

CRYOLIFE INC
Form 10-Q
April 30, 2013

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 **March 31, 2013**

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

Edgar Filing: CRYOLIFE INC - Form 10-Q

the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

Yes No

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

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

Outstanding at April 26, 2013
27,469,778 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 March 31,	
	2013	2012
	(Unaudited)	
Revenues:		
Products	\$ 19,796	\$ 16,454
Preservation services	15,677	15,659
Other	63	188
Total revenues	35,536	32,301
Cost of products and preservation services:		
Products	3,465	2,513
Preservation services	8,795	8,496
Total cost of products and preservation services	12,260	11,009
Gross margin	23,276	21,292
Operating expenses:		
General, administrative, and marketing	17,977	17,970
Research and development	1,988	1,693
Total operating expenses	19,965	19,663
Operating income	3,311	1,629
Interest expense		
Interest income	50	65
Other expense (income), net	(2)	(2)
	219	(15)
Income before income taxes	3,044	1,581
Income tax expense	852	590

Edgar Filing: CRYOLIFE INC - Form 10-Q

Net income				
		\$	2,192	\$
				991
Income per common share:				
Basic		\$	0.08	\$
				0.04
Diluted		\$	0.08	\$
				0.04
Dividends declared per share		\$	0.025	\$
				--
Weighted-average common shares outstanding:				
Basic			26,861	27,180
Diluted			27,488	27,530
Net income		\$	2,192	\$
Other comprehensive (loss) income			(33)	2
Comprehensive income		\$	2,159	\$
				993

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	March 31, 2013	December 31, 2012
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,632	\$ 13,009
Restricted securities	303	323
Receivables, net	19,878	16,520
Deferred preservation costs	26,869	27,954
Inventories	10,208	10,557
Deferred income taxes	5,637	6,100
Prepaid expenses and other	2,221	3,040
Total current assets	73,748	77,503
Property and equipment, net	11,744	11,667
Investment in equity securities	5,908	5,908
Restricted cash and securities	5,000	5,000
Goodwill	11,365	11,365
Patents, net	2,057	2,114
Trademarks and other intangibles, net	21,541	21,968
Notes receivable	2,000	2,000
Deferred income taxes	16,840	16,564
Other	3,513	3,067
Total assets	\$ 153,716	\$ 157,156
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 2,864	\$ 3,775
Accrued compensation	2,807	5,055
Accrued procurement fees	4,409	4,762
Accrued expenses and other	5,190	6,437
Deferred income	1,313	1,401
Total current liabilities	16,583	21,430
Contingent consideration liability	1,951	1,912
Other	6,200	5,702
Total liabilities	24,734	29,044

Commitments and contingencies

Edgar Filing: CRYOLIFE INC - Form 10-Q

Shareholders equity:			
Preferred stock		--	--
Common stock (issued shares of 27,726 in 2013 and 27,486 in 2012)		277	275
Additional paid-in capital		123,284	122,414
Retained earnings		7,041	5,536
Accumulated other comprehensive loss		(72)	(39)
Treasury stock at cost (shares of 257 in 2013 and 14 in 2012)		(1,548)	(74)
Total shareholders equity		128,982	128,112
Total liabilities and shareholders equity	\$	153,716	\$ 157,156

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Three Months Ended	
	March 31,	
	2013	2012
	(Unaudited)	
Net cash flows from operating activities:		
Net income	\$ 2,192	\$ 991
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	1,453	1,378
Non-cash compensation	782	753
Deferred income taxes	187	162
Other non-cash adjustments to income	398	136
Changes in operating assets and liabilities:		
Receivables	(3,321)	(802)
Deferred preservation costs and inventories	1,153	(736)
Prepaid expenses and other assets	373	74
Accounts payable, accrued expenses, and other liabilities	(4,386)	(151)
Net cash flows (used in) provided by operating activities	(1,169)	1,805
Net cash flows from investing activities:		
Capital expenditures	(988)	(700)
Other	(84)	(89)
Net cash flows used in investing activities	(1,072)	(789)
Net cash flows from financing activities:		
Cash dividends paid	(687)	--
Proceeds from exercise of stock options and issuance of common stock	229	142
Repurchases of common stock	(1,203)	(1,643)
Other	(474)	(66)
Net cash flows used in financing activities	(2,135)	(1,567)
Decrease in cash and cash equivalents	(4,376)	(551)
Effect of exchange rate changes on cash	(1)	(8)
Cash and cash equivalents, beginning of period	13,009	21,705

Cash and cash equivalents, end of period	\$	8,632	\$	21,146
---	-----------	--------------	-----------	---------------

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, 2012 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of and for the three months ended March 31, 2013 and 2012 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 months ended March 31, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. 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, 2012.

2. Financial Instruments

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

March 31, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 716	\$ --	\$ --	\$ 716
Restricted securities:				
Money market funds	303	--	--	303
Total assets	1,019	--	--	1,019
Long-term liabilities:				
Contingent consideration	--	--	(1,951)	(1,951)
Total liabilities	--	--	(1,951)	(1,951)
Net assets (liabilities)	\$ 1,019	\$ --	\$ (1,951)	\$ (932)

December 31, 2012	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 1,319	\$ --	\$ --	\$ 1,319
Restricted securities:				
Money market funds	323	--	--	323
Total assets	1,642	--	--	1,642
Long-term liabilities:				
Contingent consideration	--	--	(1,912)	(1,912)

Edgar Filing: CRYOLIFE INC - Form 10-Q

Total liabilities	--	--	(1,912)	(1,912)
Net assets (liabilities)	\$ 1,642	\$ --	\$ (1,912)	\$ (270)

The Company used prices quoted from its investment management companies to determine the Level 1 valuation of its investments in money market funds and securities. The Company has changed the presentation of its December 31, 2012 money market funds to Level 1 from Level 2, consistent with its current year presentation. The Company recorded a contingent consideration liability, classified as Level 3, as a result of its acquisition of Hemsphere, Inc. (Hemsphere) 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, 2012	\$ 1,912
Loss on remeasurement of contingent consideration	39
Balance as of March 31, 2013	\$ 1,951

3. Cash Equivalents and Restricted Cash and Securities

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

	Unrealized Holding	Estimated Market Value	
<u>March 31, 2013</u>	Cost Basis	Gains	
Cash equivalents:			
Money market funds	\$ 716	\$ --	\$ 716
Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	303	--	303
<u>December 31, 2012</u>			
Cash equivalents:			
Money market funds	\$ 1,319	\$ --	\$ 1,319
Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	323	--	323

As of March 31, 2013 and December 31, 2012 \$303,000 and \$323,000, 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 March 31, 2013 and December 31, 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 11. This restriction lapses upon expiration of the credit agreement with GE Capital on October 28, 2014.

There were no gross realized gains or losses on cash equivalents in the three months ended March 31, 2013 and 2012. As of March 31, 2013 \$303,000 of restricted securities had a maturity date of between three months and one year. As of December 31, 2012 \$323,000 of restricted securities had a maturity date within three months. As of March 31, 2013 and December 31, 2012 \$5.0 million of the Company's restricted cash had no maturity date.

4. Hemisphere Acquisition

Overview

On May 16, 2012 CryoLife completed its acquisition of 100% of the outstanding equity of Hemisphere, 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 Hemisphere as a wholly owned subsidiary.

Edgar Filing: CRYOLIFE INC - Form 10-Q

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.

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 based on unobservable inputs, including management estimates and assumptions about future revenues, and is, therefore, classified as Level 3 within the fair value hierarchy presented in Note 2. 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), net 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 \$39,000 for the three months ended March 31, 2013 on the remeasurement of the contingent consideration liability. The balance of the contingent consideration liability was \$2.0 million as of March 31, 2013.

Accounting for the Transaction

The Company recorded an 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 purchase price allocation was finalized as of December 31, 2012.

CryoLife incurred transaction and integration costs related to the acquisition of approximately \$2.4 million for the year ended December 31, 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. The Company incurred integration costs during the three months ended March 31, 2013 related to the transfer of manufacturing operations, which may continue into the second quarter of 2013. The Company does not expect to continue to incur significant transaction or integration costs in the second half of 2013.

5. ValveXchange Investment

In July 2011 the Company purchased shares of series A preferred stock of ValveXchange, Inc. (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.

During the quarter ended March 31, 2013 the Company reviewed available information and determined that no factors were present indicating that the Company should evaluate the carrying value of its cost method investment in ValveXchange preferred stock for impairment. The carrying value of the Company's 2.4 million shares of ValveXchange preferred stock was \$3.2 million as of March 31, 2013.

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 are 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 \$2.0 million advance is recorded as long-term notes receivable on the Company's Summary Consolidated Balance Sheet as of March 31, 2013. 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 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 future round of financing.

6. CardioFocus Settlement

On June 14, 2012 Cardiogenesis Corporation (Cardiogenesis) entered into a settlement agreement with respect to its litigation with CardioFocus, Inc. (CardioFocus). 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 U.S. District Court for the District of Massachusetts.

As a result of the settlement, 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 for a total of \$4.1 million in legal settlement expenses for the year ended December 31, 2012. The Company paid the \$4.5 million settlement payment to CardioFocus in July 2012 using cash on hand.

7. Medafor Matters

Investment in Medafor Common Stock

In 2009 and 2010 CryoLife purchased shares of common stock in Medafor, Inc. (Medafor). As financial information for Medafor is not readily available and as the Company does not exert significant influence over the operations of Medafor, the Company accounted for its investment in Medafor common stock using the cost method. The Company recorded the stock as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

During the quarter ended March 31, 2013 the Company reviewed available information and determined that no factors were present indicating that the Company should evaluate the carrying value of its cost method 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 March 31, 2013 and December 31, 2012.

In connection with its purchase of Medafor common stock, the Company entered into agreements with the sellers that could require CryoLife to make additional payments to the sellers if CryoLife acquired or merged with Medafor within a specified time period. The last of these provisions will expire in June 2013. The Company accounted for these provisions as an embedded derivative. CryoLife used a Black-Scholes model to value the embedded derivative, using assumptions as to the likelihood and the valuation of any additional required payments. The Company recorded the fair value of the embedded derivative as an increase to the investment in equity securities and a corresponding derivative liability on the Company's Summary Consolidated Balance Sheets.

As of March 31, 2013 and December 31, 2012 the Company believed that the likelihood of a Triggering Event was remote and the value of the Medafor Derivative was zero.

Distribution Agreement and Legal Action

CryoLife distributed a powdered hemostat for Medafor from 2008 to 2010. 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.

In June 2012 the parties entered into a settlement agreement. Per the settlement, Medafor paid \$3.5 million in cash to CryoLife in the third quarter of 2012. On June 29, 2012 the parties jointly filed stipulated dismissals with prejudice with the Georgia Court. As a result of the settlement, 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.

CryoLife received a letter from Medafor in September 2012 stating that PerClot[®], when introduced in the U.S., will, when used in accordance with the method published in CryoLife's literature and with the instructions for use, infringe Medafor's U.S. patent. CryoLife does not believe that it will infringe Medafor's patent. There have been no further communications between CryoLife and Medafor related to the September letter.

8. Deferred Preservation Costs and Inventories

Deferred preservation costs at March 31, 2013 and December 31, 2012 are comprised of the following (in thousands):

	March 31, 2013	December 31, 2012
Cardiac tissues	\$ 12,146	\$ 11,950
Vascular tissues	14,723	16,004
Total deferred preservation costs	\$ 26,869	\$ 27,954

Inventories at March 31, 2013 and December 31, 2012 are comprised of the following (in thousands):

	March 31, 2013	December 31, 2012
Raw materials and supplies	\$ 6,537	\$ 5,836
Work-in-process	797	830
Finished goods	2,874	3,891
Total inventories	\$ 10,208	\$ 10,557

9. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of March 31, 2013 and December 31, 2012 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	March 31, 2013	December 31, 2012
Goodwill	\$ 11,365	\$ 11,365
Procurement contracts and agreements	2,013	2,013
Trademarks	876	870
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. The Company believes that its trademarks and other acquired technology have an indefinite useful life as the Company currently anticipates that these trademarks and other acquired technology will contribute to cash flows of the Company indefinitely.

As of March 31, 2013 and December 31, 2012 the Company's entire goodwill balance is related to the Company's Medical Devices segment and there has been no change from the balance recorded as of December 31, 2012.

Definite Lived Intangible Assets

As of March 31, 2013 and December 31, 2012 the gross carrying values, accumulated amortization, and approximate amortization period of the Company's indefinite lived intangible assets are as follows (in thousands):

<u>March 31, 2013</u>	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	\$ 14,020	\$ 1,823	11-16 Years
Patents	4,666	2,609	17 Years
Distribution and manufacturing rights and know-how	3,559	534	15 Years
Customer lists and relationships	3,370	391	13-17 Years
Non-compete agreement	381	238	10 Years
Other	189	131	1-3 Years

<u>December 31, 2012</u>	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	\$ 14,020	\$ 1,538	11-16 Years
Patents	4,644	2,530	17 Years
Distribution and manufacturing rights and know-how	3,559	473	15 Years
Customer lists and relationships	3,370	330	13-17 Years
Non-compete agreement	381	229	10 Years
Other	198	123	1-3 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	
	March 31,	
	2013	2012
Amortization expense	\$ 514	\$ 459

As of March 31, 2013 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2013	2014	2015	2016	2017	2018
Amortization expense	\$ 1,495	\$ 1,953	\$ 1,911	\$ 1,903	\$ 1,854	\$ 1,847

10. Income Taxes

The Company's effective income tax rate was approximately 28% for the three months ended March 31, 2013 as compared to 37% for the three months ended March 31, 2012. The Company's income tax rate in 2013 was favorably impacted by the full year 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company's tax expense during the first quarter of 2013. The Company's income tax rate in 2012 was negatively impacted by the absence of a research and development tax credit, which was not enacted for the 2012 tax year during 2012.

Edgar Filing: CRYOLIFE INC - Form 10-Q

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 book write-downs, reserves, or impairments which are not immediately deductible for tax return purposes. 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. The Company currently estimates that a portion of its state net operating loss carryforwards will not be recoverable and has, therefore, recorded a valuation allowance against these state net operating loss carryforwards.

As of March 31, 2013 the Company maintained a total of \$2.3 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$22.5 million. As of December 31, 2012 the Company had a total of \$2.3 million in valuation allowances against deferred tax assets and a net deferred tax asset of \$22.7 million.

11. Debt

GE Credit Agreement

CryoLife's amended and restated credit agreement with GE Capital (the "GE Credit Agreement") provides revolving credit for working capital, acquisitions, and other corporate purposes. The GE Credit Agreement has a borrowing capacity of \$20.0 million (including a letter of credit subfacility) and expires on October 28, 2014. The commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement.

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain 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. The agreement also limits the payment of cash dividends, up to a maximum of \$3.0 million per year, subject to satisfaction of specified conditions. 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 as of March 31, 2013 and December 31, 2012 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 March 31, 2013 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 March 31, 2013 and December 31, 2012 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate was 6.50%, and the remaining availability was \$20.0 million.

Other

Interest expense was \$50,000 and \$65,000 for the three months ended March 31, 2013 and March 31, 2012, respectively, which included interest on debt and uncertain tax positions.

12. 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):

	March 31, 2013	December 31, 2012
Short-term liability	\$ 871	\$ 895
Long-term liability	797	755
Total liability	1,668	1,650
Short-term recoverable	314	320
Long-term recoverable	321	300

Edgar Filing: CRYOLIFE INC - Form 10-Q

Total recoverable		635		620
Total net unreported loss liability	\$	1,033	\$	1,030

Further analysis indicated that the liability as of March 31, 2013 could be estimated to be as high as \$3.1 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 the occurrence of certain events, including the voluntary retirement of the CEO or termination of the CEO s employment in conjunction with certain change in control events. As of both March 31, 2013 and December 31, 2012 the Company had \$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 current employment agreement took effect on January 1, 2013 and terminates on December 31, 2015. A payment of \$100,000 was made to the CEO in January 2013 in accordance with the terms of the new employment agreement.

13. Shareholders Equity

Common Stock Repurchase

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; this program expired on December 31, 2012. In February 2013 the Company s Board of Directors authorized the purchase of up to \$15.0 million of its common stock through October 31, 2014.

For the three months ended March 31, 2013 the Company purchased approximately 199,000 shares for an aggregate purchase price of \$1.2 million and had \$13.8 million in remaining authorizations under the repurchase program. For the year ended December 31, 2012 the Company purchased approximately 639,000 shares for an aggregate purchase price of \$3.3 million. These shares were recorded, at cost, as part of treasury stock on the Company s Summary Consolidated Balance Sheets.

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 Company paid dividend payments from cash on hand of \$687,000 for the three months ended March 31, 2013 and zero for the three months ended March 31, 2012. The dividend payments were recorded as a reduction to retained earnings on the Company s Summary Consolidated Balance Sheet.

14. 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 (RSA s), restricted stock units (RSU s), performance stock units (PSU s), 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 and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 324,000 shares and had an aggregate market value of \$1.9 million during the three months ended March 31, 2013. The PSUs granted in 2013 represent the right to receive from 50% to 150% of the target numbers of shares of common stock. The performance component of PSU awards granted in 2013 is based on attaining specified levels of adjusted EBITDA, as defined in the grant, for the 2013 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 and PSUs to certain Company officers which, counting PSUs at target levels, together totaled 317,000 shares of common stock and had an aggregate market value of \$1.7 million during the three months ended March 31, 2012. The PSU's granted in 2012 earned approximately 125% of the target number of shares.

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 162,000 and 159,000 shares during the three months ended March 31, 2013 and 2012, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Employees purchased common stock totaling 49,000 and 35,000 shares in the three months ended March 31, 2013 and 2012, respectively, through the Company's ESPP.

Stock Compensation Expense

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

	Three Months Ended March 31, 2013		Three Months Ended March 31, 2012	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	4.25 Years	.50 Years	4.25 Years	.50 Years
Expected stock price volatility	0.60	0.43	0.60	0.54
Dividends	1.91%	1.61%	N/A	N/A
Risk-free interest rate	0.70%	0.16%	0.71%	0.06%

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

	Three Months Ended March 31,	
	2013	2012
RSA, RSU, and PSU expense	\$ 635	\$ 491
Stock option and ESPP option expense	211	317
Total stock compensation expense	\$ 846	\$ 808

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 \$64,000 and \$55,000 in the three months ended March 31, 2013 and 2012, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

As of March 31, 2013 the Company had total unrecognized compensation costs of \$1.1 million related to unvested stock options and \$3.7 million related to RSAs, RSUs, and PSUs, before considering the effect of expected forfeitures. As of March 31, 2013 this expense is expected to be recognized over a weighted-average period of 1.86 years for stock options, 1.55 years for RSAs, 2.00 years for RSUs, and 1.56 years for PSUs.

15. 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):

<u>Basic income per common share</u>	Three Months Ended March 31,	
	2013	2012
Net income	\$ 2,192	\$ 991
Net income allocated to participating securities	(50)	(21)
Net income allocated to common shareholders	\$ 2,142	\$ 970
Basic weighted-average common shares outstanding	26,861	27,180
Basic income per common share	\$ 0.08	\$ 0.04

<u>Diluted income per common share</u>	Three Months Ended March 31,	
	2013	2012
Net income	\$ 2,192	\$ 991
Net income allocated to participating securities	(50)	(21)
Net income allocated to common shareholders	\$ 2,142	\$ 970
Basic weighted-average common shares outstanding	26,861	27,180
Effect of dilutive stock options and awards ^a	627	350
Diluted weighted-average common shares outstanding	27,488	27,530
Diluted income per common share	\$ 0.08	\$ 0.04

^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 1.2 million shares and 1.8 million shares for the three months ended March 31, 2013 and 2012, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

16. Segment Information

The Company has two reportable segments organized according to its products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), PerClot, revascularization technologies, and HeRO Graft. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

Edgar Filing: CRYOLIFE INC - Form 10-Q

The primary measure of segment performance, as viewed by the Company's management, is segment gross margin, or net external revenues less cost of products and preservation services. 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 products and services, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended	
	March 31,	
	2013	2012
Revenues:		
Medical devices	\$ 19,796	\$ 16,454
Preservation services	15,677	15,659
Other ^a	63	188
Total revenues	35,536	32,301
Cost of products and preservation services:		
Medical devices	3,465	2,513
Preservation services	8,795	8,496
Total cost of products and preservation services	12,260	11,009
Gross margin:		
Medical devices	16,331	13,941
Preservation services	6,882	7,163
Other ^a	63	188
Total gross margin	\$ 23,276	\$ 21,292

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

	Three Months Ended	
	March 31,	
	2013	2012
Products:		
BioGlue and BioFoam	\$ 15,464	\$ 13,696
PerClot	864	644
Revascularization technologies	2,191	2,114
HeRO Graft	1,277	--
Total products	19,796	16,454
Preservation services:		
Cardiac tissue	6,645	7,080
Vascular tissue	9,032	8,579
Total preservation services	15,677	15,659
Other^a	63	188
Total revenues	\$ 35,536	\$ 32,301

^a For the three months ended March 31, 2013 and 2012 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, develops, manufactures, and commercializes medical devices for cardiac and vascular applications and preserves and distributes human tissues for transplantation. CryoLife's surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and PerCryo® an absorbable powdered hemostat, which the Company distributes for Starch Medical, Inc. 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 and its subsidiary, Hemosphere, Inc. (Hemosphere), market the Hemodialysis Reliable Outflow Graft (HeRO® Graft), which is a solution for end-stage renal disease in certain hemodialysis patients. 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 SynerGraft® technology.

For the quarter ended March 31, 2013 CryoLife had all time record quarterly revenues of \$35.5 million, led by sales of BioGlue. BioGlue revenues were \$15.4 million during the quarter, which is the Company's largest BioGlue quarter ever. Revascularization technologies revenues were \$2.2 million for the quarter, an increase over both the prior quarter and the previous year's first quarter. Preservation services revenues were flat in the first quarter of 2013 as compared to the same quarter in 2012. The Company experienced a decrease in its cash position during the quarter as increased working capital needs drove a \$1.2 million decrease in operating cash during the quarter. See the Results of Operations section below for additional analysis of the three months ended March 31, 2013.

Recent Events

On January 30, 2013 CryoLife received a warning letter (Warning Letter) dated January 29, 2013 from the U.S. Food and Drug Administration (FDA). The Warning Letter followed a Form 483, Notice of Inspectional Observations from the FDA (Form 483) related to the Company's processing, preservation, and distribution of human tissue and the manufacture of medical devices. The Form 483 followed a routine quality system inspection of the Company's facilities by the FDA during the period September 17, 2012 to October 16, 2012. The Warning Letter relates to certain Observations from the Form 483 that the FDA believes were either inadequately addressed by the Company's responses or for which the FDA required further information to fully assess the Company's corrective actions. The Company has responded to the FDA's requests and has implemented and continues to implement changes that it believes will address the FDA's notice of violations contained in the Warning Letter; however, it is possible that the Company may not be able to do so in a manner satisfactory to the FDA. The Company believes that the Warning Letter and its actions regarding the Warning Letter and Form 483 will not have a material impact on the Company. However, it is possible that actions it may be required to take in response to the Form 483 and Warning Letter could materially, adversely impact the availability of the Company's tissues and products and cost structure, which could impact the Company's revenues, financial condition, profitability, or cash flows.

Following the receipt of the Warning Letter, CryoLife received a letter from the Human Tissue Authority (HTA) in London, UK, on March 28, 2013 which governs the distribution of tissues by the Company's subsidiary CryoLife Europa, Ltd. (Europa) into markets in Europe. The letter temporarily suspended Europa's license to import human tissue, due to concerns the HTA had related to the FDA Warning Letter, and directs Europa to issue a recall for tissues previously distributed which have not been implanted. The HTA subsequently issued a variance to allow Europa to continue to import tissue into Europe under certain circumstances for critically ill patients. This three month suspension could be extended or ended earlier based on the Company's ability to address the HTA's concerns. The suspension is expected to decrease European preservation services revenues, which totaled \$2.3 million in 2012 and \$444,000 in the first quarter of 2013, and were primarily related to the shipment of cardiac tissues. However, due to the low fees and high costs of distributing tissues into Europe, CryoLife does not believe that this suspension, including the related recall expenses, will have a material, adverse impact on the Company's financial condition, profitability, or cash flows.

In March 2013 the Company received FDA 510(k) clearance for a next generation HeRO device. CryoLife anticipates launching the next generation HeRO device during the fourth quarter of 2013 following scale up and validation of the manufacturing process.

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, 2012. 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 March 31, 2013 in any of its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2012.

New Accounting Pronouncements

In January 2013 the Company adopted Accounting Standards Update (ASU), 2012-02, Intangibles-Goodwill and Other (Topic 350): *Testing Indefinite-Lived Intangible Assets for Impairment*, which gives entities testing indefinite-lived intangible assets for impairment the option of performing a qualitative assessment before performing the quantitative impairment test as well as the option to bypass the qualitative assessment in any period and proceed directly to performing the quantitative impairment test. The adoption of ASU 2012-02 did not have a material effect on the Company's financial condition, profitability, or cash flows.

In February 2013 the Company adopted ASU 2013-02, Comprehensive Income (Topic 220): *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, which requires separate presentation of the components that are reclassified out of accumulated other comprehensive income either on the face of the financial statements or in the notes to the financial statements. This update also requires companies to disclose the income statement line items impacted by any significant reclassifications.

Results of Operations

(Tables in thousands)

Revenues

	Revenues for the		Revenues as a Percentage of	
	Three Months Ended		Total Revenues for the	
	March 31,		March 31,	
	2013	2012	2013	2012
Products:				
BioGlue and BioFoam	\$ 15,464	\$ 13,696	44%	42%
PerClot	864	644	2%	2%
Revascularization technologies	2,191	2,114	6%	7%
HeRO Graft	1,277	--	4%	--%
Total products	19,796	16,454	56%	51%
Preservation services:				
Cardiac tissue	6,645	7,080	19%	22%
Vascular tissue	9,032	8,579	25%	26%
Total preservation services	15,677	15,659	44%	48%
Other	63	188	--%	1%
Total	\$ 35,536	\$ 32,301	100%	100%

Edgar Filing: CRYOLIFE INC - Form 10-Q

Revenues increased 10% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. A detailed discussion of the changes in product revenues, preservation services revenues, and other revenues for the three months ended March 31, 2013 is presented below.

Products

Revenues from products increased 20% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. This increase for the three months ended March 31, 2013 was primarily due to an increase in BioGlue revenues and the addition of HeRO Graft revenues as a result of the Company's acquisition of Hemosphere in the second quarter of 2012.

A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot; revascularization technologies; and HeRO Graft are presented below.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 13% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. This increase was primarily due to a 15% increase in the volume of milliliters sold, which increased revenues by 11%, and by an increase in average sales prices, which increased revenues by 2%.

The increase in sales volume of surgical sealants for the three months ended March 31, 2013 was due to an increase in shipments of BioGlue in certain international markets, primarily Japan and, to a lesser extent, Europe. Revenues from shipments to Japan were \$2.4 million and \$1.2 million for the three months ended March 31, 2013 and 2012, 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: continued economic pressures on hospitals and 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 U.K. 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. If the exchange rates between the U.S. Dollar and the British Pound or Euro decline materially in the future, this would have a material, adverse impact on the Company's revenues denominated in these currencies.

Domestic revenues accounted for 52% of total BioGlue revenues for the three months ended March 31, 2013, and 60% of total BioGlue revenues for the three months ended March 31, 2012. BioFoam sales accounted for less than 1% of surgical sealant sales for the three months ended March 31, 2013 and 2012. 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, which may likely cause a continued decrease in BioGlue sales volume. Economic conditions in Europe could negatively impact sales in future periods. Management also believes that international BioGlue sales will be positively impacted by increased shipments to Japan for the full year 2013 as compared to 2012, although this increase will be less than the increase experienced in 2012 over 2011.

PerClot

Revenues from the sale of PerClot increased 34% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. This increase was primarily due to a 35% increase in the volume of grams sold, which increased revenues by 35%. 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 markets in Europe.

The Company will not be able to sell PerClot in the U.S. unless and until 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 filed a revised IDE in November 2012. CryoLife is working to address questions raised by the FDA in their response to the revised IDE. CryoLife anticipates submitting this revised IDE application to the FDA in the second quarter of 2013.

The Company's sales of hemostats through its direct sales force to U.K. 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. If the exchange rates between the U.S. Dollar and the British Pound or Euro decline materially in future periods, 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 PerClot revenues will increase for the remainder of 2013 as compared to the corresponding prior year periods. However, competitive pressures and economic conditions in Europe could negatively impact PerClot sales during 2013. Continued weak economic growth 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 include revenues related primarily to the sale of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from revascularization technologies increased 4% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. Revenues from the sale of laser consoles were zero and \$135,000 for the three months ended March 31, 2013 and 2012, respectively. Revenues from the sale of handpieces increased 14% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. This increase was primarily due to an increase in average sales prices, which increased revenues by 9%, and a 5% increase in unit shipments of handpieces, which increased revenues by 5%.

Revascularization technologies revenues for the three months ended March 31, 2013 consisted primarily of handpiece sales. 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. 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 the effects of competitive pressures and challenges in selling laser consoles may continue to negatively impact laser console sales, and may also affect handpiece sales, for the remainder of 2013.

HeRO Graft

Revenues from HeRO Grafts for the three months ended March 31, 2013 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.

Revenues from HeRO Grafts increased 15% for the three months ended March 31, 2013 as compared to the three months ended December 31, 2012 on a 16% increase in the number of HeRO Graft kits sold. HeRO Graft revenues for the three months ended March 31, 2013 decreased 8% when compared to the pre-acquisition revenues for the three months ended March 31, 2012. The decrease in HeRO Graft revenues compared to the pre-acquisition prior year quarter was primarily due to the timing of surgical cases. As the HeRO Graft implant is currently performed by a relatively small number of surgeons, HeRO Graft revenues are subject to more variability quarter-to-quarter due to the timing of surgical cases. As the population of implanting doctors increases, the Company expects this variability in revenues will decrease.

Preservation Services

Revenues from preservation services for the three months ended March 31, 2013 were comparable to the three months ended March 31, 2012. An increase in vascular preservation services revenues was offset by a decrease in cardiac 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 currently believes that preservation services revenues for the full year of 2013 will show an increase over revenues for the full year of 2012; however if CryoLife is unable to resolve the issues identified by the HTA, preservation services revenues could decrease slightly for the remainder of 2013 as compared to the corresponding periods in 2012. As only 4% of the Company's preservation services revenues in 2012 were from tissues shipped into Europe and due to the low fees and high costs of distributing tissues into Europe, CryoLife does not believe that the HTA suspension will have a material, adverse impact on the Company's financial condition, profitability, or cash flows. See further discussion of any specific items affecting cardiac and vascular preservation services revenues for the three months ended March 31, 2013 below.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, decreased 6% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. This decrease was primarily due to the aggregate impact of a 9% decrease in unit shipments of cardiac tissues and favorable tissue mix, which decreased revenues by 8%, partially offset by an increase in average service fees, which increased revenues by 2%.

The decrease in revenues from volume and tissue mix was primarily due to a decrease in volume of cardiac valve shipments, partially offset by increases in the volume of lower fee cardiac patch tissues. The Company believes that the decrease in unit shipments of cardiac valves was primarily due to timing of scheduling surgical cases and timing of tissue releases as compared to the prior year quarter, which can vary as discussed above. The Company's cardiac valves are primarily used in cardiac replacement and reconstruction surgeries for patients with congenital heart defects. The Company believes that the increase in unit shipments of cardiac patches was primarily due to timing of tissue releases.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 50% of total cardiac preservation services revenues for the three months ended March 31, 2013, and 35% of total cardiac preservation services revenues for the three months ended March 31, 2012. Domestic revenues accounted for 91% of total cardiac preservation services revenues for the three months ended March 31, 2013, and 88% of total cardiac preservation services revenues for the three months ended March 31, 2012.

Cardiac preservation services revenues for the second quarter of 2013, and possibly for the remainder of 2013, could be negatively impacted by the HTA's letter suspending CryoLife's license to distribute tissue in Europe, as discussed above.

Vascular Preservation Services

Revenues from vascular preservation services increased 5% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. This increase was primarily due to an increase in average service fees, which increased revenues by 3% and a 1% increase in unit shipments of vascular tissues, which increased revenues by 2%.

The increase in average service fees for the three months ended March 31, 2013 was due in part to a list fee increase for certain vascular tissues in 2013 and fee differences due to physical characteristics of vascular tissues, and due to the routine negotiation of pricing contracts with certain customers.

The increase in vascular volume for the three months ended March 31, 2013 was primarily due to increases in shipments of aortoiliac grafts, which increased due to improved availability of tissues and increased demand for aortoiliac grafts for use in the treatment of abdominal aortic aneurisms. The majority of the Company's vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. These tissues are primarily distributed in domestic markets.

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended	
	March 31,	
	2013	2012
Cost of products	\$ 3,465	\$ 2,513

Cost of products increased 38% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. Cost of products in 2013 and 2012 includes costs related to BioGlue, BioFoam, PerClot, and revascularization technologies. Cost of products in 2013 also includes costs related to HeRO Grafts.

The increase in cost of products in the three months ended March 31, 2013 was primarily due to the addition of the sales of HeRO Graft and increased volume of BioGlue shipments.

Cost of Preservation Services

Three Months Ended

	March 31,	
	2013	2012
Cost of preservation services	\$ 8,795	\$ 8,496

Cost of preservation services increased 4% for the three months ended March 31, 2013 as compared to cost of preservation services for the three months ended March 31, 2012. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three months ended March 31, 2013 due to an increase in cost of tissue preservation costs primarily as a result of a change in vascular tissue mix and a write-down of certain cardiac tissues distributed in international markets which are not expected to ship prior to the expiration date of their packaging, largely offset by a decrease in volume of cardiac tissues shipped during the period.

Gross Margin

	Three Months Ended March 31,	
	2013	2012
Gross margin	\$ 23,276	\$ 21,292
Gross margin as a percentage of total revenues	65%	66%

Gross margin increased 9% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. Gross margin increased due to an increase in product revenues during periods. Gross margin as a percentage of total revenues in the three months ended March 31, 2013 was comparable to the three months ended March 31, 2012.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended March 31,	
	2013	2012
General, administrative, and marketing expenses	\$ 17,977	\$ 17,970
General, administrative, and marketing expenses as a percentage of total revenues	51%	56%

General, administrative, and marketing expenses for the three months ended March 31, 2013 were comparable to the three months ended March 31, 2012.

General, administrative, and marketing expenses for the three months ended March 31, 2013 included marketing expenses of the expanded sales staff due to the acquisition of Hemosphere in May 2012, increased marketing costs to support revenue growth, increased general and administrative costs due to added personnel, and medical device excise taxes. These increased expenses were offset by a decrease in legal fees related to lawsuits. Medical device excise taxes were \$248,000 for the three months ended March 31, 2013 and zero for the three months ended March 31, 2012. Legal lawsuit expenses were \$188,000 for the three months ended March 31, 2013 and \$1.7 million for the three months ended March 31, 2012.

The Company expects that its general, administrative, and marketing expenses will increase for the full year 2013 as compared to 2012 primarily due to increased personnel and selling costs related to its acquisition of Hemosphere in May 2012 and due to the 2.3% excise tax on the sale of medical devices in the U.S. that went into effect on January 1, 2013 as part of the Patient Protection and Affordable Care Act passed in 2010. The Company believes that its SynerGraft processed tissues and the majority of its medical devices are subject to the tax and that its traditionally processed tissues are not subject to the tax.

Research and Development Expenses

**Three Months Ended
March 31,**

Edgar Filing: CRYOLIFE INC - Form 10-Q

	2013	2012
Research and development expenses	\$ 1,988	\$ 1,693
Research and development expenses as a percentage of total revenues	6%	5%

Research and development expenses increased 17% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. Research and development spending in these periods was primarily focused on PerClot, the Company's tissue processing, revascularization technologies, and BioGlue and BioFoam. The Company expects that research and development spending for the full year of 2013 will increase materially compared to the full year of 2012 due to planned increases in spending on clinical studies related to PerClot.

Earnings

	Three Months Ended March 31,	
	2013	2012
Income before income taxes	\$ 3,044	\$ 1,581
Income tax expense	852	590
Net income	\$ 2,192	\$ 991
Diluted income per common share	\$ 0.08	\$ 0.04
Diluted weighted-average common shares outstanding	27,488	27,530

Income before income taxes increased 93% for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012. The increase in income before income taxes for the three months ended March 31, 2013 was primarily caused by an increase in revenues, which increased margins, as discussed above.

The Company's effective income tax rate was approximately 28% for the three months ended March 31, 2013 as compared to 37% for the three months ended March 31, 2012. The Company's income tax rate in 2013 was favorably impacted by the full year 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company's tax expense during the first quarter of 2013. This rate will return to a higher rate for the remainder of 2013, as the impact of the tax credit related to 2012 was of benefit to the Company only in the first quarter of 2013. The Company's income tax rate in 2012 was negatively impacted by the absence of a research and development tax credit, which was not enacted for the 2012 tax year during 2012.

Net income and diluted income per common share increased for the three months ended March 31, 2013 as compared to the three months ended March 31, 2012 primarily due to the increase in income before income taxes, 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 in the U.S. The Company's market for BioGlue in Japan is still in a growth phase, however, the Company believes that demand for BioGlue in Japan may be lower in the second quarter as the Company's distributor prepares for the slower summer holiday season in Japan.

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.

Edgar Filing: CRYOLIFE INC - Form 10-Q

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 March 31, 2013 net working capital (current assets of \$73.8 million less current liabilities of \$16.6 million) was \$57.2 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of \$56.1 million and a current ratio of 4 to 1 at December 31, 2012.

Overall Liquidity and Capital Resources

The Company's largest cash requirement for the three months ended March 31, 2013 was cash for general working capital needs, as the Company's accounts receivable balance increased significantly and its accrual and payable balances decreased significantly from December 31, 2012. The accounts receivable increase was due to the Company's recent sales, including strong sales in late February and March, which have not yet been converted to cash, along with the fact that accounts receivable as of December 31, 2012 was lower than normal due to timing of payments. The accrual and payable decrease was due to a large number of scheduled annual payments which were made in the first quarter that are not normally paid in the rest of the year. In addition, the Company's other cash requirements included capital expenditures, repurchases of the Company's common stock, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves.

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 March 31, 2013 the outstanding balance under the GE Credit Agreement was zero and \$20.0 million was available for borrowing.

In the three months ended March 31, 2013 the Company purchased approximately 199,000 shares of its common stock for an aggregate purchase price of \$1.2 million. As of March 31, 2013 the Company had \$13.8 million in remaining authorizations under common stock repurchase programs authorized by the Company's Board of Directors. The Company is entitled to repurchase approximately \$9.1 million in additional common stock without obtaining its lender's consent. 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 grant funding received from the U.S. Department of Defense for the development of protein hydrogel technology. As of March 31, 2013 the Company had a total of \$967,000 in cash equivalents and refundable deposits due from vendors that were related to these grants. The Company has discontinued its BioFoam U.S. clinical trial. The Company expects to return any remaining unspent funds to the U.S. Department of Defense during the second quarter of 2013.

As of March 31, 2013 approximately 12% of the Company's cash and cash equivalents were held in foreign jurisdictions.

During the third and fourth quarters of 2012 the Company advanced a total of \$2.0 million in debt financing to ValveXchange, Inc. ("ValveXchange") through a revolving credit facility. 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 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 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 the cash dividend to common shareholders, and for other corporate purposes. These items may have a significant impact on its cash flows during 2013. 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 2013, 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 \$1.5 million for the 2013 tax year.

Net Cash Flows from Operating Activities

Net cash used by operating activities was \$1.2 million for the three months ended March 31, 2013 as compared to net cash provided of \$1.8 million for the three months ended March 31, 2012. 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, partially offset by net income generated by the Company during the period.

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 three months ended March 31, 2013 these non-cash items included a favorable \$1.5 million in depreciation and amortization expenses, \$782,000 in non-cash compensation, and \$187,000 in deferred income taxes.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the three months ended March 31, 2013 these changes included unfavorable adjustments of \$3.3 million due to the timing differences between the recording of receivables and the receipt of cash, and \$4.4 million due to the timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the actual payment of cash, as discussed above.

Net Cash Flows from Investing Activities

Net cash used in investing activities was \$1.1 million for the three months ended March 31, 2013 as compared to \$789,000 for the three months ended March 31, 2012. The current year cash used was primarily due to \$1.0 million in capital expenditures.

Net Cash Flows from Financing Activities

Net cash used in financing activities was \$2.1 million for the three months ended March 31, 2013 as compared to \$1.6 million for the three months ended March 31, 2012. The current year cash used was primarily due to \$1.2 million in purchases of treasury stock related to the Company's publicly announced stock repurchase plan and \$687,000 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 March 31, 2013 are as follows (in thousands):

	Total	Remainder of 2013	2014	2015	2016	2017	Thereafter
Operating leases	\$ 25,960	\$ 1,962	\$ 2,937	\$ 2,905	\$ 2,847	\$ 2,895	\$ 12,414
Purchase commitments	5,782	3,982	1,800	--	--	--	--
Contingent payments	4,500	500	--	4,000	--	--	--
Compensation payments	1,985	--	--	--	1,985	--	--
Research obligations	2,009	1,730	279	--	--	--	--
Total contractual obligations	\$ 40,236	\$ 8,174	\$ 5,016	\$ 6,905	\$ 4,832	\$ 2,895	\$ 12,414

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.

Edgar Filing: CRYOLIFE INC - Form 10-Q

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 Hemosphere 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 PerClot 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 2015 expiration date of the CEO's employment agreement; however, payment of this benefit may be accelerated upon the occurrence of certain events, including the voluntary retirement of the CEO or termination of the CEO's employment in conjunction with certain change in control events.

The Company's research obligations represent commitments for ongoing studies and payments to support research and development activities.

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 and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$2.6 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.

Capital Expenditures

Capital expenditures for the three months ended March 31, 2013 were \$1.0 million compared to \$700,000 for the three months ended March 31, 2012. Capital expenditures in the three months ended March 31, 2013 were primarily related to the routine purchases of manufacturing, tissue processing, computer, and office equipment; computer software; and leasehold improvements 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 transaction and integration costs related to the acquisition of Hemosphere;

Expectations regarding the potential issuance of shares by ValveXchange in payment of some or all of its outstanding debt balance in future periods;

The Company's belief that PerClot will not, when introduced in the U.S. and used in accordance with the method published in the Company's literature and with the instructions for use, infringe Medafor's patent;

Expectations regarding the renewal of certain contracts;

Anticipated cash flow contributions of the Company's trademarks and other acquired technology;

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

Expectations regarding the attainment of the performance component of 2013 equity grants;

Expectations regarding the recognition of expenses related to equity grants;

The Company's beliefs regarding its ability to address the FDA's notice of violations in the Warning Letter, and the impact on the Company of the Warning Letter and the Company's actions regarding the Warning Letter and Form 483;

Expectations regarding the impact of the suspension imposed by the HTA on the Company's preservation services revenues;

The Company's belief that the suspension imposed by the HTA will not have a material, adverse financial impact on the Company's financial condition, profitability, or cash flows;

Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company's anticipated launch of the next generation HeRO device during the fourth quarter of 2013;

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

The Company's belief that it will file a revised IDE application for PerClot in the second quarter of 2013;

Management's beliefs regarding PerClot sales in the remainder of 2013, and the factors impacting such sales, including the potential of a negative impact from competitive pressures and economic conditions in Europe;

The Company's beliefs regarding factors that may negatively impact laser console and handpiece sales in the remainder of 2013;

The Company's expectation that the variability in HeRO Graft revenues will decrease as the population of implanting doctors increases;

The Company's beliefs regarding preservation services revenues for 2013;

The Company's beliefs regarding the factors affecting the volume of cardiac valve and cardiac patch shipments;

The Company's expectation that general, administrative, and marketing expenses will increase for the full year 2013 as compared to 2012, and the factors impacting such expenses;

The Company's beliefs regarding which tissues and medical devices are subject to the 2.3% excise tax;

The Company's expectations that research and development expenses for the full year of 2013 will increase materially compared to 2012, and the factors impacting such expenses;

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

The Company's plans regarding the funds related to the BioFoam U.S. clinical trial;

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

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

The Company's belief that further significant business development activity in 2013 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 belief that it may seek additional borrowing capacity or financing for general corporate purposes or to fund other future cash requirements;

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;

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;

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;

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

Expectations regarding the impact of new accounting pronouncements; 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, 2012, and other factors, many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

Risks and Uncertainties

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;

Our BioGlue patent has expired in the U.S. and will expire in the rest of the world in mid-2013. Competitors may utilize the inventions disclosed in the expired patents in competing products, although the competing product will have to be approved by the appropriate regulatory authority;

Competitors have obtained FDA approval for indications in which BioGlue has been used off-label and for which we cannot market BioGlue, which has reduced, and could continue to reduce, the addressable procedures for BioGlue;

Our products and tissues are subject to many significant risks, including being recalled or placed on hold by us, the FDA or other regulatory bodies, and adverse publicity, which could lead to decreased use, additional regulatory scrutiny, or product liability lawsuits;

Regulatory agencies could require us to change or modify our processes, procedures, and manufacturing operations, and such agencies could reclassify or reevaluate our clearances and approvals to sell our medical devices and tissue services;

Our tissues, which are not sterile when processed, and our medical devices allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose, us to tissue processing and product liability claims, including the one current product liability claim that we have, and additional regulatory scrutiny and inspections as a result;

If we fail to respond to the notice of violations in the Warning Letter to the FDA's satisfaction, we may be subject to additional regulatory action by the FDA, including recalls, injunctions and/or civil money penalties, and the demand for our products and services could be negatively impacted by adverse publicity with respect to the Warning Letter. In addition, actions required to be taken in response to the Warning Letter could impact the availability of our products and tissues and our cost structure;

If we are unable to address the concerns raised by the HTA and if the suspension of the import license granted by the HTA is not lifted, our tissue preservation service revenues could be adversely impacted for the remainder of 2013;

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 to distribute PerClot in the U.S., which will require an additional commitment of funds;

Even if we receive FDA approval, we may be unsuccessful in our efforts to sell PerClot in the U.S. as other competing products may have penetrated the market by that time;

If we sell PerClot in the U.S., we will likely end up in a patent infringement lawsuit, which will be expensive, and if we lose, we may be prohibited from selling PerClot or may have to pay substantial royalties or damages when we sell PerClot;

Edgar Filing: CRYOLIFE INC - Form 10-Q

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

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

Our investment in ValveXchange may be further impaired, or our loan to ValveXchange may become uncollectible, which could have a material, adverse impact on our business;

We continue to evaluate expansion through acquisitions, licenses, investments, and other distribution arrangements in other companies or technologies, and such actions involve the risk of unknown liabilities, and could result in the dilution of our stockholders' value, the consumption of resources that may be necessary to operate our business, the incurrence of debt on unfavorable terms, and unfavorable tax consequences;

We may not realize the anticipated benefits from acquisitions, and we may be unable to integrate, upgrade or replace systems acquired in acquisitions, secure the services of key employees, or succeed in the marketplace with the acquisition;

Our sales are impacted by challenging domestic and international economic conditions and their constraining effect on hospital budgets and demand for our products and tissues 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;

Key growth strategies may not generate the anticipated benefits;

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

Extensive government regulation may adversely impact our ability to develop and market products and services, and restrictive laws, regulations, and rules could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows;

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

Our investment in Medafor has been impaired, 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;

Intense competition may impact our ability to operate profitably;

If we are not successful in expanding our business activities in international markets, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows;

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

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

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

Our existing insurance policies may not be sufficient to cover our actual claims liability, and we may be unable to obtain future insurance policies in an amount sufficient to cover our anticipated claims at a reasonable cost or at all;

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

Our current plans and ability to continue to pay a quarterly cash dividend may change;

Our credit facility, which expires in October 2014, limits our ability to pursue significant acquisitions and also may limit our ability to borrow;

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

Rapid technological change could cause our products and services to become obsolete; 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 \$8.6 million and restricted cash of \$5.0 million and interest paid on the Company's variable rate line of credit as of March 31, 2013. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended March 31, 2013, 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 March 31, 2013 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 three months ended March 31, 2013 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 March 31, 2013 the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

During the quarter ended March 31, 2013 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.

There have been no material changes to the Risk Factors as previously disclosed in Part I, Item 1A, Risk Factors in our 10-K for the year ended December 31, 2012.

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 March 31, 2013 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 and Common Stock Units

Period	Total Number of Common Shares and Common Stock Units 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
01/01/13 - 01/31/13	4,509	\$ 6.67	--	\$ --
02/01/13 - 02/28/13	245,514	6.06	198,778	13,797,393
03/01/13 - 03/31/13	32,207	6.08	--	13,797,393
Total	282,230	6.07	198,778	13,797,393

In February 2013 the Company announced that its Board of Directors had authorized the purchase of up to \$15.0 million of its common stock through October 31, 2014. 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. For the quarter ended March 31, 2013, the Company purchased approximately 199,000 shares of its common stock for an aggregate purchase price of \$1.2 million.

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. The Company is entitled to repurchase up to approximately \$10.3 million under the February 2013 authorization without obtaining its lender's consent.

Approximately 44,000 common shares and 39,000 common stock units were purchased that were not part of a publically announced plan or program. These shares and units were tendered to the Company in payment of taxes on stock compensation.

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	Release and Noncompete Agreement, by and between the Company and Gerald B. Seery. (Incorporated herein by reference to Exhibit 10.12(c) to the Registrant's Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.2*	Form of 2013 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive 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)

April 30, 2013

DATE