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	