the unfavorable impact of foreign exchange, which decreased revenues by 1%, offset by an increase in average selling prices, which increased revenues by 5%.

The decrease in sales volume for BioGlue and BioFoam for the three and nine months ended September 30, 2010 was primarily due to a decrease in shipments of BioGlue in domestic markets, particularly in the northeast region of the U.S. Management believes that the decrease in domestic BioGlue shipments is a result of various factors, including: the U.S. market introduction of sealant products with approved indications for use in clinical applications in which BioGlue has been used previously; poor economic conditions and their constraining effect on hospital budgets; the resulting attempts by hospitals to control costs by reducing spending on consumable items such as BioGlue; and the efforts of some large competitors in imposing and enforcing contract purchasing requirements for competing non-CryoLife products.

The impact of foreign exchange for the three months ended September 30, 2010 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, 2010 as compared to the respective periods in 2009. The Company s sales of BioGlue and BioFoam through its direct sales force to United Kingdom hospitals are denominated in British Pounds, and its sales to German hospitals, Austrian hospitals, and certain distributors are denominated in Euros.

The increase in average selling prices for the three and nine months ended September 30, 2010 was primarily due to list price increases on certain BioGlue products that went into effect during 2009 and 2010 and the negotiation of pricing contracts with certain customers.

Sales of BioGlue and BioFoam for the three and nine months ended September 30, 2010 included international sales of BioFoam following receipt of the CE Mark approval during the third quarter of 2009. BioFoam sales accounted for less than 1% of total BioGlue and BioFoam sales for the three and nine months ended September 30, 2010. Domestic revenues accounted for 70% and 69% of total BioGlue revenues for the three and nine months ended September 30, 2010, respectively, and 70% of total BioGlue revenues for both the three and nine months ended September 30, 2009.

BioGlue has reached a level of market maturity in the U.S. and is experiencing increasing competitive pressures while continuing to achieve higher levels of growth and penetration in international markets due to its expanded clinical indications. Management believes that as economic conditions begin to improve, growth of BioGlue revenues in future periods would most likely be due to price increases and smaller volume increases or expansions into new markets. The Company expects a decrease in usage of BioGlue in the U.S. in those clinical applications for which new sealant products have FDA approval, partially offset by volume growth of BioGlue due to increases in cardiac and vascular surgical procedure volumes where BioGlue is used. The Company anticipates that it will begin shipping BioGlue to Japan in the first half of 2011, as BioGlue was recently approved in Japan for use in the repair of aortic dissections.

HemoStase

Revenues from the sale of HemoStase increased 36% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009. This increase was primarily due to a 32% increase in the volume of grams sold, which increased revenues by 33% and an increase in average selling prices, which increased revenues by 4%, partially offset by the unfavorable impact of foreign exchange, which decreased revenues by 1%.

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Revenues from the sale of HemoStase increased 48% for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009. This increase was primarily due to a 45% increase in the volume of grams sold, which increased revenues by 46% and an increase in average selling prices, which increased revenues by 3%, partially offset by the unfavorable impact of foreign exchange, which decreased revenues by 1%.

The increase in sales volume for the three and nine months ended September 30, 2010 was primarily due to an increase in shipments of HemoStase in domestic markets and to a lesser extent in international markets.

Management believes that the Company lost additional sales of HemoStase during the third quarter due to uncertainty in the market as to whether the Company had authority to market HemoStase and as to whether it would be able to continue to supply the product in the future. Management believes that third quarter HemoStase sales were also adversely impacted by continued sales by Medafor of Medafor s product into the Company s exclusive territory in violation of the EDA.

The increase in average selling prices for the three and nine months ended September 30, 2010 was primarily due to an increase in domestic average selling prices.

Domestic revenues accounted for 77% and 75% of total HemoStase revenues for the three and nine months ended September 30, 2010, respectively, and 76% of total HemoStase revenues for both the three and nine months ended September 30, 2009.

As discussed in Recent Events above, on September 27, 2010 Medafor informed CryoLife that it had fully and finally terminated the EDA based upon CryoLife s alleged repudiation. Based on this communication and subsequent communications CryoLife has received from Medafor, CryoLife does not believe that Medafor will make any further inventory shipments to CryoLife. CryoLife expects to continue to sell HemoStase until March 26, 2011, six months from the date Medafor sent the September 27, 2010 termination notice. Therefore, CryoLife does not expect to record revenues for HemoStase after that date. CryoLife expects HemoStase revenues during the fourth quarter of 2010 and the first quarter of 2011 to be flat or to decline from the level of revenues experienced for the three months ended September 30, 2010. Although it is difficult to determine, CryoLife s HemoStase revenues could be significantly negatively impacted during this period by confusion in the marketplace, continued competition from Medafor and other Medafor distributors selling into the Company s markets, and by discounts that the Company has offered and expects to continue to offer to its existing HemoStase customers during the period. See also Cost of Products below, Part I, Item 2, Risks and Uncertainties, and Part II, Item 1, Legal Proceedings.

Other Revenues

Other revenues for the three and nine months ended September 30, 2010 and 2009 included revenues related to funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the (DOD Grants). As of September 30, 2010 CryoLife had been awarded and had received a total of $5.4 million for the development of protein hydrogel technology, which the Company is currently developing for use in organ sealing. At September 30, 2010 CryoLife had $2.2 million of deferred income on the Company s Summary Consolidated Balance Sheet from the DOD Grants, of which $1.8 million remains in unspent cash advances recorded as cash and cash equivalents.

Cost of Preservation Services and Products

Cost of Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of preservation services	$ 8,911	$ 8,903	$ 27,322	$ 24,421
Cost of preservation services as a percentage of preservation services revenues	59%	59%	60%	57%

Cost of preservation services was flat for the three months and increased 12% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, respectively.

Cost of preservation services in the three months ended September 30, 2010 was primarily impacted by an increase in the per unit cost of processing tissues, offset by a decrease in cardiac tissues shipped, as discussed above. The increase in cost of preservation services in the nine months ended September 30, 2010 was primarily due to an increase in the per unit cost of processing tissues and an increase in vascular and cardiac tissues shipped, as discussed above.

The increase in cost of preservation services as a percentage of preservation services revenues for the nine months ended September 30, 2010 was primarily due to the increase in the per unit cost of processing tissues. The increase in the per unit cost of processing tissues in 2010, due to differences in the first half of 2010 as compared to the first half of 2009, was largely a result of decreased processing and packaging throughput.

Cost of Products

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of products	$ 4,310	$ 2,275	$ 9,318	$ 6,478
Cost of products as a percentage of product revenues	33%	18%	23%	16%

Cost of products increased 89% for the three months and 44% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009.

The increase in cost of products in the three and nine months ended September 30, 2010 was primarily due to a $1.6 million write-down of HemoStase inventory. To a lesser extent the increase in the three and nine months ended September 30, 2010 was due to the increase in shipments of HemoStase, as discussed above, and a slight increase in the per unit cost of BioGlue, partially offset by a decrease in the per unit cost of HemoStase and a slight decrease in shipments of BioGlue, as discussed above.

The write-down of HemoStase inventory was based on the Company s review of its inventory balances after Medafor s September 27, 2010 notice that it had fully and finally terminated the EDA with CryoLife to distribute HemoStase. Per the Company s review of the EDA, it expects to continue to sell HemoStase through March 26, 2011. Based on this review, the Company determined that the carrying value of the HemoStase inventory was impaired and increased its cost of products by $1.6 million to write-down HemoStase inventory. See also Recent Events and Revenues above, Part I, Item 2, Risks and Uncertainties, and Part II, Item 1, Legal Proceedings.

The amount of this write-down reflects management s estimate based on information currently available. Management will continue to evaluate the recoverability of its HemoStase inventory as more information becomes available and may record additional write-downs if it becomes clear that additional impairments have occurred. The write-down creates a new cost basis which cannot be written back up if the inventory becomes saleable. The cost of products in future periods may be favorably impacted if the Company is able to sell more HemoStase than the amounts estimated as discussed above.

The increase in cost of products as a percentage of product revenues for the three and nine months ended September 30, 2010 was primarily due to a $1.6 million write-down of HemoStase inventory, and to a lesser extent a slight increase in the per unit cost of BioGlue and increasing revenues from HemoStase, which has a lower profit margin than BioGlue, partially offset by an increase in BioGlue average selling prices, as discussed above.

Although the Company does not expect that an inventory write-down of a similar magnitude will affect cost of products and cost of products as a percentage of product revenues in future quarters, costs could be impacted in the fourth quarter of 2010 by additional write-downs or by discounts on sales of HemoStase that the Company has offered and expects to continue to offer, which would negatively impact cost of products as a percentage of product revenues.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
General, administrative, and marketing expenses	$ 11,376	$ 12,386	$ 36,863	$ 37,440

General, administrative, and marketing expenses as a percentage of total revenues	40%	44%	42%	45%

General, administrative, and marketing expenses decreased 8% for the three months and decreased 2% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009.

The decrease in general, administrative, and marketing expenses for the three and nine months ended September 30, 2010 was primarily due to a decrease in marketing expenses for the Ross Summit, which were incurred in the fourth quarter of 2010, while comparable marketing expenses for the 2009 Ross Summit were included in the third quarter of 2009. Additionally, marketing expenses including personnel costs and spending on marketing materials decreased, partially offset by an increase in spending on legal and professional fees.

Expenses in the three months ended September 30, 2010 included approximately $283,000 in costs associated with litigation with Medafor. Expenses in the nine months ended September 30, 2010 included $729,000 in previously capitalized legal fees associated with BioGlue patent litigation in Germany, approximately $1.1 million in costs associated with litigation with Medafor, and approximately $542,000 in business development costs, primarily associated with the Company s proposal to acquire Medafor.

The Company s general, administrative, and marketing expenses included $398,000 and $468,000 for the three months ended September 30, 2010 and 2009, respectively, and $1.7 million and $1.6 million for the nine months ended September 30, 2010 and 2009, respectively, related to the grant of stock options and restricted stock awards.

General, administrative, and marketing expenses for the fourth quarter of 2010 will be negatively impacted as compared to 2009 as a result of the Ross Summit expenses. The Company believes that expenses associated with lawsuits, including lawsuits with Medafor, and business development opportunities, including costs associated with potential acquisitions, may materially impact the Company s general, administrative, and marketing expenses for the remainder of 2010 and during 2011.

Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	$ 1,354	$ 1,461	$ 3,886	$ 3,854
Research and development expenses as a percentage of total revenues	5%	5%	4%	5%

Research and development spending in 2010 and 2009 was primarily focused on the Company s BioGlue family of products, including: BioGlue and BioFoam, and SynerGraft tissues and products, including: CryoValve SGPV, CryoValve SG aortic heart valves, CryoPatch SG, and xenograft SynerGraft tissue products.

Write-Down of Acquired In-Process Research and Development

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Write-down of acquired in-process research and development	$ 3,749	$	$ 3,749	$
Write-down of acquired in-process research and development as a percentage of total revenues	13%	%	4%	%

As part of the consideration paid to SMI, the Company allocated $3.7 million to an intangible asset for PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This $3.7 million is considered in-process research and development as it is dependant upon regulatory approvals which have not yet been obtained. Therefore, CryoLife wrote-down the $3.7 million as in-process research and development upon acquisition.

Other Income and Expenses

Interest expense was $29,000 and $58,000 for the three months ended September 30, 2010 and 2009, respectively, and $145,000 and $168,000 for the nine months ended September 30, 2010 and 2009, respectively. Interest expense for the three and nine months ended September 30, 2010 and 2009 included interest incurred related to the Company s debt and interest related to uncertain tax positions.

Interest income was $6,000 and $10,000 for the three months ended September 30, 2010 and 2009, respectively, and $16,000 and $73,000 for the nine months ended September 30, 2010 and 2009, respectively. Interest income for the three and nine months ended September 30, 2010 and 2009 was primarily due to interest earned on the Company s cash, cash equivalents, and restricted

securities. The decrease in interest income in 2010 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.

The other than temporary investment impairment was $3.6 million for both the three and nine months ended September 30, 2010, due to the impairment in the value of the Company s investment in Medafor common stock during the third quarter of 2010. The carrying value of the Company s investment in Medafor common stock after this write-down was $2.6 million or $1.09 per share as of September 30, 2010. The Company will continue to evaluate the carrying value of this investment as appropriate. If the Company subsequently determines that the value of its Medafor common stock has been impaired further or if the Company decides to sell its Medafor common stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in Medafor could be material.

The gain on valuation of derivative was $143,000 and $1.3 million for the three and nine months ended September 30, 2010, respectively. During the fourth quarter of 2009 and during 2010, the Company made several purchases of Medafor common stock that contained purchase price make-whole provisions, which the Company accounted for as embedded derivatives. The decrease in the value of the liability for these embedded derivatives, largely resulting from a significant decrease in the likelihood of a triggering event occurring, resulted in a non-cash gain for the three and nine months ended September 30, 2010. CryoLife believes that the likelihood of a triggering event occurring was substantially reduced in the first quarter and was zero as of September 30, 2010.

Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
(Loss) income before income taxes	$ (4,588)	$ 3,138	$ 3,819	$ 10,682
Income tax (benefit) expense	(1,557)	1,276	1,990	4,369
Net (loss) income	$ (3,031)	$ 1,862	$ 1,829	$ 6,313
Diluted weighted-average common shares outstanding	27,783	28,382	28,356	28,261
Diluted (loss) income per common share	$ (0.11)	$ 0.07	$ 0.06	$ 0.22

(Loss) income before income taxes decreased for the three months and the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009. (Loss) income before income taxes for the three and nine months ended September 30, 2010 was negatively impacted primarily by the write-down of acquired in-process research and development with no alternative future use, the other than temporary investment impairment, and the write-down of HemoStase inventory, as discussed above. These effects were partially offset by the gain on valuation of derivative for the nine months ended September 30, 2010.

The Company s effective income tax rate was a benefit of 34% for the three months ended September 30, 2010 and expense of 52% for the nine months ended September 30, 2010 as compared to expense of 41% for both the three and nine months ended September 30, 2009. The Company s income tax rate for the three and nine months ended September 30, 2010 was negatively impacted by the write-downs discussed above, which reduced pretax net income. The Company s effective income tax rate in the fourth quarter of 2010 is expected to be closer to the rates experienced in the first half of 2010.

Net (loss) income and diluted (loss) income per common share for the three and nine months ended September 30, 2010 decreased compared to the corresponding periods in 2009 due to the decrease in income before income taxes and income taxes as discussed above. Basic and diluted income per common share will be impacted in future periods unfavorably by the issuance of common stock to SMI and favorably by the Company s repurchase of its common stock. Stock repurchases are impacted by many factors, however, including stock price, available funds, and competing demands for such funds, and as a result, may be suspended or discontinued at any time.

Seasonality

The Company believes the demand for its cardiac preservation services is 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.

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The Company believes the demand for its vascular preservation services is seasonal, with lowest demand generally occurring in the fourth quarter. Management believes this trend for vascular preservation services is primarily due to fewer surgeries being scheduled during the winter holiday months.

The Company believes the demand for BioGlue is 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.

Liquidity and Capital Resources

Net Working Capital

At September 30, 2010 net working capital (current assets of $98.6 million less current liabilities of $18.3 million) was $80.3 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $76.3 million and a current ratio of 5 to 1 at December 31, 2009.

Overall Liquidity and Capital Resources

The Company s primary cash requirements for the nine months ended September 30, 2010 arose out of general working capital needs, consideration paid for the transaction with SMI, the acquisition of Medafor common stock, repurchases of the Company s common stock, and the payment of legal and professional fees. Legal and professional fees during the three and nine months ended September 30, 2010 included costs associated with the Company s litigation with Medafor and business development costs. The Company funded its cash requirements primarily through its operating activities, which generated cash during the period.

During 2009 the Company analyzed its deferred preservation cost balances and their recent growth and began a series of initiatives to reduce the growth of deferred preservation costs. As a result of these initiatives, the growth rate of the Company s deferred preservation costs slowed during 2009, and the balance of the Company s deferred preservation costs decreased by $4.1 million during the first nine months of 2010. The Company believes that its deferred preservation cost balances will continue to decrease for the remainder of 2010; however, the rate of decrease may slow in future months. The Company will continue to manage its incoming tissue procurement and other costs in an effort to manage its deferred preservation cost balances. However, the Company cannot predict its specific deferred preservation cost balances in the future with certainty. The Company believes that the current balance of its deferred preservation costs along with its ongoing preservation service activities is sufficient to support its current and projected revenues.

CryoLife entered into a credit facility with GE Capital in March of 2008, as amended (the GE Credit Agreement) which provides for up to $15.0 million in revolving credit for working capital, acquisitions, and other corporate purposes, of which $14.8 million was available for borrowing as of September 30, 2010. As of September 30, 2010 the outstanding balance under this agreement was zero. 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 in restricted securities on the Company s Summary Consolidated Balance Sheet. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined, of at least $20.0 million.

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, 2010 $1.8 million of the Company s cash equivalents were related to these DOD Grants, which must be used for the specified purposes.

The Company believes that its anticipated cash from operations and existing cash and cash equivalents 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 business development activities, including acquisitions and attempted acquisitions, to purchase license agreements, future repurchases of the Company s common stock, to fund the Medafor litigation, and for other corporate purposes. The Company has net operating loss carryforwards that will reduce otherwise required cash payments for federal and state income taxes for the 2010 tax year. Cash payments for taxes will increase in 2011 as the Company s federal net operating loss carryforwards are expected to be fully utilized in 2010.

Liability Claims

As of September 30, 2010 the Company had accrued a total $3.1 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to September 30, 2010 and had recorded a receivable of $1.2 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 $5.2 million, based on a higher estimate of future claims frequency. The $3.1 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 $13.8 million for the nine months ended September 30, 2010 as compared to $10.2 million for the nine months ended September 30, 2009.

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, 2010 these non-cash items included a favorable $3.7 million for the write-down of acquired in-process research and development as a result of the transaction with SMI, $2.9 million in depreciation and amortization expense, $3.6 million in other than temporary investment impairment, $2.0 million in write-downs of deferred preservation costs and inventory, primarily HemoStase, and $1.9 million in non-cash stock based compensation, partially offset by a $1.3 million non-cash gain on valuation of derivative.

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, 2010 these changes included a favorable $4.2 million due to decreases in deferred preservation costs, largely offset by an unfavorable $1.7 million increase in inventory balances, primarily HemoStase purchases prior to the non-cash write-down discussed above, and $2.1 million due to the timing difference between making cash payments and the expensing of assets, primarily prepaid royalties from the transaction with SMI.

The Company expects that the favorable impact of deferred preservation costs on its net cash from operating activities, as discussed above, will continue for the remainder of 2010.

Net Cash from Investing Activities

Net cash used in investing activities was $9.9 million for the nine months ended September 30, 2010 as compared to $1.3 million for the nine months ended September 30, 2009. The current year cash used was primarily due to $5.4 million in payments related to the transaction with SMI, $2.7 million in purchases of marketable securities and investments, largely related to the purchase of Medafor common stock, and $1.5 million in capital expenditures.

Net Cash from Financing Activities

Net cash used in financing activities was $3.0 million for the nine months ended September 30, 2010 as compared to net cash provided of $995,000 for the nine months ended September 30, 2009. The current year cash used was primarily due to $4.3 million in purchases of treasury stock, related to the Company s publicly announced stock repurchase plan, and $1.1 million in principal payments on capital leases and short-term notes payable, partially offset by $1.5 million in proceeds from the financing of insurance policies.

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, 2010 are as follows (in thousands):

	Total	Remainder of 2010	2011	2012	2013	2014	Thereafter
Operating leases	$ 29,232	$ 427	$ 2,601	$ 2,542	$ 2,472	$ 2,487	$ 18,703
Purchase commitments	8,523	1,312	1,128	2,583	3,500		
Compensation payments	3,589		1,604		992	993	
Research obligations	3,077	1,060	821	767	429		
SMI contingent payments	2,250		750		500	1,000	
Royalty payments	597		597				
Insurance premium obligations	487	355	132				
Other obligations	366	353	10	3			
Total contractual obligations	$ 48,121	$ 3,507	$ 7,643	$ 5,895	$ 7,893	$ 4,480	$ 18,703

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, leases on Company vehicles, and leases on a variety of office equipment.

The Company s purchase commitments include minimum purchase requirements for PerClot related to the Company s transaction with SMI. These minimum purchases are included through 2013, as that is when the Company expects to receive U.S. FDA approval for PerClot. Upon U.S. FDA approval the Company may terminate its minimum purchase requirements, which it expects to do, but if the Company does not terminate this provision, it will have minimum purchase obligations in 2014 and through the end of the contract term. The Company s purchase commitments also includes 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 and telecommunication services.

The Company s compensation payment obligations represent estimated cash payments to be made for its 2010 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 2012 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, which will be partially funded by the advances received under the DOD Grants. The timing of these obligations is based on the Company s estimates and will likely change as the related projects progress toward completion. Subsequent to September 30, 2010 the Company entered into a research obligation of $688,000 related to PerClot, which is not included in the scheduled contractual obligations and related payments above.

The obligation for SMI contingent payments represents the contingent milestone payments that the Company will pay if certain FDA regulatory approvals and other commercial milestones are achieved, as discussed in Recent Events above. The schedule excludes one contingent milestone payment of $500,000 as the Company cannot make a reasonably reliable estimate of timing of this future payment.

The Company s royalty payments are related to BioGlue and BioFoam revenues. The Company s insurance premium obligations represent the 2010 renewal of certain of the Company s insurance policies. The Company s other obligations contain various items including estimated real and personal property tax payments, advertising commitments, 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 $869,000, because the Company can not make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made for specific litigation or by any taxing authorities.

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Capital Expenditures

Capital expenditures for the nine months ended September 30, 2010 were $1.5 million compared to $1.3 million for the nine months ended September 30, 2009. Capital expenditures in the nine months ended September 30, 2010 were primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment, computer software, and renovations to the Company s corporate headquarters needed to support the Company s business.

Forward-Looking Statements

This Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. Forward-looking statements give the Company s current expectations or forecasts of future events. The words could, may, might, will, would, shall, should, pro forma, potential, pending, intend, believe, expect, anticipate, e similar expressions generally identify forwarding-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q. Such forward-looking statements reflect the views of 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 Form 10-Q.

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

The timing of the anticipated start of manufacturing of PerClot from plant starch modified by SMI;

The expected timing of contingent payments in the SMI transaction;

Expectations regarding the costs and timing related to the development and product launch of PerClot, the securing of Premarket Approval and U.S. FDA approval for PerClot, and the termination of the Distribution Agreement for PerClot;

The Company s belief that Medafor will not make any further HemoStase shipments to CryoLife;

The Company s expectations about usage and expiration of its income tax net operating loss carryforwards;

The Company s expectations regarding its borrowing capacity under the GE Credit Agreement;

Estimated liability for uncertain tax positions and interest and penalties;

Expectations regarding the factors that will affect basic and diluted income per common share in future periods, including stock repurchases and the SMI transaction;

The Company s estimate of probable losses and anticipated recoveries for unreported liability claims;

Anticipated future demand for cardiac and vascular tissues;

The Company s belief that it may experience additional favorable tissue mix during the remainder of 2010 if the Company continues shipping a higher percentage CryoValve SGPVs than in the corresponding year periods;

Expectations regarding growth of BioGlue volume and revenues in future periods;

The Company s expectations regarding BioGlue usage in the U.S. in clinical applications for which new sealant products have FDA approval;

The Company s expectation that it will begin selling BioGlue in Japan in the first half of 2011;

Expectations that the Company will continue to distribute HemoStase for a six-month period following the most recent termination of the EDA and that the Company will not record HemoStase revenues after the expiration of the six-month period;

The Company s expectations for HemoStase revenues during the fourth quarter of 2010 and the first quarter of 2011;

The Company s belief that the remaining value of the HemoStase inventory after write-down is recoverable over the six-month period following the most recent termination of the EDA;

Expectations related to discounted sales of HemoStase inventory and any future write-down of HemoStase inventory, and any resultant impact on cost of products and cost of products as a percentage of product revenues;

Expectations regarding any future impairment charges or realized losses related to the Company s investment in Medafor, or the likelihood of the occurrence of a Triggering Event with respect to the Company s investment in Medafor;

Expectations that the Company s general, administrative, and marketing expenses for the remainder of 2010 and during 2011 may be materially impacted by expenses associated with lawsuits and business development opportunities, and that such expenses will be negatively impacted for the fourth quarter of 2010 as compared to 2009 as a result of the Ross Summit expenses;

Expectations regarding the Company s effective income tax rate in the fourth quarter of 2010;

The Company s belief that its deferred preservation cost balances will continue to decrease for the remainder of 2010, and that the rate of decrease may slow in future months;

The Company s belief that the current balance of its deferred preservation costs along with its ongoing preservation service activities is sufficient to support its current and projected revenues;

The Company s expectations that the favorable impacts of deferred preservation costs and deferred income taxes on its net cash from operating activities will continue for the remainder of 2010;

The Company s belief that it will have sufficient cash to meet its operational liquidity needs for at least the next twelve months;

Expectations that the Company s future cash requirements may include cash for general working capital needs, to fund business development activities, including acquisitions and attempted acquisitions, to purchase license agreements, future repurchases of the Company s common stock, to fund the Medafor litigation, and for other corporate purposes;

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

The Company s expectations regarding the timing of court rulings in its legal proceedings, actions the Company may take during the course of litigation, and any loss that may occur as a result of litigation; 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, the risks set forth under Part II, Item 1A of the Company s Form 10-Q for the quarter ended March 31, 2010, the risk factors set forth under Part I, Item 1A of the Company s Form 10-K for the year ended December 31, 2009, 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 are subject to stringent domestic and foreign regulation which may impede the approval process of our tissues and products, hinder our development activities and manufacturing processes and, in some cases, result in the recall or seizure of previously cleared or approved tissues and products;

Our investment in Medafor has been diluted as a result of Medafor s issuance of 1.8 million shares to Magle Life Sciences, and in the future Medafor could issue additional shares to dilute which could result in an additional impairments in the value of our investment in Medafor common stock, which could have a material adverse effect on our financial condition and profitability;

Our investment in Medafor may be impacted by Medafor s decision to terminate our EDA with Medafor, as CryoLife was Medafor s largest distributor in 2009 and 2008. As a result, we could in the future determine that further impairment in the value of our investment in Medafor common stock has occurred, which could have a material adverse effect on our financial condition and profitability;

We may not be able to readily liquidate our investment in Medafor, and if we are able to liquidate our investment, we may receive less cash than our original investment and we may receive less than the carrying value of our investment;

Medafor has terminated the EDA and ceased shipments of HemoStase to us, and our remaining sales of HemoStase, may be at a discount, which may have a material adverse effect on our revenues and profitability;

We have made a substantial investment in our distribution and license and manufacturing agreements with SMI and will commit additional funds in order to attempt to obtain FDA approval for PerClot in the U.S., and our short-term liquidity and earnings in 2010 and 2011 will be impacted by these expenditures and we will not fully realize the benefit of our investment in future years unless we are able to obtain FDA approval for PerClot in the U.S.;

We may be unsuccessful in our attempts to sell PerClot in the U.S., we may be prevented by Medafor from selling PerClot in both international and domestic markets, and our ability to successfully market and sell PerClot may take longer than expected;

Medafor has filed counter-claims against us with respect to our lawsuit against Medafor, and if Medafor is successful in its claims, our revenues, profitability, and cash flows may be materially, adversely affected;

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us;

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 distributed by CryoLife may adversely affect the ability of CryoLife to distribute those products;

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

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

Our CryoValve SGPV post-clearance study may not provide expected results;

Demand for our tissues and products could decrease in the future, which could have a material adverse effect on our business;

The success of many of our tissues and products depends upon strong relationships with physicians;

Consolidation in the healthcare industry could lead to demands for price concessions or limits or eliminate our ability to sell to certain of our significant market segments;

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;

The loss of any of our sole-source suppliers could have an adverse effect on our revenues, financial condition, profitability, and cash flows;

Intense competition may affect our ability to operate profitably;

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

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

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

Our credit facility limits our ability to pursue significant acquisitions;

Key growth strategies may not generate the anticipated benefits;

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

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 services and products in development, and our new services and products may not achieve market acceptance;

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

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 may be unable to increase our revenues;

We are not insured against all potential losses. Natural disasters or other catastrophes could adversely affect our business, financial condition, and profitability;

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; and

We have not paid cash dividends on our capital stock and may be unable to do so due to legal or contractual restrictions.

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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 $31.0 million and $5.0 million of the Company s restricted securities as of September 30, 2010, and could impact interest paid on future borrowings under the Company s variable rate line of credit. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended September 30, 2010, affecting the Company s cash and cash equivalents, restricted securities, 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 and BioFoam revenues, a portion of the Company s HemoStase revenues, the majority of the Company s future international PerClot revenues, 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.

Changes in exchange rates which occurred during the nine months ended September 30, 2010 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 2010. An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2010 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, 2010 as compared to the weighted-average exchange rates experienced by the Company for the nine months ended September 30, 2010 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 of Finance, 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, 2010 the CEO and CFO have concluded that the Company s Disclosure Controls were effective at the

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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, 2010, 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.

CryoLife s Lawsuit and Claims with Medafor

As previously reported in CryoLife s Annual Report on Form 10-K for the year ended December 31, 2009, and CryoLife s Forms 10-Q for the quarters ended March 31, 2010, and June 30, 2010, CryoLife filed a lawsuit against Medafor, Inc. in 2009 in the U.S. District Court for the Northern District of Georgia (the Court), alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia s Racketeer Influenced and Corrupt Organizations Act (Georgia RICO). The lawsuit arises out of an exclusive distribution agreement between the parties (the EDA), which gave CryoLife the right to distribute a product manufactured by Medafor under the name HemoStase. The Court dismissed CryoLife s Georgia RICO claim on August 9, 2010. On October 20, 2010 CryoLife filed supplemental claims against Medafor for additional breaches of contract, including those related to Medafor s wrongful termination of the EDA.

CryoLife s Potential Damages

The Company seeks to recover its damages from Medafor, accompanied by preliminary and permanent injunctive relief, punitive damages, and reimbursement of its attorneys fees. In addition, the Company will seek damages related to Medafor s wrongful termination of the EDA, which will be based upon the Company s lost profits for the period of time during which the EDA would have continued in effect but for Medafor s termination of it. The amount of these damages will be determined through discovery in the lawsuit. No trial date has been set.

Medafor s Counter-claims

On September 8, 2010 Medafor answered CryoLife s complaint and filed a counter-complaint against CryoLife, alleging claims for, among other things, breach of contract, breach of the implied duty of good faith and fair dealing, violation of the Georgia trade secrets act, tortious interference with business relationships, libel, violation of the uniform deceptive trade practices act, fraud and negligent misrepresentation. In addition, Medafor requested that the Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Uniform Commercial Code.

Background on Current Status of the EDA Medafor s Decision to Terminate the EDA Due to CryoLife s Alleged Repudiation

As previously reported in CryoLife s Current Report on Form 8-K dated March 19, 2010, and CryoLife s Forms 10-Q for the quarters ended March 31, 2010 and June 30, 2010, Medafor informed CryoLife on March 18, 2010 of its contention that CryoLife had repudiated the EDA, thereby entitling Medafor to terminate the EDA. Medafor asserted that it had made a valid statutory demand, in a February 10, 2010 letter to CryoLife, for adequate assurances of CryoLife s future performance under the EDA, and that CryoLife had repudiated the EDA by failing to respond in a timely manner. On March 22, 2010, CryoLife informed Medafor that it disputed Medafor s assertions, and that Medafor had no right to terminate the EDA. CryoLife then filed a motion for preliminary injunction, asking the Court to enjoin Medafor from proceeding with its termination of the EDA.

As previously reported in CryoLife s Current Report on Form 8-K dated September 20, 2010, the Court, on September 20, 2010, issued an order denying CryoLife s request for a preliminary injunction against Medafor. Although the order denied the preliminary injunction, it did not address the merits of the parties respective positions on the underlying issues, which the Court viewed as more appropriately addressed at summary judgment.

As previously reported in CryoLife s Current Report on Form 8-K dated September 28, 2010, on September 27, 2010, Medafor sent CryoLife a letter stating that it had fully and finally terminated the EDA based upon CryoLife s alleged repudiation. This was Medafor s sixth termination or termination attempt with respect to the EDA.

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Medafor s Letters to CryoLife Asserting Additional Claims

On September 29, 2010 Medafor notified CryoLife that it was Medafor s position that CryoLife s interactions with Starch Medical, Inc. had resulted in numerous breaches of the EDA by CryoLife that could not be cured. Medafor additionally informed CryoLife that Medafor believed these alleged breaches were additional bases for termination of the EDA. Finally, Medafor informed CryoLife that Medafor would promptly move to amend its counter-claim to add additional claims for breach of contract and fraud, and for conspiracy and aiding and abetting, and other undefined claims.

On October 1, 2010 Medafor notified CryoLife that it was Medafor s position that CryoLife s continued selling of HemoStase tortiously interferes with Medafor s customer relationships and violates the Lanham Act and Georgia s Deceptive Trade Practices Act. Medafor informed CryoLife that if CryoLife continued to sell HemoStase, Medafor would amend its counter-claim to add claims for violations of the Lanham Act and Georgia s Deceptive Trade Practices Act, and other undefined claims.

As of November 4, 2010 Medafor has not amended its counter-claims, although CryoLife expects Medafor to do so by November 12, 2010.

Summary of Medafor s Potential Damages Claims

Pursuant to its counter-claims to date, Medafor seeks to recover its alleged damages from CryoLife, including rescinding the EDA to restore to Medafor all of the benefits that CryoLife has received under the EDA, compensatory damages, injunctive relief, prejudgment interest, punitive damages, and attorneys fees and expenses.

Current Status of the Lawsuit

No trial date has been set. Discovery began on October 8, 2010. CryoLife has filed Rule 12(e) and (f) motions, requesting that the Court compel Medafor to make more definitive claims with regards to its counter-claims for libel, violations of the Uniform Deceptive Trade Practices Act, and rescission and to strike several of Medafor s affirmative defenses to CryoLife s claims. Medafor filed a motion in response to CryoLife s Rule 12(e) and (f) motions generally opposing CryoLife s requests. CryoLife may also file a Rule 12(c) motion for judgment on the pleadings in order to have the Court dismiss certain claims made by Medafor. CryoLife intends to vigorously prosecute the case and defend itself and contest the matter.

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 10-K for the year ended December 31, 2009, as updated by Part II, Item 1A, Risk Factors in our Forms 10-Q for the quarters ended March 31, 2010 and June 30, 2010.

Medafor Has Terminated The EDA And Ceased Shipments Of HemoStase To Us, Competition From Medafor May Negatively Impact HemoStase Sales And Our Remaining Sales Of HemoStase May Be At A Discount Which May Have A Material Adverse Effect On Our Revenues And Profitability.

On March 18, 2010 Medafor announced that it was treating the EDA as terminated. Medafor alleged that it was entitled under Georgia law to demand adequate assurances from us that we would perform under the EDA, and that we had repudiated the EDA by not timely providing adequate assurances. We, thereafter, moved the Court to preliminarily enjoin Medafor from proceeding with its termination. On September 20, 2010 the Court issued an order denying our request for the preliminary injunction. On September 27, 2010 Medafor informed us that it had fully and finally terminated the EDA based upon our alleged repudiation.

Because Medafor has terminated the EDA and ceased shipments of HemoStase to us, we are no longer able to distribute HemoStase as contemplated by the EDA. As such, we may not be able to sell our remaining inventory of HemoStase. We have begun selling HemoStase at a discount and a portion of our remaining HemoStase inventory will likely continue to be sold at a discount, which may have a material adverse effect on our revenues and profitability in 2010 and into 2011. Also, while we believe that we are entitled, pursuant to the terms of the EDA, to distribute our remaining inventory through March 26, 2011, Medafor may file a claim in court to challenge our ability to continue to distribute the remaining inventory or otherwise attempt to prevent further sales of HemoStase. If we are not able to sell our remaining inventory of HemoStase, our revenues and profitability may be materially, adversely impacted in the remainder of 2010 and into 2011. If we are able to sell our remaining HemoStase inventory, we will not be able to obtain additional product from Medafor and once our current inventory is depleted, we will have no further HemoStase sales. Additionally, competition from Medafor may diminish the sale of our current inventory.

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Revenues from HemoStase were approximately $2.1 million, $6.1 million, and $6.0 million for the three months ended September 30, 2010, the nine months ended September 30, 2010, and the year ended December 31, 2009, respectively.

See Part I, Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations, for further information regarding the EDA with Medafor and see Part II, Item 1, Legal Proceedings, for further information regarding our litigation with Medafor.

We Have Made A Substantial Investment In Our Distribution And License And Manufacturing Agreements With SMI And Will Commit Additional Funds In Order To Attempt To Obtain FDA Approval For PerClot In The U.S., And Our Short-Term Liquidity And Earnings In 2010 And 2011 Will Be Materially Impacted By These Expenditures And We Will Not Fully Realize The Benefit Of Our Investment In Future Years Unless We Are Able To Obtain FDA Approval For PerClot In The U.S.

On September 28, 2010 we entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI, pursuant to which we will distribute and ultimately manufacture PerClot. We are also authorized, pursuant to the license and manufacturing agreement, to pursue, obtain, and maintain regulatory approval for PerClot in the U.S., as such regulatory approvals do not yet exist in the U.S. If this approval is not obtained prior to October 1, 2017, SMI may terminate our rights with respect to U.S. regulatory approval and require us to negotiate a reasonable revision to the agreement.

As part of the transaction, we paid SMI $6.75 million in cash which includes $1.5 million in prepaid royalties and $1.25 million in restricted CryoLife common stock. We will pay up to an additional $2.75 million to SMI if certain U.S. regulatory and other commercial milestones are achieved, and will also pay royalties on sales of PerClot manufactured by CryoLife. We anticipate that we will spend between $5.0 million and $6.0 million to gain U.S. regulatory approval in the next several years, most of which will be incurred in 2011 and 2012. Our costs may be greater than anticipated, as the costs to begin manufacturing PerClot from plant starch modified by SMI and the costs involved in the rollout of our new product are estimates and may ultimately be greater than anticipated.

Our investment in our agreements with SMI will impact our short-term liquidity and earnings in 2010 and 2011 and we will not be able to fully realize the benefit of our investment in future years unless we are able to obtain the necessary regulatory approvals in the U.S. to distribute PerClot.

We May Be Unsuccessful In Our Attempts To Sell PerClot In The U.S., Medafor May Attempt To File A Lawsuit, Including A Patent Infringement Case, Against Us Which May Prevent Us From Selling PerClot In Both International And Domestic Markets, And Our Ability To Successfully Market And Sell PerClot May Take Longer Than Expected.

Even if we are able to obtain FDA approval to distribute PerClot in the U.S. according to our estimated timeline, we may be unsuccessful in our attempts to sell PerClot in the U.S. as other competing products may have penetrated the market by that time. Also, while we do not believe Medafor would have a valid reason to do so, based on our past history with Medafor, it is possible that Medafor may attempt to challenge the legality of our distribution of PerClot in both the U.S. and international markets or file a patent infringement action against us. If we are ultimately unable to distribute PerClot in the U.S., we would not be able to fully realize the benefit of our investment in PerClot.

Also, some level of confusion in the marketplace may exist in the short-term as we transition to selling both HemoStase and PerClot, and then to selling only PerClot. Any such confusion among our customers may lead to lower than anticipated sales of PerClot in 2010 and 2011. Further, Medafor may attempt to compete directly with us with respect to our current HemoStase customers and convince them to purchase its hemostatic agent instead of purchasing PerClot from us.

Medafor Has Filed Counter-Claims Against Us With Respect To Our Lawsuit Against Medafor, And If Medafor Is Successful In Its Claims, Our Revenues And Profitability May Be Materially, Adversely Affected.

CryoLife filed a lawsuit against Medafor in 2009 in the Court, alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia s Racketeer Influenced and Corrupt Organizations Act (Georgia RICO). The lawsuit arises out of the EDA that has recently been terminated by Medafor.

Medafor has filed counter-claims against CryoLife. We have disputed the validity of Medafor s counter-claims and intend to continue to vigorously defend our rights. If Medafor is successful and the Court rules in their favor, then we could be required to make substantial payments to Medafor as part of the judgment. While the details of any judgment that may be rendered against CryoLife in such a scenario are uncertain, the possibility exists that a judgment against CryoLife could have a material adverse effect on our profitability and cash flows.

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See Part I, Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations, for further information regarding the EDA with Medafor and see Part II, Item 1, Legal Proceedings, for further information regarding our litigation with Medafor.

Our Investment In Medafor May Be Impacted By Medafor s Decision To Terminate Our EDA With Medafor, As CryoLife Was Medafor s Largest Distributor In 2009 And 2008. As A Result, We Could In The Future Determine That Further Impairment In The Value Of Our Investment In Medafor Common Stock Has Occurred, Which Could Have A Material Adverse Effect On Our Financial Condition And Profitability.

In November 2009 and in 2010, CryoLife purchased approximately 2.4 million shares of Medafor common stock. The carrying value of that investment on our books was reduced in the third quarter of 2010 to $2.6 million primarily because Medafor terminated our EDA with Medafor. CryoLife was Medafor s largest distributor in 2009 and 2008, accounting for 19% and 15%, respectively of Medafor s total revenues.

Medafor s decision to terminate the EDA may negatively impact its revenues and profitability. In accordance with accounting principles generally accepted in the U.S. (GAAP) we reviewed available information and determined that as of September 30, 2010, factors were present indicating that we should evaluate our investment in Medafor common stock for impairment and we then determined that an impairment in our investment in Medafor had occurred. We could subsequently determine that, in accordance with GAAP, a further impairment in the value of our investment in Medafor common stock has occurred if, among other things, Medafor s revenues decline further than anticipated due to its loss of its largest distributor. If further impairment occurs in the future, we would be required to take a non-cash charge to earnings, which could have a material adverse effect on our financial condition and profitability. Also, Medafor could take future actions beyond our control that could further impair the value of our investment.

See Part I, Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations, for further information regarding the EDA with Medafor and see Part II, Item 1, Legal Proceedings, for further information regarding our litigation with Medafor.

We May Not Be Able To Readily Liquidate Our Investment In Medafor, And If We Are Able To Liquidate Our Investment, We May Receive Less Cash Than Our Original Investment And We May Receive Less Than The Carrying Value Of Our Investment.

In November 2009 and in 2010, CryoLife purchased approximately 2.4 million shares of Medafor common stock. The carrying value of that investment on our books was reduced in the third quarter of 2010 to $2.6 million. We are a minority Medafor shareholder and may not be able to readily liquidate our investment in Medafor because Medafor is privately held, and there is not a public market for Medafor shares. In addition, the value of the Medafor common stock may further decline in value in the future for reasons including those disclosed in the three immediately preceding risk factors. If we wish to liquidate our investment in Medafor to raise cash, we might not be able to do so in a timely fashion or at all and we may not receive a value that we believe is appropriate at that time. In addition, the cash we receive from such as sale could be less than the $4.9 million initially paid for the Medafor common stock. In the event that we chose to sell our Medafor stock for less than $2.6 million, the recorded value of our investment in Medafor, the difference would be recorded as a charge against earnings, which could have a material adverse effect on our financial condition and profitability.

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

(a) On September 28, 2010 CryoLife agreed to issue $1.25 million in restricted CryoLife common stock to Starch Medical, Inc. (SMI) as determined by the average closing CryoLife stock price for the trailing ten trading days pursuant to the terms of the distribution agreement and the license and manufacturing agreement between CryoLife and SMI, both dated September 28, 2010, as more fully described in CryoLife s Current Report on Form 8-K filed with the SEC on October 4, 2010. Accordingly, on October 13, 2010, CryoLife issued 209,240 shares of restricted CryoLife common stock to SMI.

The shares have not been registered under the Securities Act of 1933, as amended (the Securities Act), or applicable state securities laws upon the basis that the transaction involving their sale is exempt from such registration requirements as a transaction by an issuer not involving any public offering in reliance on Rule 506 of Regulation D, as promulgated by the SEC pursuant to the Securities Act. SMI is an accredited investor, as that term is defined in Regulation D.

(c) The following table provides information about purchases by the Company during the quarter ended September 30, 2010 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	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
07/01/10	07/31/10	238,901	$ 5.49	237,279	$ 12,186,892
08/01/10	08/31/10	145,051	5.51	145,051	11,387,468
09/01/10	09/30/10	110,878	5.76	110,878	10,748,898
Total		494,830	5.55	493,208	10,748,898

On June 1, 2010 the Company publicly announced that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions on such terms as management deems appropriate, and will be dependant upon various factors, including price, regulatory requirements, and other market conditions. As of September 30, 2010 the Company had purchased 767,000 shares of its common stock for an aggregate purchase price of $4.3 million.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. (Removed and Reserved).

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 Current Report on Form 8-K filed January 6, 2010.)
4.1	Form of Certificate for the Company s Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant s Annual Report on Form 10-K for the fiscal 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.)
10.1*+	Distribution Agreement between the Company and Starch Medical, Inc., dated September 28, 2010.
10.2*+	License Agreement between the Company and Starch Medical, Inc., dated September 28, 2010.
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.

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

SIGNATURES

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

CRYOLIFE, INC.

(Registrant)

/s/ STEVEN G. ANDERSON
STEVEN G. ANDERSON

Chairman, President, and

Chief Executive Officer

(Principal Executive Officer)

/s/ D. ASHLEY LEE
D. ASHLEY LEE

Executive Vice President,

Chief Operating Officer, and

Chief Financial Officer

(Principal Financial and Accounting Officer)

November 5, 2010

DATE