

CRYOLIFE INC
Form 10-Q
October 30, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended **September 30, 2012**

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
(State or other jurisdiction of
incorporation or organization)

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

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

30144
(Zip Code)

(770) 419-3355

(Registrant's telephone number, including area code)

Not Applicable

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Edgar Filing: CRYOLIFE INC - Form 10-Q

Yes

No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

Yes

No

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

Class
Common Stock, \$.01 par value per share

Outstanding at October 25, 2012
27,440,437 Shares

Part I FINANCIAL INFORMATION**Item 1. Financial Statements.****CRYOLIFE, INC. AND SUBSIDIARIES****SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME****(IN THOUSANDS, EXCEPT PER SHARE DATA)**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
	(Unaudited)		(Unaudited)	
Revenues:				
Preservation services	\$ 16,399	\$ 14,656	\$ 48,371	\$ 45,018
Products	16,893	14,923	50,043	43,932
Other	137	75	504	279
Total revenues	33,429	29,654	98,918	89,229
Cost of preservation services and products:				
Preservation services	9,005	8,349	26,645	25,709
Products	3,114	2,393	8,300	7,051
Total cost of preservation services and products	12,119	10,742	34,945	32,760
Gross margin	21,310	18,912	63,973	56,469
Operating expenses:				
General, administrative, and marketing	16,533	14,726	48,374	42,676
Research and development	1,829	1,690	5,192	5,099
Total operating expenses	18,362	16,416	53,566	47,775
Operating income	2,948	2,496	10,407	8,694
Interest expense	42	49	159	116
Interest income	(1)	(1)	(4)	(13)
Other expense (income), net	283	159	442	(12)
Income before income taxes	2,624	2,289	9,810	8,603
Income tax expense	1,086	270	3,947	3,098
Net income	\$ 1,538	\$ 2,019	\$ 5,863	\$ 5,505

Income per common share:

Edgar Filing: CRYOLIFE INC - Form 10-Q

Basic	\$ 0.06	\$ 0.07	\$ 0.21	\$ 0.20
Diluted	\$ 0.06	\$ 0.07	\$ 0.21	\$ 0.19
Dividends declared per share	\$ 0.025	\$ --	\$ 0.025	\$ --
Weighted-average common shares outstanding:				
Basic	26,810	27,523	26,951	27,431
Diluted	27,210	27,850	27,329	27,765
Net income	\$ 1,538	\$ 2,019	\$ 5,863	\$ 5,505
Other comprehensive income (loss)	20	(5)	28	5
Comprehensive income	\$ 1,558	\$ 2,014	\$ 5,891	\$ 5,510

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	September 30, 2012	December 31, 2011
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,790	\$ 21,705
Restricted securities	324	312
Trade receivables, net	17,322	15,767
Other receivables	1,453	1,738
Deferred preservation costs	28,032	29,039
Inventories	10,246	7,320
Deferred income taxes	3,828	5,247
Prepaid expenses and other	3,234	2,742
Total current assets	72,229	83,870
Property and equipment, net	11,924	12,308
Investment in equity securities	5,908	6,248
Restricted cash and securities	5,000	5,000
Goodwill	11,300	4,220
Patents, net	2,166	2,739
Trademarks and other intangibles, net	22,389	17,656
Notes receivable	1,000	--
Deferred income taxes	18,492	13,265
Other	3,082	2,558
Total assets	\$ 153,490	\$ 147,864
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,661	\$ 4,370
Accrued compensation	4,423	3,946
Accrued procurement fees	4,292	3,982
Accrued expenses and other	6,017	7,269
Deferred income	1,471	1,890
Total current liabilities	19,864	21,457
Contingent consideration liability	1,902	--
Other	5,808	4,869
Total liabilities	27,574	26,326
Commitments and contingencies		
Shareholders' equity:		

Edgar Filing: CRYOLIFE INC - Form 10-Q

Preferred stock	--	--
Common stock (issued shares of 27,454 in 2012 and 30,067 in 2011)	275	301
Additional paid-in capital	121,553	135,003
Retained earnings (deficit)	4,140	(1,037)
Accumulated other comprehensive income (loss)	22	(6)
Treasury stock at cost (shares of 14 in 2012 and 2,265 in 2011)	(74)	(12,723)
Total shareholders equity	125,916	121,538
Total liabilities and shareholders equity	\$ 153,490	\$ 147,864

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,	
	2012	2011
	(Unaudited)	
Net cash flows from operating activities:		
Net income	\$ 5,863	\$ 5,505
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	4,176	3,557
Non-cash compensation	2,251	2,140
Deferred income taxes	1,636	41
Other non-cash adjustments to income	1,054	487
Changes in operating assets and liabilities:		
Receivables	(790)	1
Deferred preservation costs and inventories	(1,365)	2,300
Prepaid expenses and other assets	(792)	(968)
Accounts payable, accrued expenses, and other liabilities	(1,025)	644
Net cash flows provided by operating activities	11,008	13,707
Net cash flows from investing activities:		
Acquisition of Hemosphere, net of cash acquired	(17,040)	--
Acquisition of Cardiogenesis, net of cash acquired	--	(21,062)
Advances under notes receivable	(1,000)	--
Capital expenditures	(2,210)	(1,993)
Purchases of restricted securities and investments	--	(3,569)
Other	(760)	(506)
Net cash flows used in investing activities	(21,010)	(27,130)
Net cash flows from financing activities:		
Cash dividends paid	(686)	--
Proceeds from exercise of stock options and issuance of common stock	302	703
Repurchases of common stock	(3,463)	(1,607)
Other	(74)	(109)
Net cash flows used in financing activities	(3,921)	(1,013)
Decrease in cash and cash equivalents	(13,923)	(14,436)
Effect of exchange rate changes on cash	8	(11)
Cash and cash equivalents, beginning of period	21,705	35,497

Cash and cash equivalents, end of period	\$ 7,790	\$ 21,050
---	-----------------	------------------

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, 2011 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, 2012 and 2011 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, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. 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, 2011.

2. Financial Instruments

The Company's financial instruments include cash equivalents, marketable securities, restricted securities, accounts receivable, notes receivable, and accounts payable. The Company typically values financial assets and liabilities such as receivables, accounts payable, and debt obligations at their carrying values, which approximate fair value due to their generally short-term duration.

The Company records certain financial instruments at fair value, including: cash equivalents, certain marketable securities, and certain restricted securities. These financial instruments are discussed in further detail in the notes below. The Company may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis, although as of September 30, 2012 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels.

The following is a summary of the Company's financial instruments measured at fair value (in thousands):

September 30, 2012	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ --	\$ 781	\$ --	\$ 781
Restricted securities:				
Money market funds	--	324	--	324
Total assets	--	1,105	--	1,105
Long-term liabilities:				
Contingent consideration	--	--	(1,902)	(1,902)
Total liabilities	--	--	(1,902)	(1,902)
Net assets (liabilities)	\$ --	\$ 1,105	\$ (1,902)	\$ (797)

December 31, 2011	Level 1	Level 2	Level 3	Total
--------------------------	----------------	----------------	----------------	--------------

Edgar Filing: CRYOLIFE INC - Form 10-Q

Cash equivalents:								
Money market funds	\$	--	\$	7,334	\$	--	\$	7,334
Restricted securities:								
Money market funds		--		5,312		--		5,312
Total assets	\$	--	\$	12,646	\$	--	\$	12,646

The Company used prices quoted from its investment management companies to determine the Level 2 valuation of its investments in money market funds and securities. The Company recorded contingent consideration liability, classified as Level 3, as

Edgar Filing: CRYOLIFE INC - Form 10-Q

a result of its acquisition of Hemosphere, Inc. (Hemosphere) in May 2012. Refer to Note 4 for further discussion of the Level 3 contingent consideration liability. Changes in fair value of Level 3 liabilities are listed below (in thousands):

	Contingent Consideration
Balance as of December 31, 2011	\$ --
Discounted value of contingent consideration at acquisition	1,840
Loss on remeasurement of contingent consideration	62
Balance as of September 30, 2012	\$ 1,902

The Company also measures certain non-financial assets at fair value on a non-recurring basis when applying accounting for business combinations or when asset impairments are recorded. The Company uses the fair value hierarchy to value these assets and reports these fair values in the periods in which they are recorded or written down. During the nine months ended September 30, 2012 the Company initially recorded certain non-financial assets at fair value related to the acquisition of Hemosphere. Refer to the discussion of the inputs and methods used in the non-recurring valuation of the Company's assets acquired from Hemosphere in Note 4. During the year ended December 31, 2011 the Company initially recorded certain non-financial assets at fair value related to the acquisition of Cardiogenesis Corporation (Cardiogenesis). Refer to the discussion of the inputs and methods used in the non-recurring valuation of the Company's assets acquired from Cardiogenesis in Note 6. As of September 30, 2012 the Company revalued its investment in ValveXchange, Inc. (ValveXchange) preferred stock on a non-recurring basis after initial recognition using a Level 3 valuation. Refer to the discussion of the inputs and methods used in the non-recurring valuation of the Company's investment in ValveXchange in Note 5. No non-financial assets were measured at fair value on a non-recurring basis after initial recognition in the Company's Summary Consolidated Balance Sheets as of December 31, 2011.

3. Cash Equivalents and Restricted Cash and Securities

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

	Cost Basis	Unrealized Holding Gains	Estimated Market Value
September 30, 2012			
Cash equivalents:			
Money market funds	\$ 781	\$ --	\$ 781
Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	324	--	324

December 31, 2011

Cash equivalents:			
Money market funds	\$ 7,334	\$ --	\$ 7,334
Restricted securities:			
Money market funds	5,312	--	5,312

As of September 30, 2012 and December 31, 2011 \$324,000 and \$312,000, respectively, 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, 2012 \$5.0 million of the Company's cash was designated as long-term restricted cash and securities due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation (GE Capital) as discussed in Note 12. As of December 31, 2011 \$5.0 million of the Company's money market funds were designated as long-term restricted cash and securities under the same covenant. This restriction lapses upon expiration of the credit agreement with GE Capital on October 28, 2014.

There were no material realized gains or losses on cash equivalents in the nine months ended September 30, 2012 and 2011. As of September 30, 2012 \$324,000 of restricted securities had a maturity date of between three months and one year. As of December 31, 2011 \$5.0 million of the Company's restricted securities had no maturity date, and \$312,000 of restricted securities had a maturity date within three months.

4. Hemosphere Acquisition

Overview

On May 16, 2012 CryoLife completed its acquisition of 100% of the outstanding equity of Hemosphere, a privately held company, for \$17.0 million in cash, an additional \$3.2 million to pay for cash acquired, and contingent consideration with a fair value estimated to be approximately \$1.8 million at acquisition, for a total purchase price of approximately \$22.0 million. CryoLife used cash on hand to fund the transaction and operates Hemosphere as a wholly owned subsidiary.

Hemosphere is the developer and marketer of the Hemodialysis Reliable Outflow Graft (HeRO[®] Graft), a proprietary graft-based solution for end-stage renal disease hemodialysis patients with limited access options and central venous obstruction. CryoLife believes that the HeRO Graft will fit well into its product portfolio of medical devices for cardiac and vascular surgery and believes that there is a significant opportunity for CryoLife's sales team to leverage their strong relationships with vascular surgeons to introduce and to expand utilization of the HeRO Graft in the U.S.

Contingent Consideration

As of the acquisition date, CryoLife recorded a contingent consideration liability of \$1.8 million in long-term liabilities on its Summary Consolidated Balance Sheet, representing the estimated fair value of the contingent consideration expected to be paid to the former shareholders of Hemosphere upon the achievement of certain revenue-based milestones. The acquisition agreement provides for a maximum of \$4.5 million in future consideration payments through December 2015 based on specified sales targets.

The fair value of the contingent consideration liability was estimated by discounting to present value the contingent payments expected to be made based on a probability-weighted scenario approach. The Company applied a risk-based estimate of the probability of achieving each scenario and then applied a cost of debt based discount rate of 8%. This fair value measurement is based on unobservable inputs, including management estimates and assumptions, and is, therefore, classified as Level 3 within the fair value hierarchy presented in Note 2 above. The Company will remeasure this liability at each reporting date and will record changes in the fair value of the contingent consideration in other expense (income) on the Company's Summary Consolidated Statement of Operations and Comprehensive Income. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the timing and amount of Company revenue estimates.

The Company recorded a loss of \$37,000 and \$62,000 for the three and nine months ended September 30, 2012, respectively, on the remeasurement of the contingent consideration liability. The balance of the contingent consideration liability was \$1.9 million as of September 30, 2012.

Accounting for the Transaction

The Company has recorded a preliminary allocation of the \$22.0 million purchase price to Hemosphere's tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of May 16, 2012. Goodwill has been recorded based on the amount by which the purchase price exceeds the fair value of the net assets acquired, and is not deductible for tax purposes. Goodwill from this transaction has been allocated to the Company's medical devices segment. The preliminary purchase price allocation is as follows (in thousands):

	Opening Balance Sheet
Cash and cash equivalents	\$ 3,155
Receivables	653
Inventories	554
Intangible assets	5,790
Goodwill	7,080
Deferred tax assets, net	5,444
Other assets	331
Liabilities assumed	(972)
Total purchase price	\$ 22,035

Edgar Filing: CRYOLIFE INC - Form 10-Q

The preliminary allocation of the purchase price to intangible assets is based on preliminary valuations performed to determine the fair value of such assets as of the acquisition date. The Company may adjust the amounts recorded as of September 30, 2012 to reflect any revised evaluations of the assets acquired or liabilities assumed.

CryoLife incurred transaction and integration costs related to the acquisition of approximately \$702,000 for the three months and \$1.7 million for the nine months ended September 30, 2012. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on the Company's Summary Consolidated Statement of Operations and Comprehensive Income.

Pro Forma Results

Hemisphere's revenues of \$2.0 million from the date of acquisition for the nine months ended September 30, 2012 are included in the Summary Consolidated Statement of Operations and Comprehensive Income. The Company's selected unaudited pro forma results of operations for the nine months ended September 30, 2012 and 2011, assuming the Hemisphere acquisition had occurred as of January 1, 2011 are presented for comparative purposes below. These amounts are based on available information of the results of operations of Hemisphere prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the acquisition been completed on January 1, 2011. This unaudited pro forma information does not project operating results post acquisition. This pro forma information is as follows (in thousands, except per share amounts):

	Nine Months Ended September 30,	
	2012	2011
Total revenues	\$ 100,922	\$ 93,269
Net income	6,376	2,287
Pro forma income per common share - basic	\$ 0.23	\$ 0.08
Pro forma income per common share - diluted	\$ 0.23	\$ 0.08

Pro forma results for the nine months ended September 30, 2011 include the Company's acquisition and integration related costs of approximately \$1.7 million, on a pre-tax basis, and other costs as appropriate. Pro forma disclosures were calculated using a tax rate of approximately 38%.

5. ValveXchange Investment

In July 2011 the Company purchased approximately 2.4 million shares of series A preferred stock of ValveXchange for approximately \$3.5 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. The Company's carrying value of this investment includes the purchase price and certain transaction costs, and CryoLife's investment represents an approximate 19% equity ownership in ValveXchange. As ValveXchange's stock is not actively traded on any public stock exchange and as the Company's investment is in preferred stock, the Company accounts for this investment using the cost method. The Company recorded its investment as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

The Company will evaluate the carrying value of the ValveXchange preferred stock investment if factors become known that indicate an impairment review is warranted. If ValveXchange does not continue to make advances in developing its technology, if ValveXchange sells additional securities at a price less than the book value of the Company's investment, if the Company subsequently determines that the value of its ValveXchange stock has been impaired, or if the Company decides to sell its ValveXchange preferred stock for less than the carrying value, the Company would record an impairment charge or realized loss on sale of the investment in ValveXchange, which could be material.

During the quarter ended September 30, 2012 the Company reviewed available information to determine if factors indicated that the Company should evaluate its investment in ValveXchange preferred stock for impairment. The Company determined that available information indicated that the Company should evaluate its investment in ValveXchange preferred stock for impairment.

The Company used available information to analyze its investment for impairment, and the information indicated that the fair value of the investment was less than the carrying value. Therefore, based on this analysis, the Company believes that its investment in ValveXchange was impaired as of September 30, 2012, and the impairment was other than temporary. As a result the Company recorded an other non-operating expense of \$340,000 to write-down its investment in ValveXchange preferred stock. The carrying value of the Company's 2.4 million shares of ValveXchange preferred stock after this write down was \$3.2 million as of September 30, 2012.

Loan Agreement

In July 2011 the Company entered into an agreement with ValveXchange, as amended, to make available up to \$2.0 million to ValveXchange in debt financing through a revolving credit facility (ValveXchange Loan). The ValveXchange Loan includes various affirmative and negative covenants, including financial covenant requirements, and expires on July 30, 2018, unless terminated earlier. Amounts loaned under the ValveXchange Loan will earn interest at an 8% annual rate and will be secured by substantially all of the tangible and intangible assets of ValveXchange. The Company incurred loan origination costs, net of fees charged to ValveXchange, of approximately \$117,000, which are being expensed on a straight-line basis over the life of the loan facility. The Company advanced \$1.0 million to ValveXchange under this loan in July 2012 and advanced the remaining \$1.0 million in October 2012. The \$1.0 million advance made in July is recorded as long-term notes receivable on the Company's Summary Consolidated Balance Sheet as of September 30, 2012. The Company may decide to allow ValveXchange to issue shares in payment of some or all of the outstanding debt balance in connection with the currently proposed financing or a future round of financing.

Option Agreement

Concurrently with the ValveXchange Loan described above, CryoLife entered into an option agreement with ValveXchange through which CryoLife obtained the right of first refusal to acquire ValveXchange during a period that extends through the completion of initial commercialization milestones and the right to negotiate with ValveXchange for European distribution rights. The Company's rights may be modified or reduced in connection with a currently proposed financing or a future round of financing.

6. Cardiogenesis Acquisition

Overview

On May 17, 2011 CryoLife completed its acquisition of all of the outstanding shares of Cardiogenesis for \$0.457 per share or approximately \$21.7 million. CryoLife used cash on hand to fund the transaction and operates Cardiogenesis as a wholly owned subsidiary.

Cardiogenesis is a leading developer of surgical products used in the treatment of patients with severe angina resulting from diffuse coronary artery disease. Cardiogenesis markets its revascularization technologies, which include the Holmium: YAG laser console and single use, fiber-optic handpieces. These products are U.S. Food and Drug Administration (FDA) approved for performing a surgical procedure known as Transmyocardial Revascularization, used for treating patients with stable angina that is not responsive to conventional therapy.

Accounting for the Transaction

The Company recorded an allocation of the \$21.7 million purchase price to Cardiogenesis' tangible and identifiable intangible assets acquired and liabilities assumed based on their acquisition date fair values. The allocation of the purchase price to intangible assets was based on valuations performed to determine the fair value of such assets as of the acquisition date. Goodwill was recorded based on the amount by which the purchase price exceeded the fair value of the net assets acquired. The liability amounts recorded included the Company's estimate of contingent liabilities assumed. The purchase price allocation was finalized as of December 31, 2011.

CryoLife incurred approximately \$3.0 million in transaction and integration costs related to the acquisition in both the nine months ended September 30, 2011 and the year ended December 31, 2011. The Company does not expect to continue to incur significant transaction or integration costs in 2012.

Legal Action

As previously discussed in CryoLife's Form 10-Q for the quarter ended June 30, 2012 and its prior filings, in 2008 CardioFocus, Inc. (CardioFocus) filed a complaint in the U.S. District Court for the District of Massachusetts (Massachusetts Court) against Cardiogenesis and a number of other companies. The litigation related to an alleged infringement by Cardiogenesis of two patents held by CardioFocus that have now expired.

On June 14, 2012 Cardiogenesis entered into a settlement agreement with respect to its litigation with CardioFocus. The settlement provides that each party release the other from all claims and liabilities related to the patents in question and that all claims and counterclaims in the litigation be withdrawn with prejudice. Pursuant to the terms of the settlement agreement,

Cardiogenesis paid \$4.5 million in cash to CardioFocus. Cardiogenesis and CardioFocus agreed and acknowledged that each party would bear its own costs and expenses, including attorneys' fees, incurred in or as a result of the litigation.

On June 14, 2012 the parties filed a stipulation of dismissal with prejudice in the Massachusetts Court.

Accounting for the Settlement

As a result of the settlement described above, the Company recorded an additional loss of \$3.6 million in general, administrative, and marketing expenses on its Summary Consolidated Statement of Operations and Comprehensive Income in the second quarter of 2012. The Company recorded \$4.1 million in legal settlement expenses for the nine months ended September 30, 2012. The Company paid the \$4.5 million settlement payment to CardioFocus in July 2012 using cash on hand.

7. PerClot® Technology Acquisition

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 powdered 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, 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, subject to certain exclusions, to commercialize PerClot for all approved surgical indications and a license to manufacture the PerClot product. CryoLife also received an assignment of the PerClot trademark from SMI as part of the terms of the agreements.

The Distribution Agreement contains certain minimum purchase requirements and has a term of 15 years. CryoLife may begin manufacturing PerClot under the terms of the License Agreement, which extends for an indefinite period. Upon FDA approval, the Company may terminate such minimum purchase requirements. Following the start of manufacturing and U.S. regulatory approval, CryoLife may terminate the Distribution Agreement and sell PerClot pursuant to the License 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 granted CryoLife a three-year option to purchase certain remaining related technology from SMI, which the Company exercised in September 2011.

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, approximately 209,000 shares of 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, recorded a deferred tax asset of \$145,000, 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 \$327,000 for the PerClot trademark, \$2.6 million for the PerClot distribution and manufacturing rights in certain international countries, and \$3.5 million for the PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This \$3.5 million was considered in-process research and development, as it is dependent upon regulatory approvals which have not yet been obtained. Therefore, CryoLife expensed the \$3.5 million as in-process research and development upon acquisition in the third quarter of 2010. 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 annual impairment testing. The \$2.6 million intangible asset will be amortized over its useful life of 15 years.

In the year ended December 31, 2011 CryoLife recorded research and development expenses of \$250,000 for the contractual milestone payment due to SMI upon filing of the investigational device exemption. The Company recorded the additional technology purchased in 2011 and 2012 as an intangible asset, which will be amortized over its useful life of 14 years. CryoLife expects to record future contingent payment amounts of up to \$2.5 million initially as research and development expense or, after FDA approval or issuance of a patent, as acquired intangible assets.

8. Medafor Matters

Overview

CryoLife began distributing HemoStase in 2008 for Medafor, Inc. (Medafor) under an Exclusive Distribution Agreement (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 Company's carrying value of this investment 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, because Medafor is a non-reporting company for which financial information is not readily available, and as the Company does not exert significant influence over the operations of Medafor, the Company accounted for this investment using the cost method and recorded it as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

HemoStase Inventory

Based on Medafor's final termination of the EDA in late September 2010, the Company performed a review of its HemoStase inventory and determined that the carrying value was impaired. As a result CryoLife wrote down the value of this inventory in the third quarter of 2010. The amount of this write-down reflected management's estimate based on information available at that time. The Company was able to sell more HemoStase than it originally estimated and that had previously been written down; therefore, cost of products in the first quarter of 2011 was favorably impacted by approximately \$330,000. As of September 30, 2012 and December 31, 2011 the Company had zero in remaining value of HemoStase inventory on its Summary Consolidated Balance Sheets.

Investment in Medafor Common Stock

During the quarter ended September 30, 2012 the Company reviewed available information and determined that no factors were present indicating that the Company should evaluate the carrying value of its investment in Medafor common stock for impairment. The carrying value of the Company's 2.4 million shares of Medafor common stock was approximately \$2.6 million as of both September 30, 2012 and December 31, 2011.

The Company will continue to evaluate the carrying value of this investment if factors become known that indicate the Company should evaluate its investment in Medafor common stock for impairment. If the Company subsequently determines that the value of its Medafor common stock has been impaired, 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. If the Company subsequently sells its Medafor common stock for higher than the carrying value, the resulting gain on the 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 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 Sheets.

As of September 30, 2012 and December 31, 2011 the Company believed that the likelihood of a Triggering Event was remote and the value of the Medafor Derivative was zero.

Legal Action

As previously discussed in CryoLife's Form 10-Q for the quarter ended June 30, 2012 and its prior filings, CryoLife filed a lawsuit against Medafor in 2009 in the U.S. District Court for the Northern District of Georgia (Georgia Court). In 2010 Medafor filed counterclaims against CryoLife in the same case. The litigation related to an exclusive distribution agreement that the parties entered into in April 2008.

On June 8, 2012 the parties agreed to a settlement of their litigation and entered into a further settlement agreement on June 25, 2012. Per the settlement, Medafor paid \$3.5 million in cash to CryoLife in the third quarter of 2012. Pursuant to the terms of the settlement, all claims and counterclaims in the litigation were dismissed with prejudice, including Medafor's counterclaim for payment of approximately \$1.2 million for product purchased by CryoLife, which amount had previously been recorded as a payable on CryoLife's balance sheet. Each party also released the other from all claims and liabilities, except with respect to possible claims that Medafor may have against CryoLife regarding certain patent-related rights, which were not counterclaims filed by Medafor. CryoLife and Medafor agreed and acknowledged that each party would bear its own costs and expenses, including attorneys' fees, incurred in or as a result of the litigation.

On June 29, 2012 the parties jointly filed stipulated dismissals with prejudice with the Georgia Court.

Accounting for the Settlement

As a result of the settlement described above, CryoLife recorded a gain of \$4.7 million as a reduction in general, administrative, and marketing expenses on its Summary Consolidated Statement of Operations and Comprehensive Income in the second quarter of 2012 and recorded a reduction in accounts payable of \$1.2 million to write off a payable for previous inventory purchases, which was discharged pursuant to the settlement agreement.

9. Inventories

Inventories are comprised of the following (in thousands):

	September 30, 2012	December 31, 2011
Raw materials and supplies	\$ 5,971	\$ 4,759
Work-in-process	573	218
Finished goods	3,702	2,343
Total inventories	\$ 10,246	\$ 7,320

10. Goodwill and Other Intangible Assets

The Company's intangible assets consist of goodwill, patents, trademarks, and other intangible assets, as discussed further below. These assets include assets acquired from Hemosphere, as discussed in Note 4 above, assets acquired from Cardiogenesis, as discussed in Note 6 above, and PerClot assets acquired from SMI as discussed in Note 7 above.

Indefinite Lived Intangible Assets

The carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	September 30, 2012	December 31, 2011
Goodwill	\$ 11,300	\$ 4,220
Procurement contracts and agreements	2,013	2,013
Trademarks	858	847
Other	250	250

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.

Edgar Filing: CRYOLIFE INC - Form 10-Q

A roll-forward of the Company's goodwill balances by reportable segment for the nine months ended September 30, 2012 is as follows (in thousands):

	Medical Devices Segment
Balance as of December 31, 2011	\$ 4,220
Goodwill from Hemosphere acquisition	7,080
Balance as of September 30, 2012	\$ 11,300

Definite Lived Intangible Assets

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

September 30, 2012	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	\$ 14,020	\$ 1,254	11-16 Years
Patents	4,621	2,455	17 Years
Distribution and manufacturing rights and know-how	3,559	413	15 Years
Customer lists and relationships	3,370	270	13-17 Years
Non-compete agreement	381	219	10 Years
Other	199	105	1-3 Years

December 31, 2011	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	\$ 9,230	\$ 524	11 Years
Patents	5,610	2,871	17 Years
Distribution and manufacturing rights and know-how	3,559	231	15 Years
Customer lists and relationships	2,370	114	13 Years
Non-compete agreement	381	191	10 Years
Other	114	48	2-3 Years

Amortization Expense

The following is a summary of amortization expense as recorded in general, administrative, and marketing expenses on the Company's Summary Consolidated Statement of Operations and Comprehensive Income (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2012	2011	September 30, 2012	2011
Amortization expense	\$ 521	\$ 436	\$ 1,454	\$ 917

As of September 30, 2012 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

2013	2014	2015	2016	2017
------	------	------	------	------

	Remainder of 2012					
Amortization expense	\$ 518	\$ 2,014	\$ 1,961	\$ 1,915	\$ 1,906	\$ 1,857
11. 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 generates 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; asset impairments; and, in prior periods, due to operating losses. The Company acquired significant

deferred tax assets, primarily net operating loss carryforwards, from its acquisitions of Hemosphere and Cardiogenesis in the second quarters of 2012 and 2011, respectively, as discussed below.

As of September 30, 2012 the Company maintained a total of \$2.6 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$22.3 million. As of December 31, 2011 the Company had a total of \$2.4 million in valuation allowances against deferred tax assets and a net deferred tax asset of \$18.5 million.

The Company believes that the realizability of its acquired net operating loss carryforwards will be limited in future periods due to a change in control of its subsidiaries Hemosphere and Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisition of Hemosphere constituted a change in control and that prior to the Company's acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. The Company also believes that its acquisition of Cardiogenesis constituted a change in control. The deferred tax assets recorded on the Company's Summary Consolidated Balance Sheets do not include amounts that it expects will not be realizable due to these changes in control. A portion of the acquired net operating loss carryforwards is related to state income taxes and can only be used by the Company's subsidiaries Hemosphere and Cardiogenesis. Due to the history of losses of these subsidiaries when operated as stand-alone companies, management believes it is more likely than not that these deferred tax assets will not be realized. Therefore, the Company recorded a valuation allowance against these state net operating loss carryforwards. See also Notes 4 and 6 above for a further discussion of the Company's acquisitions of Hemosphere and Cardiogenesis, respectively.

The Company's effective income tax rate was approximately 41% for the three months ended September 30, 2012 as compared to 12% for the three months ended September 30, 2011. The Company's effective income tax rate was approximately 40% for the nine months ended September 30, 2012 as compared to 36% for the nine months ended September 30, 2011.

The Company's tax years 2008 through 2011 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2008, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

12. Debt

GE Credit Agreement

On October 28, 2011 CryoLife amended and restated its March 26, 2008 credit agreement with GE Capital (the "GE Credit Agreement") which provides revolving credit for working capital, acquisitions, and other corporate purposes. The amendment increased the borrowing capacity under the GE Credit Agreement from \$15.0 million to \$20.0 million (including a letter of credit subfacility) and extended the expiration from October 31, 2011 to October 28, 2014. The initial commitment may continue to be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. In September 2012 the Company amended the agreement to allow the payment of cash dividends subject to satisfaction of specified conditions. Since 2009, as requested by the German courts, the Company has been maintaining a letter of credit of \$157,000 relating to the Company's patent infringement legal proceeding against Tenaxis, Inc. ("Tenaxis") in Germany, which reduces the aggregate borrowing capacity. The letter of credit had a one-year initial term and automatically renews for additional one-year periods. The Company plans to terminate the letter of credit in the fourth quarter of 2012 due to the settlement agreement with Tenaxis as previously discussed in the Company's Form 10-Q for the quarter ended June 30, 2012.

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. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as restricted cash and securities as of September 30, 2012 and December 31, 2011 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 within the agreement, of at least \$20.0 million. The GE Credit Agreement includes customary conditions on incurring new indebtedness. Commitment fees are paid based on the unused portion of the facility. As of September 30, 2012 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 as determined by GE Capital at either LIBOR, with a minimum rate of 4.25%, or GE Capital's base rate, with a minimum rate of 3.25% each, plus the applicable margin. As of September 30, 2012 and December 31,

2011 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate was 6.50%, and the remaining availability was \$19.8 million.

Other

Interest expense was \$42,000 and \$159,000 for the three and nine months ended September 30, 2012, respectively, and \$49,000 and \$116,000 for the three and nine months ended September 30, 2011, respectively. Interest expense for the nine months ended September 30, 2012 and 2011 included interest on debt, capital leases, and uncertain tax positions.

13. Commitments and Contingencies

Liability Claims

The estimated unreported tissue processing and product loss liability and any related recoverable insurance amounts are as follows (in thousands):

	September 30, 2012	December 31, 2011
Short-term liability	\$ 952	\$ 1,030
Long-term liability	919	960
Total liability	1,871	1,990
Short-term recoverable	296	350
Long-term recoverable	360	350
Total recoverable	656	700
Total net unreported loss liability	\$ 1,215	\$ 1,290

Further analysis indicated that the liability as of September 30, 2012 could be estimated to be as high as \$3.5 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreement

The Company has an employment agreement with its Chief Executive Officer (CEO) that confers benefits which become payable upon a change in control or upon certain termination events, such as voluntary retirement. As of both September 30, 2012 and December 31, 2011 the Company has recorded \$2.1 million in accrued expenses and other current liabilities on the Summary Consolidated Balance Sheets representing benefits payable upon the CEO s voluntary retirement, for which he is currently eligible. The CEO s employment agreement terminates on December 31, 2012. A new agreement, which takes effect on January 1, 2013 and terminates on December 31, 2015, was signed in October 2012. Payments to the CEO under the new agreement are not significantly different from those in the prior agreement. However, the new agreement includes an additional \$100,000 payment if the CEO remains employed by CryoLife on January 1, 2013.

14. Shareholders Equity

Common Stock Repurchase

On June 1, 2010 the Company announced that its Board of Directors had authorized the purchase of up to \$15.0 million of its common stock over the course of the following two years. On November 1, 2011 the Company announced that its Board of Directors had authorized the Company s purchase of \$15.0 million of its common stock through December 31, 2012, which included approximately \$7.7 million remaining from the June 1, 2010 repurchase program and an additional \$7.3 million, for a total authorization of \$22.3 million. The purchase of shares may

Edgar Filing: CRYOLIFE INC - Form 10-Q

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.

For the nine months ended September 30, 2012 the Company purchased approximately 639,000 shares for an aggregate purchase price of \$3.3 million. For the year ended December 31, 2011 the Company purchased approximately 593,000 shares for

an aggregate purchase price of \$2.9 million. These shares were recorded, at cost, as part of treasury stock on the Company's Summary Consolidated Balance Sheets.

As of September 30, 2012 the Company had purchased a total of 2.3 million shares for an aggregate purchase price of \$12.0 million and had \$10.3 million in remaining authorizations under these programs.

Treasury Stock

On August 7, 2012 the Company retired 2.7 million shares of treasury stock with an aggregate value of \$15.1 million. The retirement was recorded as a reduction of \$15.1 million in treasury stock, \$27,000 in common stock, and approximately \$15.1 million in additional paid in capital. These shares remain available for issuance as authorized unissued shares.

Cash Dividends

On August 21, 2012 the Company announced that its Board of Directors had approved the initiation of a quarterly cash dividend of \$0.025 per share of common stock outstanding. The initial quarterly cash dividend of \$0.025 per share was paid on September 21, 2012 to all common stockholders of record as of September 14, 2012. The dividend payment of \$686,000 was paid from cash on hand and was recorded as a reduction to retained earnings on the Company's Summary Consolidated Balance Sheet. The Company currently anticipates paying the quarterly dividends in March, June, September, and December of each year.

15. 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 (RSAs), restricted stock units (RSUs), performance stock units (PSUs), 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 from approved stock incentive plans of RSAs to non-employee Directors and RSAs and PSUs to certain Company officers, which together totaled 387,000 shares and had an aggregate market value of \$2.1 million during the nine months ended September 30, 2012. The performance component of PSU awards granted in 2012 is based on attaining specified levels of adjusted EBITDA, as defined in the grant, for the 2012 calendar year. The Company currently believes that achievement of the performance component is probable, and will reevaluate this likelihood on a quarterly basis.

The Compensation Committee of the Company's Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee Directors and certain Company officers, which totaled 360,000 shares and had an aggregate market value of \$1.9 million during the nine months ended September 30, 2011.

The Compensation Committee of the Company's Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers totaling 159,000 and 599,000 shares during the nine months ended September 30, 2012 and 2011, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Employees purchased common stock totaling 72,000 and 64,000 shares in the nine months ended September 30, 2012 and 2011, respectively, through the Company's ESPP.

Stock Compensation Expense

The Company values its RSAs, RSUs, and PSUs based on the stock price on the date of grant. The Company expenses the related compensation cost of RSAs and RSUs and of PSUs, for which achievement of the performance component is probable, 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

Edgar Filing: CRYOLIFE INC - Form 10-Q

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, 2012		Nine Months Ended September 30, 2012	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	.50 Years	4.25 Years	.50 Years
Expected stock price volatility	N/A	0.44	0.60	0.54
Risk-free interest rate	N/A	0.16%	0.71%	0.06%

	Three Months Ended September 30, 2011		Nine Months Ended September 30, 2011	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	.50 Years	4.00 Years	.50 Years
Expected stock price volatility	N/A	0.36	0.65	0.41
Risk-free interest rate	N/A	0.10%	1.25%	0.16%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
RSA, RSU, and PSU expense	\$ 513	\$ 369	\$ 1,533	\$ 1,038
Stock option and ESPP option expense	295	388	875	1,270
Total stock compensation expense	\$ 808	\$ 757	\$ 2,408	\$ 2,308

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the Company's ESPP. These amounts were recorded as stock compensation expense and were subject to the Company's normal allocation of expenses to deferred preservation costs and inventory costs. The Company capitalized \$53,000 and \$61,000 in the three months ended September 30, 2012 and 2011, respectively, and \$157,000 and \$168,000 in the nine months ended September 30, 2012 and 2011, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

As of September 30, 2012 the Company had total unrecognized compensation costs of \$1.3 million related to unvested stock options and \$2.6 million related to RSAs, RSUs, and PSUs, before considering the effect of expected forfeitures. As of September 30, 2012 this expense is expected to be recognized over a weighted-average period of 1.43 years for stock options, 1.34 years for RSAs, 1.73 years for RSUs, and 1.18 years for PSUs.

16. Income Per Common Share

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

Edgar Filing: CRYOLIFE INC - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
<u>Basic income per common share</u>				
Net income	\$ 1,538	\$ 2,019	\$ 5,863	\$ 5,505
Net income allocated to participating securities	(36)	(43)	(133)	(110)
Net income allocated to common shareholders	\$ 1,502	\$ 1,976	\$ 5,730	\$ 5,395
Basic weighted-average common shares outstanding	26,810	27,523	26,951	27,431
Basic income per common share	\$ 0.06	\$ 0.07	\$ 0.21	\$ 0.20

<u>Diluted income per common share</u>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income	\$ 1,538	\$ 2,019	\$ 5,863	\$ 5,505
Net income allocated to participating securities	(36)	(42)	(131)	(108)
Net income allocated to common shareholders	\$ 1,502	\$ 1,977	\$ 5,732	\$ 5,397
Basic weighted-average common shares outstanding	26,810	27,523	26,951	27,431
Effect of dilutive stock options and awards ^a	70	95	57	118
Effect of dilutive RSAs and RSUs	330	232	321	216
Diluted weighted-average common shares outstanding	27,210	27,850	27,329	27,765
Diluted income per common share	\$ 0.06	\$ 0.07	\$ 0.21	\$ 0.19

^a The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to income per common share. Accordingly, stock options to purchase a weighted-average 1.7 million shares for both the three and nine months ended September 30, 2012 and 2.1 million for the three months ended and 2.0 million for the nine months ended September 30, 2011 were excluded from the calculation of diluted weighted-average common shares outstanding.

17. 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. The Medical Devices segment includes external revenues from product sales of BioGlue[®] Surgical Adhesive (BioGlue), BioFoam[®] Surgical Matrix (BioFoam), PerClot, HemoStase, revascularization technologies, and HeRO Graft. 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 services and products, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Preservation services	\$ 16,399	\$ 14,656	\$ 48,371	\$ 45,018
Medical devices	16,893	14,923	50,043	43,932
Other ^a	137	75	504	279
Total revenues	33,429	29,654	98,918	89,229

Edgar Filing: CRYOLIFE INC - Form 10-Q

Cost of preservation services and products:

Preservation services	9,005	8,349	26,645	25,709
Medical devices	3,114	2,393	8,300	7,051
Total cost of preservation services and products	12,119	10,742	34,945	32,760

Gross margin:

Preservation services	7,394	6,307	21,726	19,309
Medical devices	13,779	12,530	41,743	36,881
Other ^a	137	75	504	279
Total gross margin	\$ 21,310	\$ 18,912	\$ 63,973	\$ 56,469

Edgar Filing: CRYOLIFE INC - Form 10-Q

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Preservation services:				
Cardiac tissue	\$ 8,239	\$ 6,764	\$ 22,662	\$ 19,989
Vascular tissue	8,160	7,892	25,709	25,029
Total preservation services	16,399	14,656	48,371	45,018
Products:				
BioGlue and BioFoam	12,725	12,190	39,858	36,936
PerClot	734	620	2,069	1,911
HemoStase	--	--	--	1,795
Revascularization technologies	2,060	2,113	6,107	3,290
HeRO Graft	1,374	--	2,009	--
Total products	16,893	14,923	50,043	43,932
Other ^a	137	75	504	279
Total revenues	\$ 33,429	\$ 29,654	\$ 98,918	\$ 89,229

^a For the three and nine months ended September 30, 2012 and 2011, the Other designation includes grant revenue.

PART I - FINANCIAL INFORMATION**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.****Overview**

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, preserves and distributes human tissues for transplantation and develops, manufactures, and commercializes medical devices for cardiac and vascular applications. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve[®] SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch[®] SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife's proprietary Synergra[®] technology. CryoLife's surgical sealants and hemostats include BioGlue[®] Surgical Adhesive (BioGlue), BioFoam[®] Surgical Matrix (BioFoam), and PerClot[®] an absorbable powdered hemostat, which the Company distributes for Starch Medical, Inc. (SMI) in the European Community and other select international markets. CryoLife's subsidiary, Cardiogenesis Corporation (Cardiogenesis), specializes in the treatment of coronary artery disease using a laser console system and single use, fiber-optic handpieces to treat patients with severe angina. CryoLife's subsidiary, Hemosphere, Inc. (Hemosphere), markets the Hemodialysis Reliable Outflow Graft (HeRO[®] Graft), which is a solution for end-stage renal disease in certain hemodialysis patients.

During the quarter ended September 30, 2012 CryoLife initiated payment of the first cash dividend in Company history. The cash dividend of \$0.025 per share totaled \$686,000 and was paid on September 21, 2012 to common stockholders of record as of September 14, 2012. CryoLife currently anticipates paying quarterly dividends in March, June, September, and December of each year.

CryoLife reported record quarterly revenues of \$33.4 million for the quarter ended September 30, 2012. This is the fourth quarter in succession that CryoLife has set a new Company record for quarterly revenue performance. The Company increased revenues for its cardiac tissue, vascular tissue, BioGlue, and PerClot for both the quarter and year to date periods over the respective prior year periods. One of the highlights of the quarter was in cardiac preservation services revenues, which exceeded \$8 million for the quarter for the first time since 2001. The Company's newer product lines, revascularization technologies and HeRO Grafts, also contributed to the Company's increase in revenues, as the comparative nine month period did not include a full period of revascularization technologies revenues and the comparative three and nine month periods did not include any HeRO Graft sales. Although revascularization technologies revenues for the quarter decreased when compared to the prior year quarter, revenues increased 7% in the third quarter of 2012 when compared to the second quarter of 2012, with sales of disposable handpieces alone increasing 18% when compared to the second quarter of 2012. See the Results of Operations section below for additional analysis of the results of operations for the three and nine months ended September 30, 2012.

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, 2011. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company's operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require the Company to make estimates and assumptions. The Company did not experience any significant changes during the quarter ended September 30, 2012 in any of its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2011.

New Accounting Pronouncements

In January 2012 the Company adopted Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820): *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The adoption of ASU 2011-04 did not have a material effect on the Company's financial condition, profitability, and cash flows.

In January 2012 the Company adopted ASU 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income*, and ASU 2011-12 related to presentation of comprehensive income in interim and annual financial statements.

In January 2012 the Company adopted ASU 2011-08, Intangibles-Goodwill and Other (Topic 350): *Testing Goodwill for Impairment*, which gives entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of a reporting unit in step 1 of the goodwill impairment test. The adoption of ASU 2011-08 did not have a material effect on the Company's financial condition, profitability, and cash flows.

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,	
	2012	2011	2012	2011
Preservation services:				
Cardiac tissue	\$ 8,239	\$ 6,764	25%	23%
Vascular tissue	8,160	7,892	24%	27%
Total preservation services	16,399	14,656	49%	50%
Products:				
BioGlue and BioFoam	12,725	12,190	38%	41%
PerClot	734	620	2%	2%
Revascularization technologies	2,060	2,113	6%	7%
HeRO Graft	1,374	--	5%	--%
Total products	16,893	14,923	51%	50%
Other	137	75	--%	--%
Total	\$ 33,429	\$ 29,654	100%	100%

	Revenues for the Nine Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2012	2011	2012	2011
Preservation services:				
Cardiac tissue	\$ 22,662	\$ 19,989	23%	23%
Vascular tissue	25,709	25,029	26%	28%
Total preservation services	48,371	45,018	49%	51%
Products:				
BioGlue and BioFoam	39,858	36,936	40%	41%
PerClot	2,069	1,911	2%	2%
HemoStase	--	1,795	--%	2%
Revascularization technologies	6,107	3,290	6%	4%
HeRO Graft	2,009	--	2%	--%
Total products	50,043	43,932	50%	49%

Edgar Filing: CRYOLIFE INC - Form 10-Q

Other		504		279		1%	--%
Total	\$	98,918	\$	89,229		100%	100%

Revenues increased 13% for the three months and 11% for the nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively. A detailed discussion of the changes in preservation services revenues, product revenues, and other revenues is presented below.

Preservation Services

Revenues from preservation services increased 12% for the three months and 7% for the nine months ended September 30, 2012 over revenues for the three and nine months ended September 30, 2011, respectively. The increase was for both cardiac and vascular preservation services revenues.

Preservation services revenues, particularly revenues for certain high demand tissues, can vary from quarter-to-quarter and year-to-year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services. The Company believes that preservation services revenues for the full year of 2012 will show an increase over revenues for the full year of 2011. See further discussion of any specific items affecting cardiac and vascular preservation services revenues for the three and nine months ended September 30, 2012 below.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 22% for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. This increase was primarily due to the aggregate impact of an 18% increase in unit shipments of cardiac tissues and favorable tissue mix, which increased revenues by 21%.

Revenues from cardiac preservation services increased 13% for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. This increase was primarily due to the aggregate impact of a 7% increase in unit shipments of cardiac tissues and favorable tissue mix, which increased revenues by 11%.

The increase in revenues from volume and tissue mix was primarily due to an increase in volume of cardiac valve shipments. This increase was partially offset by decreases in the volume of lower fee cardiac patch tissues for the nine months ended September 30, 2012. The Company believes that the increase in unit shipments of cardiac valves was due to the activities of its expanded sales staff, which increased as a result of the Company's acquisition of Cardiogenesis, and the Company's ongoing physician education activities, and may have also benefited from the guidance of The Society of Thoracic Surgeons, which indicates that human aortic valves are the ideal replacement in certain cardiac reconstructive procedures involving endocarditis. The Company's cardiac valves are primarily used in cardiac replacement and reconstruction surgeries for patients with congenital heart defects.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 49% and 45% of total cardiac preservation services revenues for the three and nine months ended September 30, 2012, respectively, and 47% and 40% of total cardiac preservation services revenues for the three and nine months ended September 30, 2011, respectively. Domestic revenues accounted for 91% and 90% of total cardiac preservation services revenues for the three and nine months ended September 30, 2012, respectively, and 91% of total cardiac preservation services revenues for both the three and nine months ended September 30, 2011.

Vascular Preservation Services

Revenues from vascular preservation services increased 3% for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. This increase was primarily due to a 3% increase in unit shipments of vascular tissues, which increased revenues by 5%, partially offset by a decrease in average service fees, which decreased revenues by 2%.

Revenues from vascular preservation services increased 3% for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. This increase was primarily due to a 3% increase in unit shipments of vascular tissues, which increased revenues by 5%, partially offset by a decrease in average service fees, which decreased revenues by 2%.

The increase in vascular volume for the three and nine months ended September 30, 2012 was primarily due to increases in shipments of saphenous veins and aortoiliac grafts, which increased due to improved availability of certain tissues. Saphenous veins are primarily used in peripheral vascular reconstruction surgeries to avoid limb amputations and aortoiliac grafts are primarily used in surgeries to treat abdominal aortic aneurisms. These tissues are primarily distributed in domestic markets.

The decrease in average service fees for the three and nine months ended September 30, 2012 was due in part to a list fee decrease for certain vascular tissues in 2012 and fee differences due to physical characteristics of vascular tissues, partially offset by the routine negotiation of pricing contracts with certain customers.

Products

Revenues from products increased 13% for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. Revenues from products increased 14% for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. This increase for the three months ended September 30, 2012 was primarily due to the addition of HeRO Graft revenues as a result of the Company's acquisition of Hemosphere in the second quarter of 2012, and an increase in BioGlue revenues. The increase for the nine months ended September 30, 2012 was primarily due to the addition of

HeRO Graft revenues, an increase in BioGlue revenues, and an increase in revascularization technologies revenues as a result of the Company's acquisition of Cardiogenesis in the second quarter of 2011, partially offset by a lack of HemoStase revenues as the Company is no longer distributing this product. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot and HemoStase; revascularization technologies; and HeRO Grafts are presented below.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 4% for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. This increase was primarily due to a 4% increase in the volume of milliliters sold, which increased revenues by 2%, and by an increase in average sales prices, which increased revenues by 4%, partially offset by the unfavorable impact of foreign exchange rates, which decreased revenues by 2%.

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 8% for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. This increase was primarily due to a 9% increase in the volume of milliliters sold, which increased revenues by 6%, and by an increase in average sales prices, which increased revenues by 3%, partially offset by the unfavorable impact of foreign exchange rates, which decreased revenues by 1%.

The increase in sales volume of surgical sealants for the three and nine months ended September 30, 2012 was due to an increase in shipments of BioGlue in certain international markets, primarily Japan and, to a lesser extent, Europe. The Company began shipping BioGlue to Japan in April 2011, following the Japanese approval of BioGlue for use in the repair of aortic dissections. Revenues from shipments to Japan were \$1.1 million and \$651,000 for the three months ended September 30, 2012 and 2011, respectively, and \$3.4 million and \$1.2 million for the nine months ended September 30, 2012 and 2011, respectively. These increases were partially offset by volume decreases in the Company's more mature domestic markets.

Management believes that the decrease in BioGlue shipments in its domestic markets is a result of various factors, including: 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, the efforts of some large competitors in imposing and enforcing contract purchasing requirements for competing non-CryoLife products, and the U.S. market introduction of sealant products with approved indications for use in clinical applications in which BioGlue has been used off-label previously.

The Company's sales of surgical sealants through its direct sales force to United Kingdom hospitals are denominated in British Pounds, and its sales to German, Austrian, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. The unfavorable effect of foreign exchange rates for the three and nine months ended September 30, 2012 was primarily due to a decline in the value of the Euro when compared to the corresponding periods in 2011. If the exchange rates between the U.S. Dollar and the Euro or British Pound decline materially for the remainder of 2012 as compared to the corresponding periods in 2011, this would have a material adverse impact on the Company's revenues denominated in these currencies.

Domestic revenues accounted for 60% of total BioGlue revenues for both the three and nine months ended September 30, 2012, and 63% and 64% of total BioGlue revenues for the three and nine months ended September 30, 2011, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for each of the three and nine months ended September 30, 2012 and 2011. BioFoam is currently approved for sale in certain international markets.

BioGlue is a mature product in the U.S. and Europe that has experienced increasing competitive pressures. Management believes that BioGlue sales volume in domestic markets will continue to be impacted by the factors discussed above. Management believes that poor economic conditions in Europe could negatively impact sales during the remainder of 2012 and into 2013. Management believes that international BioGlue sales will be positively impacted by increased shipments to Japan in 2012 as compared to the corresponding periods in 2011.

PerClot and HemoStase

Revenues from the sale of PerClot increased 18% for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. This increase was primarily due to a 20% increase in the volume of grams sold, which increased revenues by 23% and by an increase in average sales prices, which increased revenues by 1%, partially offset by the unfavorable impact of foreign exchange rates, which decreased revenues by 6%. Revenues during these three month periods were for sales in certain international markets, as PerClot is not yet approved for domestic distribution or widespread international distribution. This increase was primarily due to increased sales into the Company's direct markets in Europe and due to the recent approval of PerClot in additional countries. HemoStase was not distributed during the three months ended September 30, 2012 or 2011.

Revenues from the sale of hemostats, consisting of PerClot and HemoStase, decreased 44% for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. The revenue decrease in the nine months ended September 30, 2012 was primarily due to a decrease in hemostat sales volume in domestic markets, as discussed further below, and the unfavorable impact of foreign exchange rates, which decreased revenues by 3%.

International hemostat revenues decreased 15% for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011. This decrease in international hemostat revenues was primarily due to a decrease in sales in certain international markets, particularly in Canada and South America due to large HemoStase orders filled in the first quarter of 2011 in anticipation of a disruption in the availability of hemostats to the Company's distributors in these countries beginning in 2011. This disruption was due to the Company's planned March 2011 discontinuance of HemoStase sales subsequent to the termination of its Exclusive Distribution Agreement (EDA) for this product.

The decrease in domestic sales volume for the nine months ended September 30, 2012 was due to the Company's discontinuation of sales of HemoStase as discussed above. The Company recognized domestic hemostat sales in the first quarter of 2011 and recognized no domestic hemostat sales in the corresponding period in 2012. Domestic hemostat sales ended with the discontinuance of HemoStase sales, as PerClot is not yet approved for commercial distribution in domestic markets. The Company will not be able to sell PerClot in the U.S. in future years unless and until U.S. Food and Drug Administration (FDA) approval is granted. On March 30, 2012 CryoLife refiled for an investigational device exemption (IDE) with the FDA seeking approval to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S. The FDA responded to the Company's IDE during the second quarter of 2012, and the Company plans to file a revised IDE in the fourth quarter of 2012, which the Company believes will address the comments made by the FDA.

The Company's sales of hemostats through its direct sales force to United Kingdom hospitals are denominated in British Pounds, and its sales to German, Austrian, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. The unfavorable effect of foreign exchange rates for the three and nine months ended September 30, 2012 was primarily due to a decline in the value of the Euro when compared to the corresponding periods in 2011. If the exchange rates between the U.S. Dollar and the Euro or British Pound decline materially for the remainder of 2012 as compared to the corresponding period in 2011, this would have a material adverse impact on the Company's revenues denominated in these currencies. Changes in exchange rates will have a more material impact on hemostat revenues than the Company's other product lines, as a larger percentage of the Company's hemostat sales are denominated in foreign currencies.

Management believes that economic conditions in Europe could negatively impact hemostat sales for the remainder of 2012 and into 2013. Poor economic conditions and their constraining effect on hospital budgets are expected to drive continued pricing pressures, especially due to the many hemostatic agents currently competing for market share in Europe.

Revascularization Technologies

Revenues from revascularization technologies decreased 3% for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011. This decrease was primarily due to a decrease in volume, which decreased revenues by 9%, largely offset by an increase in average sales prices, which increased revenues by 6%. Although revascularization technologies revenues decreased for the three months ended September 30, 2012 when compared to the prior year quarter, revenues increased 7% in the third quarter of 2012 when compared to the second quarter of 2012.

Revenues from revascularization technologies increased for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011, as revascularization technologies were not marketed by the Company for the full nine month prior year period. The Company began marketing revascularization technologies following its acquisition of Cardiogenesis in May 2011. Revascularization technologies revenues for the nine months ended September 30, 2012 decreased when compared to the combined pre- and post-acquisition revenues for the nine months ended September 30, 2011.

Revenues from revascularization technologies include revenues related to the sale of handpieces and accessories and, in certain periods, revenues from the sale of laser consoles. Revascularization technologies revenues for the three and nine months ended September 30, 2012 consisted primarily of handpiece sales. Revenues from the sale of laser consoles accounted for 5% of total revascularization technologies revenues for the nine months ended September 30, 2012. There were no revenues from the sale of laser consoles in the three months ended September 30, 2012 or in the three or nine months ended September 30, 2011. The amount of revenues from console sales can vary significantly from quarter-to-quarter due to the long lead time required to generate sales of capital equipment and due to the higher selling price of consoles as compared to handpieces. Handpieces and laser consoles are primarily distributed in domestic markets.

The decreases in revascularization technologies revenues discussed above are primarily due to increasing competitive pressures and challenges in selling laser consoles in recent periods, both of which have negatively impacted handpiece revenues. Revenues from laser consoles have been negatively impacted by the current economic environment, which makes hospitals

reluctant to invest in large capital purchases. The Company believes that these effects may continue for the remainder of 2012. Although the Company believes that the consecutive quarter growth seen in the third quarter 2012 revenues over second quarter 2012 revenues will continue into the fourth quarter of 2012, there can be no assurance that this increase in revenues will continue.

HeRO Graft

Revenues from HeRO Grafts for the three and nine months ended September 30, 2012 were a result of the Company's acquisition of Hemosphere in May 2012. Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. HeRO Grafts are primarily distributed in domestic markets.

Other Revenues

Other revenues for the three and nine months ended September 30, 2012 and 2011 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, 2012 CryoLife has been awarded \$6.1 million and has 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, 2012 CryoLife had \$1.1 million included in deferred income on the Company's Summary Consolidated Balance Sheet from the DOD Grants, of which \$740,000 remains in unspent cash advances recorded as cash and cash equivalents.

Cost of Preservation Services and Products

Cost of Preservation Services

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011

Cost of preservation services	\$ 9,005	\$ 8,349	\$ 26,645	\$ 25,709
Cost of preservation services as a percentage of preservation services revenues	55%	57%	55%	57%

Cost of preservation services increased 8% for the three months and 4% for the nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The increase in cost of preservation services in the three and nine months ended September 30, 2012 was primarily due to increased shipments of cardiac and vascular tissues during these periods. The slight decrease in cost of preservation services as a percentage of preservation services revenues for the three and nine months ended September 30, 2012 was primarily due to a decrease in the per unit cost of processing tissues. The decrease in the per unit cost of processing tissues in 2012 was largely a result of increased processing and packaging throughput, as fixed costs were allocated to a greater volume of processed tissues.

Cost of Products

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011

Cost of products	\$ 3,114	\$ 2,393	\$ 8,300	\$ 7,051
Cost of products as a percentage of product revenues	18%	16%	17%	16%

Cost of products increased 30% for the three months and 18% for the nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively. Cost of products in 2012 includes costs related to BioGlue, BioFoam, PerClot,

Edgar Filing: CRYOLIFE INC - Form 10-Q

revascularization technologies, and HeRO Grafts. Cost of products in 2011 includes costs related to BioGlue, BioFoam, PerClot, HemoStase, and revascularization technologies.

The increase in cost of products in the three months ended September 30, 2012 was primarily due to the addition of HeRO Graft revenues. The increase in cost of products in the nine months ended September 30, 2012 was primarily due to the addition of HeRO Graft and revascularization technologies handpiece revenues, and the increase in BioGlue sales volume, partially offset by the discontinuation of HemoStase sales.

The slight increase in cost of products as a percentage of product revenues for the three and nine months ended September 30, 2012 was primarily due to changes in product mix due to the addition of HeRO Graft revenues.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
General, administrative, and marketing expenses	\$ 16,533	\$ 14,726	\$ 48,374	\$ 42,676
General, administrative, and marketing expenses as a percentage of total revenues	49%	50%	49%	48%
General, administrative, and marketing expenses increased 12% for the three months and 13% for the nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively.				

General, administrative, and marketing expenses for the nine months ended September 30, 2012 include a \$4.7 million gain on the settlement of the lawsuit with Medafor, Inc. (Medafor) and a \$4.1 million loss for the settlement of the lawsuit with CardioFocus, Inc. (CardioFocus) related to patent infringement by the Company's Cardiogenesis laser products. Both of these lawsuits were settled in the second quarter of 2012. Legal fees related to lawsuits, primarily the Medafor and CardioFocus lawsuits, were \$3.7 million for the nine months ended September 30, 2012, and reductions to legal fees for insurance reimbursements for certain litigation expenses were \$3.4 million for the nine months ended September 30, 2012.

Business development costs, primarily related to the acquisition and integration of Hemosphere, were \$796,000 and \$1.9 million for the three and nine months ended September 30, 2012, respectively. Business development costs, primarily related to the acquisition and integration of Cardiogenesis, were \$1.1 million and \$4.1 million for the three and nine months ended September 30, 2011, respectively.

General, administrative, and marketing expenses for the three and nine months ended September 30, 2012 also increased due to an increase in marketing expenses, including the costs of the Company's expanded sales staff and increases in spending on advertising.

The Company expects that it will incur additional general, administrative, and marketing expenses for the full year of 2012 as compared to 2011 related to its expanded sales staff and the ongoing operations of Hemosphere, which the Company acquired in May 2012, and the expanded sales staff of Cardiogenesis, which was not part of the Company's business until May 2011. The Company expects that it will incur additional general, administrative, and marketing expenses in 2013 as compared to 2012 related to its acquisition of Hemosphere, and due to the 2.3% excise tax on the sale of medical devices in the U.S. that goes into effect on January 1, 2013 as part of the Patient Protection and Affordable Care Act passed in 2010.

Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development expenses	\$ 1,829	\$ 1,690	\$ 5,192	\$ 5,099
Research and development expenses as a percentage of total revenues	5%	6%	5%	6%
Research and development expenses increased 8% for the three months and 2% for the nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively. Research and development spending in these periods was primarily focused on PerClot, HeRO Graft, the Company's SynerGraft tissues and products, BioFoam, and revascularization technologies. The Company expects that research and development spending for the full year of 2012 will increase compared to the full year of 2011 due to planned increases in spending on clinical studies related to PerClot.				

Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Income before income taxes	\$ 2,624	\$ 2,289	\$ 9,810	\$ 8,603
Income tax expense	1,086	270	3,947	3,098
Net income	\$ 1,538	\$ 2,019	\$ 5,863	\$ 5,505
Diluted income per common share	\$ 0.06	\$ 0.07	\$ 0.21	\$ 0.19
Diluted weighted-average common shares outstanding	27,210	27,850	27,329	27,765

Income before income taxes increased 15% for the three months and 14% for the nine months ended September 30, 2012 as compared to the three and nine months ended September 30, 2011, respectively. The increase in income before income taxes for the three and nine months ended September 30, 2012 was primarily caused by an increase in revenues, partially offset by an increase in costs and expenses as discussed above.

The Company's effective income tax rate was approximately 41% and 40% for the three and nine months ended September 30, 2012 as compared to 12% and 36% for the three and nine months ended September 30, 2011, respectively. The Company's income tax rates in 2012 were negatively impacted by the unfavorable tax treatment of certain acquisition related expenses due to the acquisition of Hemosphere and by the research and development tax credit, which has not yet been enacted for the 2012 tax year. The Company's lower effective income tax rate for the three months ended September 30, 2011 was due to the discrete and favorable effect of deductions taken on the Company's 2010 federal tax returns, which were filed in the third quarter of 2011. For the nine months ended September 30, 2011, this favorable effect was largely offset by the unfavorable tax treatment, recognized in the second quarter of 2011, of certain acquisition related expenses, which the Company incurred related to its acquisition of Cardiogenesis.

Net income and diluted income per common share decreased for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 due to the increase in income tax expense, partially offset by an increase in income before income taxes, as discussed above. Net income and diluted income per common share increased for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 due to the increase in income before income taxes, adjusted by the effect of income tax expense, as discussed above.

Diluted income per common share could be unfavorably impacted in future periods by the issuance of additional shares of common stock and favorably impacted by the Company's repurchase of its common stock. Stock repurchases are impacted by many factors, 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's demand for its cardiac preservation services has traditionally been seasonal, with peak demand generally occurring in the third quarter. Management believes this trend for cardiac preservation services is primarily due to the high number of surgeries scheduled during the summer months for school-aged patients. Management believes that this trend is lessening in recent years as the Company is distributing a higher percentage of its tissues to adult populations.

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.

Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company is uncertain whether the demand for PerClot will be seasonal, as PerClot is a new product and the nature of any seasonal trends in PerClot sales may be obscured.

The Company is uncertain whether the demand for revascularization technologies will be seasonal, as the Company only recently acquired this product line in May 2011, and the historical data does not indicate a significant trend.

The Company is uncertain whether the demand for HeRO Grafts will be seasonal, as the Company only recently acquired this product line in May 2012, and the historical data does not indicate a significant trend.

Liquidity and Capital Resources

Net Working Capital

At September 30, 2012 net working capital (current assets of \$72.2 million less current liabilities of \$19.9 million) was \$52.3 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of \$62.4 million and a current ratio of 4 to 1 at December 31, 2011.

Overall Liquidity and Capital Resources

The Company's largest cash requirements for the nine months ended September 30, 2012 were the acquisition of Hemosphere and the related transaction and integration costs. The total acquisition cost, net of cash acquired, was \$17.0 million. CryoLife used cash on hand to fund the acquisition and operates Hemosphere as a wholly owned subsidiary. In addition, during the nine months ended September 30, 2012 the Company paid \$4.5 million in a settlement to CardioFocus, which was largely offset by \$3.5 million received in a settlement from Medafor. See *Liability Claims* below for further discussion of these settlements. The Company's other cash requirements included cash for general working capital needs, repurchases of the Company's common stock, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves and its operating activities, which generated cash during the period.

CryoLife's credit agreement with GE Capital (the *GE Credit Agreement*) provides revolving credit for working capital, acquisitions, and other corporate purposes. The borrowing capacity under the *GE Credit Agreement* is \$20.0 million (including a letter of credit subfacility), and the *GE Credit Agreement* expires October 28, 2014. The borrowing capacity may be reduced or increased from time to time pursuant to the terms of the *GE Credit Agreement*. As required under the terms of the *GE Credit Agreement*, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company's liquidity needs during the term of the *GE Credit Agreement* and, as such, have been recorded as restricted cash and securities on the Company's Summary Consolidated Balance Sheets. Also, the *GE Credit Agreement* requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined in the agreement, of at least \$20.0 million. As of September 30, 2012 the outstanding balance under the *GE Credit Agreement* was zero and \$19.8 million was available for borrowing.

In the nine months ended September 30, 2012 the Company purchased approximately 639,000 shares of its common stock for an aggregate purchase price of \$3.3 million. As of September 30, 2012 the Company had \$10.3 million in remaining authorizations under common stock repurchase programs authorized by the Company's Board of Directors. 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.

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, 2012 \$740,000 of the Company's cash equivalents were related to these DOD Grants, which must be used for the specified purposes or repaid to the Department of Defense. The Company currently plans to discontinue its BioFoam U.S. clinical trial and, after the cessation of the U.S. clinical trial, any remaining unspent funds will be returned to the Department of Defense.

As of September 30, 2012 less than 7% of the Company's cash and cash equivalents were held in foreign jurisdictions.

The Company agreed to provide funding of up to \$2.0 million in debt financing to ValveXchange, Inc. (*ValveXchange*) through a revolving credit facility. The Company advanced \$1.0 million to ValveXchange under this loan in July 2012 and advanced the remaining \$1.0 million in October 2012. The Company may decide to allow ValveXchange to issue shares in payment of some or all of the outstanding debt balance in connection with a currently proposed financing or a future round of financing.

The Company believes that its anticipated cash from operations and existing cash and cash equivalents will enable the Company to meet its current operational liquidity needs for at least the next twelve months. The Company's future cash requirements will include cash to fund the integration of Hemosphere and may include cash to fund the PerClot clinical trials, research and development expenditures for revascularization technologies and HeRO Graft, and other business development activities, to purchase license agreements, for general working capital needs, to repurchase the Company's common stock, to fund a cash dividend to common shareholders, and for other corporate purposes. The Company believes that these items could have a significant impact on its cash flows in the remainder of 2012 and thereafter. The Company may seek additional borrowing capacity or financing pursuant to its shelf registration statement, for general corporate purposes, or to fund other future cash requirements. If the Company undertakes further significant business development activity in 2012, it will likely need to finance

such activities by drawing down monies under the GE Credit Agreement, obtaining additional debt financing, or using its shelf registration statement to sell equities.

The Company acquired net operating loss carryforwards from its acquisitions of Hemosphere and Cardiogenesis that the Company believes will reduce required cash payments for federal income taxes by approximately \$1.3 million for the 2012 tax year.

Liability Claims

In the second quarter of 2012 the Company settled a lawsuit with CardioFocus related to patent infringement by the Company's Cardiogenesis laser products. In accordance with this settlement, the Company made a payment of \$4.5 million in July 2012 to CardioFocus using cash on hand. Also in the second quarter of 2012, the Company settled its lawsuit with Medafor. In accordance with this settlement, CryoLife received \$3.5 million from Medafor in the third quarter of 2012. During the nine months ended September 30, 2012 the Company received \$3.1 million in legal expense reimbursements from insurance carriers and received an additional \$893,000 in October 2012.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was \$11.0 million for the nine months ended September 30, 2012 as compared to \$13.7 million for the nine months ended September 30, 2011. The decrease in cash provided in the current year period was primarily due to the effect of working capital needs, which had an unfavorable impact on cash during the period. In addition, during the nine months ended September 30, 2012 the Company paid \$4.5 million in a settlement to CardioFocus, which was largely offset by \$3.5 million received in a settlement from Medafor, as discussed above.

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, 2012 these non-cash items included a favorable \$4.2 million in depreciation and amortization expenses, \$2.3 million in non-cash compensation, and \$1.6 million in deferred income taxes.

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, 2012 these changes included unfavorable adjustments of \$790,000 due to the timing differences between the recording of revenue or gains and the receipt of cash, and \$1.4 million due to increases in deferred preservation costs and inventory balances.

Net Cash Flows from Investing Activities

Net cash used in investing activities was \$21.0 million for the nine months ended September 30, 2012 as compared to \$27.1 million for the nine months ended September 30, 2011. The current year cash used was primarily due to the payment of \$17.0 million for the acquisition of Hemosphere, net of cash acquired, \$2.2 million in capital expenditures, and \$1.0 million in advances to ValveXchange under the revolving credit facility.

Net Cash Flows from Financing Activities

Net cash used in financing activities was \$3.9 million for the nine months ended September 30, 2012 as compared to \$1.0 million for the nine months ended September 30, 2011. The current year cash used was primarily due to \$3.5 million in purchases of treasury stock, largely related to the Company's publicly announced stock repurchase plan and \$686,000 in cash dividends paid.

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, 2012 are as follows (in thousands):

	Total	Remainder of 2012	2013	2014	2015	2016	Thereafter
Operating leases	\$ 25,064	\$ 470	\$ 2,705	\$ 2,652	\$ 2,620	\$ 2,640	\$ 13,977
Purchase commitments	7,027	1,626	3,586	1,815	--	--	--
Contingent payments	4,500	--	500	500	3,500	--	--
Compensation payments	1,985	--	992	993	--	--	--
Research obligations	1,591	580	898	113	--	--	--
Total contractual obligations	\$ 40,167	\$ 2,676	\$ 8,681	\$ 6,073	\$ 6,120	\$ 2,640	\$ 13,977

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 2014, as the Company expects to receive FDA approval for PerClot in 2015. Upon FDA approval, the Company may terminate its minimum purchase requirements, which it expects to do. However, if the Company does not terminate this provision, it will have minimum purchase obligations of \$1.75 million per year through the end of the contract term in 2025. The Company's purchase commitments also include obligations from agreements with suppliers and contractual payments for licensing computer software and telecommunication services.

The contingent payment obligations include obligations related to the Company's acquisition of Hemosphere and transaction with SMI. The contingent payment obligation for Hemosphere represents the payments that the Company will make if certain revenue milestones are achieved. The schedule includes one contingent milestone payment for \$2.5 million that the Company believes it is likely to pay in 2015, although the timing of this payment may change. The schedule excludes one contingent milestone payment of up to \$2.0 million, as the Company cannot make a reasonably reliable estimate of when this future payment may be made, if at all. The contingent payment obligation for PerClot represents the payments that the Company will make if certain FDA regulatory approvals and other commercial milestones are achieved. 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 compensation payment obligations represent 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 current employment agreement. The CEO signed a new employment agreement in October 2012, which takes effect on January 1, 2013 and expires on December 31, 2015. The new agreement is expected to extend the timing of the payment until 2016; however, payment of this benefit may be accelerated under either agreement 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 schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$2.3 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made for specific litigation or by any taxing authorities, (iii) a lease for a new manufacturing facility with total payments of approximately \$2.2 million over the next ten years, as this lease was entered into after September 30, 2012, and (iv) a \$100,000 payment due to the CEO if he remains employed by CryoLife on January 1, 2013, as this was part of the CEO's new employment agreement which was entered into after September 30, 2012.

Capital Expenditures

Capital expenditures for the nine months ended September 30, 2012 were \$2.2 million compared to \$2.0 million for the nine months ended September 30, 2011. Capital expenditures in the nine months ended September 30, 2012 were primarily related to the routine purchases of manufacturing, tissue processing, 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," and similar expressions generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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:

Expectations regarding the accounting treatment and costs of certain transactions;

Expectations regarding the renewal of certain contracts;

Expectations regarding net operating loss carryforwards and the related impact on the Company's taxes;

Expectations regarding the attainment of the performance component of 2012 equity grants;

Expectations regarding the recognition of expenses related to equity grants;

The Company's belief that preservation services revenues over the full year of 2012 will show an increase over revenues for the full year of 2011;

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

The Company's belief that it will file a revised IDE for PerClot in the fourth quarter of 2012 which will address the comments made by the FDA;

The Company's belief that the HeRO Graft will fit well into its product portfolio of medical devices;

The Company's belief that there is a significant opportunity for CryoLife's sales team to leverage their strong relationships with vascular surgeons to introduce and expand utilization of the HeRO Graft in the U.S.;

Expectations regarding payments to former shareholders of Hemosphere upon the achievement of certain revenue-based milestones, and management's estimates and assumptions regarding the achievement of such milestones;

Management's beliefs regarding BioGlue sales volume in domestic and international markets and the factors impacting such sales;

Edgar Filing: CRYOLIFE INC - Form 10-Q

Management's beliefs regarding hemostat sales in 2012 and into 2013, and the factors impacting such sales, including the potential of a negative impact from economic conditions in Europe;

The Company's belief that revascularization technologies revenues will increase in the fourth quarter of 2012 as compared to the third quarter of 2012;

The Company's beliefs regarding factors that may impact revascularization technologies revenues in the remainder of 2012;

Expectations regarding ValveXchange issuing shares in payment of some or all of its outstanding debt balance in future periods;

Anticipated cost of preservation services as a percentage of preservation services revenues;

Expectations regarding general, administrative, and marketing expenses for the remainder of 2012 and for 2013 and the factors impacting such costs;

The Company's expectations that research and development expenses for the full year of 2012 will increase compared to 2011, and the factors impacting such expenses;

Expectations regarding business development opportunities and related costs;

The Company's beliefs regarding the seasonal nature of the demand for some of its preservation services and products;

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

Expectations regarding the Company's future cash requirements and the impact of certain items on the Company's cash flows;

The Company's belief that it may seek additional borrowing capacity or financing for general corporate purposes or to fund other future cash requirements;

The Company's belief that further significant business development activity in 2012 would likely require the Company to draw down monies on its credit facility, obtain additional debt financing, or sell equity under its shelf registration statement;

The Company's expectation that it will receive FDA approval for PerClot in 2015;

The Company's expectation that it will terminate its minimum purchase requirements for PerClot after the product receives FDA approval;

Company plans regarding the BioFoam U.S. clinical trial and related funds;

Expectations regarding obligations for certain contingent payments and purchase commitments related to asset purchases and acquisitions, and the timing of such payments and purchases;

Estimated liability for uncertain tax positions and interest and penalties;

The Company's plans to terminate its letter of credit related to the Tenaxis litigation in the fourth quarter of 2012;

The Company's anticipation that it will pay quarterly dividends going forward;

Expectations regarding the impact of new accounting pronouncements;

The Company's belief that it will be able to address the FDA's observations contained in the October 16, 2012 Form 483 Notice of Observations and that the actions required to respond will not be material;

The Company's belief that PerClot will not, when used in accordance with the methods that will be published in the Company's literature and the related instructions for use, infringe Medafor's U.S. patent; 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 risk factors set forth under Part I, Item 1A of the Company's Form 10-K for the year ended December 31, 2011, the risk factors set forth under Part II, Item 1A of the Company's Form 10-Q for the quarter ended June 30, 2012, the risk factors set forth under Part II, Item 1A of this Form 10-Q, 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

Edgar Filing: CRYOLIFE INC - Form 10-Q

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

Along with the risks identified in Part II, Item 1A of this Form 10-Q, the risks and uncertainties which might impact the forward-looking statements and the Company, its ability to continue as a going concern, and the trading value of its common stock include concerns that:

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

The continued introduction into the market of products that compete with BioGlue could have an irreversible adverse impact on our sales of BioGlue;

Our BioGlue patent has expired in the U.S. and will expire in the rest of the world in mid-2013;

Our tissues and products allegedly have caused, and may in the future cause, injury to patients, and we have been, and may in the future be, exposed to tissue processing and product liability claims, including one currently outstanding product liability lawsuit, and additional regulatory scrutiny as a result;

Our investment in Medafor has been impaired due to Medafor's termination of our Exclusive Distribution Agreement with Medafor and our investment could be further impaired by risks associated with Medafor's business or by Medafor's actions, which could have a material adverse impact on our financial condition and profitability;

We will not fully realize the benefit of our investment in our distribution and license and manufacturing agreements with Starch Medical, Inc. unless we are able to obtain FDA approval for PerClot in the U.S., which will require an additional commitment of funds;

The receipt of impaired materials or supplies that do not meet our standards or the recall of materials or supplies by our vendors or suppliers could have a material adverse impact on our revenues, financial condition, profitability, and cash flows;

Our sales are impacted by challenging domestic and international economic conditions and their constraining effect on hospital budgets and demand for our tissues and products could decrease in the future, which could have a material adverse impact on our business;

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

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

We may be unsuccessful in our efforts to market and sell PerClot in the U.S. and internationally;

Factors that have negatively impacted revascularization technologies revenues in the first nine months of 2012 may continue for the remainder of 2012;

Edgar Filing: CRYOLIFE INC - Form 10-Q

We have inherited risks and uncertainties related to Cardiogenesis business;

We have inherited risks and uncertainties related to Hemosphere's business;

We may expand through acquisitions, or licenses of, or investments in, other companies or technologies, which may result in additional dilution to our stockholders and consume resources that may be necessary to sustain our business;

We may not realize the anticipated benefits from acquisitions and we may find it difficult to integrate recent or potential future acquisitions of technology or business combinations, which could disrupt our business, dilute stockholder value, and adversely impact our operating results;

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 HemoStase sales ceased in late March 2011, and we will not be able to participate in the hemostats market in the U.S. or other markets where we lack regulatory approval unless we can obtain FDA or other regulatory approval for PerClot;

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;

Uncertainties related to patents and other proprietary technology rights may adversely impact the value of our intellectual property or may result in our payment of significant monetary damages and/or royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary technology rights against others;

Intense competition may impact our ability to operate profitably;

If we are not successful in expanding our business activities in international markets, we may be unable to increase our revenues;

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

Key growth strategies may not generate the anticipated benefits;

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

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

Consolidation in the healthcare industry could continue to result in demands for price concessions, limits on the use of our tissues and products, and limitations on our ability to sell to certain of our significant market segments;

Extensive government regulations may adversely impact our ability to develop and market services and products;

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

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

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

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

We may be unsuccessful in our attempts to recover certain insurance reimbursements to be received;

Our credit facility, which expires in October of 2014, limits our ability to pursue significant acquisitions;

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

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

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

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

Our investment in ValveXchange, Inc. has been impaired and may, in the future, become further impaired, which could have a material adverse impact on our earnings; and

We are dependent on our key personnel.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company's interest income and interest 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 \$7.8 million and restricted cash and securities of \$5.0 million and interest paid on the Company's variable rate line of credit as of September 30, 2012. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the nine months ended September 30, 2012, affecting the Company's cash and cash equivalents, restricted cash and 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 significant portion of the Company's international BioGlue revenues are denominated in British Pounds and Euros, and a portion of the Company's general, administrative, and marketing expenses are denominated in British Pounds and Euros. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2012 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 weighted-average exchange rates experienced by the Company for the nine months ended September 30, 2012 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. Due to 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. The Company's Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of September 30, 2012 the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

The Securities and Exchange Commission's general guidance permits the exclusion of an assessment of the effectiveness of a registrant's disclosure controls and procedures as they relate to its internal control over financial reporting for an acquired business during the first year following such acquisition if, among other circumstances and factors, there is not adequate time between the acquisition date and the date of assessment. As previously noted in this Form 10-Q, the Company completed the acquisition of Hemosphere, Inc. (Hemosphere) during the second quarter of 2012. Management's assessment and conclusion on the effectiveness of the Company's disclosure controls and procedures as of September 30, 2012 excludes an assessment of the internal control over financial reporting of Hemosphere. See Note 4 of the Notes to Summary Consolidated Financial Statements contained in this Form 10-Q for a description of the significance of the acquired business to the Company.

During the quarter ended September 30, 2012 there were no other 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.

None.

Item 1A. Risk Factors.

The risks relating to the Medafor, Tenaxis, and CardioFocus litigation described in Part I, Item 1A, Risk Factors in our Form 10-K for the year ended December 31, 2011 are no longer applicable because of the settlements described elsewhere in this Form 10-Q.

Our Tissues And Products Are Subject To Regulatory Scrutiny, And The FDA Or Other Regulatory Body Could Revoke Our Registration, Require Us To Recall Our Tissues And Products, Change Our Processes Or Procedures, Or Take Other Enforcement Actions.

The processing, preservation, and distribution of human tissues, and the manufacture and sale of medical devices has inherent risks, and these processes are subject to FDA and other regulatory bodies' scrutiny and inspections.

For example, in 2002 the FDA issued an order regarding our non-valved cardiac, vascular, and orthopaedic tissues processed by us from October 3, 2001 until August 13, 2002, which we refer to as the FDA Order. Pursuant to the FDA Order, we recalled these tissues or placed them on quarantine hold. Shortly after the FDA Order, the FDA posted a notice, now archived, on its website stating its concerns regarding our heart valve tissues. As a result, some surgeons and hospitals decided not to use our heart valves, and our financial condition, profitability, and cash flows were materially adversely impacted.

On October 16, 2012 we received a Form 483 Notice of Observations from the FDA related to our processing, preservation, and distribution of human tissue and the manufacture of our medical devices. We believe that we will be able to address the FDA's observations contained in the 483, however, it is possible that we may not be able to do so in a manner satisfactory to the FDA. Although we do not believe that they will be material, actions we may be required to take in response to the 483 could materially adversely impact the availability of our tissues and products and our cost structure, which could impact our revenues, financial condition, profitability, or cash flows.

If we are unable to satisfy the observations cited by the FDA, the FDA can institute a wide variety of enforcement actions ranging from public warning letters to more severe sanctions such as fines; injunctions; civil penalties; recall of our tissues and/or products; operating restrictions; suspension of production; non-approval or withdrawal of approvals or clearances for new products or existing products and criminal prosecution. A warning letter, recall, hold, or other negative publicity from the FDA resulting from the observations contained in this 483 or otherwise may decrease demand for our tissues or products or cause us to write down our deferred preservation costs or inventory and could have a material adverse impact on our revenues, financial condition, profitability, and cash flows. In addition any adverse publicity resulting from an FDA action or a recall or hold could encourage recipients of our tissues and our medical devices to bring lawsuits against us. Although we believe our insurance coverage is adequate, our insurance coverage has in the past been and may in the future be insufficient to cover damages and settlement obligations. Adverse judgments and settlements in excess of our available insurance coverage could materially adversely impact our financial condition, profitability, or cash flows.

We May Be Unable To Profitably Market And Sell PerClot In The U.S. Because We Are Unable To Obtain FDA Approval, Or Because We Are Found To Infringe Medafor s Or Another Third Party s Patent Rights, And Patent Infringement Lawsuits Are Expensive.

We must obtain FDA approval before we can distribute PerClot in the U.S, and there is no guaranty that we will be able to do so on a timely basis, or at all. In addition Medafor sent us a letter in September 2012 stating that PerClot when introduced in the U.S. will, when used in accordance with the method published in our literature and with the instructions for use, infringe their U.S. patent. We do not believe that PerClot will, when used in accordance with the methods that will be published in our literature and the related instructions for use, infringe their U.S. patent. If we are able to obtain FDA approval for PerClot, however, Medafor will likely sue us for patent infringement. If we are unable to receive FDA approval, we will not be able to distribute PerClot in the U.S. If we do obtain FDA approval, but are found by a court to have infringed Medafor s or another third party s patent rights, we may ultimately not be able to distribute PerClot in the U.S. or we may have to pay a material license fee that may not allow us to fully realize the benefit of our investment in PerClot. Any of these occurrences could materially adversely impact our future revenues, financial condition, profitability, and cash flows. In addition patent litigation is expensive and if we are involved in patent litigation with Medafor or another party, it could materially adversely impact our financial condition, profitability, or cash flows.

Our Current Plans To Continue To Pay A Quarterly Cash Dividend May Change.

We initiated the payment of a quarterly cash dividend during the third quarter of fiscal 2012, and we anticipate the continued payment of a cash dividend to our shareholders in future quarters. However, the projected timing and amount of any future dividend payments are subject to change based on a variety of factors, including: management s assessment of our overall needs at the time; our ability to generate current and sustained future earnings and cash flows; and financial requirements, including the requirements of our credit agreement.

Management must determine the proper allocation of available resources among operating needs, capital expenditures, research and development spending, acquisitions or other investments in our business, stock repurchases, dividends, and other needs. Our credit agreement imposes limits on our ability to declare cash dividends, including that we may only make dividend payments if, on the date of the dividend payment, no default or event of default under the agreement has occurred and is continuing, and that we are in compliance with certain financial covenants contained in the agreement, including maintenance of our leverage ratio at a certain level and certain liquidity requirements. Our total annual dividend may vary from current expectations based on management decisions regarding the timing and per share value of any future cash dividends, or may be discontinued at any time, due to any of the factors described above, or other factors, as well as due to changes to the number of shares outstanding.

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

- (c) The following table provides information about purchases by the Company during the quarter ended September 30, 2012 of equity securities that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934:

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
07/01/12 - 07/31/12	--	\$ --	--	\$ 10,338,165
08/01/12 - 08/31/12	--	--	--	10,338,165
09/01/12 - 09/30/12	13,570	5.47	13,570	10,263,880
Total	13,570	5.47	13,570	10,263,880

Edgar Filing: CRYOLIFE INC - Form 10-Q

On June 1, 2010 the Company announced that its Board of Directors had authorized the purchase of up to \$15.0 million of its common stock over the course of the following two years. On November 1, 2011 the Company announced that its Board of Directors had authorized the Company's purchase of \$15.0 million of its common stock through December 31, 2012, which

included approximately \$7.7 million remaining from the June 1, 2010 repurchase program and an additional \$7.3 million, for a total authorization of \$22.3 million. 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. Under the Company's credit agreement with GE Capital, the Company is required, after giving effect to stock repurchases, to maintain liquidity, as defined within the agreement, of at least \$20.0 million.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other information.

None.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form S-3 filed February 22, 2012.)
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 July 27, 2011.)
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*	First Amendment, dated August 20, 2012, to the Amended and Restated Credit Agreement, dated October 28, 2011, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner.
10.2*	Second Amendment, dated July 18, 2012, to the Loan and Security Agreement by and between ValveXchange, Inc. and CryoLife, Inc.
10.3*	First Amendment, dated July 24, 2012, to the CryoLife, Inc. 2007 Executive Incentive Plan.
10.4*	First Amendment, dated July 23, 2012, to the 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan.
10.5*	First Amendment, dated July 24, 2012, to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan.
31.1*	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith. Pursuant to applicable securities laws and regulations, the Company is deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and is not subject to liability under any anti-fraud provisions of the federal securities laws as long as the Company has made a good faith attempt to comply with the submission requirements and promptly amends the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

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

/s/ D. ASHLEY LEE

STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer
(Principal Executive Officer)

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

October 30, 2012

DATE