

CRYOLIFE INC
Form 10-Q
April 30, 2014

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, 2014**

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

Edgar Filing: CRYOLIFE INC - Form 10-Q

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes
x No "

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

Yes x 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 "
Non-accelerated filer " (Do not check if a smaller reporting company) Accelerated filer x
Smaller reporting company "

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

Yes "
No x

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

Class	Outstanding at April 25, 2014
Common Stock, \$.01 par value per share	28,084,041 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,	
	2014	2013
	(Unaudited)	
Revenues:		
Products	\$ 19,455	\$ 19,796
Preservation services	16,276	15,677
Other	--	63
Total revenues	35,731	35,536
Cost of products and preservation services:		
Products	3,801	3,465
Preservation services	9,457	8,795
Total cost of products and preservation services	13,258	12,260
Gross margin	22,473	23,276
Operating expenses:		
General, administrative, and marketing	18,275	17,977
Research and development	2,502	1,988
Total operating expenses	20,777	19,965
Operating income	1,696	3,311
Interest expense	61	50
Interest income	(3)	(2)
Other (income) expense, net	(99)	219
Income before income taxes	1,737	3,044

Edgar Filing: CRYOLIFE INC - Form 10-Q

Income tax expense	678	852
Net income	\$ 1,059	\$ 2,192
Income per common share:		
Basic	\$ 0.04	\$ 0.08
Diluted	\$ 0.04	\$ 0.08
Dividends declared per common share	\$ 0.0275	\$ 0.0250
Weighted-average common shares outstanding:		
Basic	27,376	26,861
Diluted	28,463	27,488
Net income	\$ 1,059	\$ 2,192
Other comprehensive loss	(35)	(33)
Comprehensive income	\$ 1,024	\$ 2,159

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES
SUMMARY CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	March 31, 2014	December 31, 2013
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,763	\$ 37,643
Restricted cash and securities	5,684	5,350
Receivables, net	21,000	18,307
Deferred preservation costs	26,215	27,297
Inventories	11,489	9,771
Deferred income taxes	5,713	5,162
Prepaid expenses and other	2,988	2,797
Total current assets	105,852	106,327
Property and equipment, net	11,994	12,171
Goodwill	11,365	11,365
Patents, net	1,852	1,934
Trademarks and other intangibles, net	19,829	19,985
Notes receivable	2,000	2,000
Deferred income taxes	16,370	16,885
Other	4,255	4,016
Total assets	\$ 173,517	\$ 174,683
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 5,000	\$ 5,514
Accrued compensation	3,087	4,886
Accrued procurement fees	5,013	5,427
Accrued expenses and other	4,883	4,579
Deferred income	380	316
Total current liabilities	18,363	20,722
Contingent consideration liability	1,786	1,884
Other	7,798	7,330

Total liabilities	27,947	29,936
Commitments and contingencies		
Shareholders equity:		
Preferred stock	--	--
Common stock (issued shares of 28,567 in 2014 and 28,244 in 2013)	286	282
Additional paid-in capital	129,966	128,585
Retained earnings	19,028	18,741
Accumulated other comprehensive (loss) income	(28)	7
Treasury stock at cost (shares of 495 in 2014 and 413 in 2013)	(3,682)	(2,868)
Total shareholders equity	145,570	144,747
Total liabilities and shareholders equity	\$ 173,517	\$ 174,683

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,	
	2014	2013
	(Unaudited)	
Net cash flows from operating activities:		
Net income	\$ 1,059	\$ 2,192
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	1,462	1,453
Non-cash compensation	845	782
Deferred income taxes	(36)	187
Other non-cash adjustments to income	(323)	398
Changes in operating assets and liabilities:		
Receivables	(2,693)	(3,321)
Deferred preservation costs and inventories	(821)	1,153
Prepaid expenses and other assets	(430)	373
Accounts payable, accrued expenses, and other liabilities	(1,101)	(4,386)
Net cash flows used in operating activities	(2,038)	(1,169)
Net cash flows from investing activities:		
Capital expenditures	(1,037)	(988)
Other	(642)	(84)
Net cash flows used in investing activities	(1,679)	(1,072)
Net cash flows from financing activities:		
Cash dividends paid	(772)	(687)
Proceeds from exercise of stock options and issuance of common stock	357	229
Repurchases of common stock	--	(1,203)
Other	(705)	(474)
Net cash flows used in financing activities	(1,120)	(2,135)

Effect of exchange rate changes on cash	(43)	(1)
Decrease in cash and cash equivalents	(4,880)	(4,377)
Cash and cash equivalents, beginning of period	37,643	13,009
Cash and cash equivalents, end of period	\$ 32,763	\$ 8,632

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, 2013 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of and for the three months ended March 31, 2014 and 2013 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, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. 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, 2013.

2. Financial Instruments

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

March 31, 2014	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 2,482	\$ --	\$ --	\$ 2,482
U.S. Treasury debt securities	20,000	--	--	20,000
Restricted securities:				
Money market funds	684	--	--	684
Total assets	\$ 23,166	\$ --	\$ --	\$ 23,166
Long-term liabilities:				
Contingent consideration	\$ --	\$ --	\$ (1,786)	\$ (1,786)
Total liabilities	\$ --	\$ --	\$ (1,786)	\$ (1,786)

December 31, 2013	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 5,349	\$ --	\$ --	\$ 5,349
Certificates of deposit	749	--	--	749
Restricted securities:				

Edgar Filing: CRYOLIFE INC - Form 10-Q

Money market funds		350		--		--		350
Total assets	\$	6,448	\$	--	\$	--	\$	6,448
Long-term liabilities:								
Contingent consideration	\$	--	\$	--	\$	(1,884)	\$	(1,884)
Total liabilities	\$	--	\$	--	\$	(1,884)	\$	(1,884)

The Company used prices quoted from its investment management companies to determine the Level 1 valuation of its investments in money market funds, certificates of deposit, and securities. The Company recorded a contingent consideration liability, classified as Level 3, as a result of its acquisition of Hemosphere, Inc. (Hemosphere) in May 2012. Refer to Note 5 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, 2013	\$ 1,884
Gain on remeasurement of contingent consideration	(98)
Balance as of March 31, 2014	\$ 1,786

3. Cash Equivalents and Restricted Cash and Securities

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

	Cost Basis	Unrealized Holding Gains	Estimated Market Value
March 31, 2014			
Cash equivalents:			
Money market funds	\$ 2,482	\$ --	\$ 2,482
U.S. Treasury debt securities	20,000	--	20,000
Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	684	--	684

December 31, 2013

Cash equivalents:			
Money market funds	\$ 5,349	\$ --	\$ 5,349
Certificates of deposit	749	--	749
Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	350	--	350

As of March 31, 2014 and December 31, 2013 \$684,000 and \$350,000, 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 primarily to international tax obligations. As of March 31, 2014 and December 31, 2013 \$5.0 million of the Company's cash was designated as short-term restricted cash 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 will lapse 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, 2014 and 2013. As of March 31, 2014 \$20,000 of the Company's restricted securities had a maturity date within three months and \$664,000 of the Company's restricted securities had a maturity date of between three months and one year. As of December 31, 2013 \$328,000 of the Company's restricted securities had a maturity date within three months and \$22,000 of the Company's restricted securities had a maturity date between three months and one year. As of March 31, 2014 and December 31, 2013 \$5.0 million of the Company's restricted cash had no maturity date.

4. ProCol Distribution Agreement

In March 2014 CryoLife acquired the exclusive worldwide distribution rights for ProCol® Vascular Bioprosthesis (ProCol) from Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). The agreement between CryoLife and Hancock Jaffe (the HJ Agreement) has an initial three-year term and is renewable for two one-year periods at CryoLife's option. Per the terms of the HJ Agreement, CryoLife has the option to acquire the ProCol product line from Hancock Jaffe beginning in March 2016.

ProCol, which is approved for sale in the U.S., is a biological graft derived from a bovine mesenteric vein that provides vascular access for end-stage renal disease (ESRD) hemodialysis patients. It is intended for the creation of a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft. ProCol is complementary to the Company's Hemodialysis Reliable Outflow Graft (HeRO Graft), which also serves patients with ESRD. ProCol provides vascular access for earlier-stage ESRD patients, while HeRO Graft is designed for patients with limited access options and central venous obstruction.

CryoLife will make payments to Hancock Jaffe of up to \$2.3 million during 2014, with no more than \$650,000 payable in any quarter. The first payment of \$430,000 was made in the first quarter of 2014. In exchange for these payments, CryoLife will receive a designated amount of ProCol inventory for resale, including a small amount of existing commercially salable inventory and additional inventory as it is manufactured and after Hancock Jaffe receives U.S. Food and Drug Administration (FDA) approval of the Premarket Approval Supplement associated with its new manufacturing facilities. Subsequent to this initial inventory purchase, CryoLife can purchase additional units from Hancock Jaffe at an agreed upon transfer price.

5. Hemisphere Acquisition

On May 16, 2012 CryoLife acquired Hemisphere, which the company now operates as a wholly owned subsidiary. Hemisphere is the developer and marketer of the HeRO Graft, a proprietary graft-based solution for ESRD hemodialysis patients with limited access options and central venous obstruction.

As of the Hemisphere 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 Hemisphere 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 liability in other (income) expense, 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 gain of \$98,000 and a loss of \$39,000 in the three months ended March 31, 2014 and 2013, respectively, on the remeasurement of the contingent consideration liability. The gains and losses in the current and prior year periods are due to the effect of the passage of time on the fair value measurements and changes in the Company's estimates. The balance of the contingent consideration liability was \$1.8 million as of March 31, 2014 and \$1.9 million as of December 31, 2013.

6. ValveXchange

Preferred Stock 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. 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 initially accounted for this investment using the cost method. The Company initially recorded its investment as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

During the fourth quarter of 2013 the Company reevaluated its investment in ValveXchange preferred stock for impairment. Based on this analysis, the Company believed that its investment in ValveXchange was fully impaired as of December 31, 2013, and the impairment was other than temporary. Therefore, in the fourth quarter of 2013 the Company recorded an other non-operating expense of \$3.2 million to write-down the remaining value of its

investment in ValveXchange preferred stock. As of March 31, 2014 and December 31, 2013 the carrying value of the Company's investment in ValveXchange preferred stock was zero.

Loan Agreement

The Company's agreement with ValveXchange, as amended, makes available up to \$2.0 million to ValveXchange in debt financing through a revolving credit facility (the "Loan"). The Loan includes various affirmative and negative covenants, including financial covenant requirements, and expires on July 30, 2018, unless terminated earlier. Amounts outstanding under the Loan 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. In 2012 the Company advanced \$2.0 million to ValveXchange under the Loan. The \$2.0 million advance is recorded as long-term notes receivable on the Company's Summary Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013.

During 2013 CryoLife repeatedly notified ValveXchange that ValveXchange was in default of certain loan covenants, due to various factors including ValveXchange's failure to obtain CryoLife's consent for certain convertible note financings that ValveXchange previously obtained. In April 2014, in conjunction with ValveXchange's series B preferred stock fundraising (the Series B), CryoLife and ValveXchange entered into an amendment to the Loan agreement pursuant to which CryoLife waived ValveXchange's previous Loan defaults in exchange for an agreement that 10% of any amounts raised in the Series B in excess of \$1.25 million would be paid to CryoLife. As of April 25, 2014, ValveXchange had raised \$1.4 million under the Series B.

Management believes that ValveXchange will continue to need additional funds to support its short-term and long-term operations, as it is currently not selling any product. However, even if ValveXchange is able to secure additional funds, if those funds are insufficient and ValveXchange cannot meet its business obligations, CryoLife may need to foreclose on the related collateral to secure repayment of the Loan. Although CryoLife currently believes that the value of the collateral is adequate to repay the Loan, there is no guarantee that the security for the notes will be sufficient to repay the Loan.

Option Agreement

Concurrently with the Loan agreement described above, CryoLife entered into an option agreement with ValveXchange pursuant to which CryoLife obtained (i) the right of first refusal to acquire ValveXchange during a period that extends through the completion of initial commercialization milestones and (ii) the right to negotiate with ValveXchange for European distribution rights. As part of the Series B, CryoLife agreed to forego its rights to negotiate with ValveXchange for European distribution rights. The Company's rights may be further modified or reduced in connection with a future round of financing.

7. Medafor Matters

Investment in Medafor Common Stock

In 2009 and 2010 CryoLife purchased shares of common stock in Medafor, Inc. (Medafor). The Company initially recorded its investment using the cost method as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

On October 1, 2013 C.R. Bard, Inc. (Bard) completed its previously announced acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately \$15.4 million for its 2.4 million shares of Medafor common stock and recorded an initial gain of approximately \$12.7 million on the sale in the fourth quarter of 2013. The Company could receive additional payments totaling up to \$8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to approximately \$525,000, if released, would be received in late 2014, although this amount is subject to possible offsets. These payments will be recorded as an additional gain when, and if, received by the Company.

Legal Action

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 (now Bard's) U.S. patent. CryoLife has received no further communications from Medafor or Bard related to the September letter.

CryoLife does not believe that its sales of PerClot will infringe Bard's patent. Accordingly, as discussed in Part II, Item 1, Legal Proceedings of this Form 10-Q, in April 2014, the Company filed a declaratory judgment action against

Bard and certain of its subsidiaries, including Medafor, in federal court, requesting that the court confirm that CryoLife's anticipated sales of PerClot, when it is approved by the FDA, and certain of its derivative products, such as PerClot Topical, which has been cleared by the FDA, will not infringe upon the patent held by Bard and/or that the Bard patent is invalid. See also Recent Events - PerClot.

8. Deferred Preservation Costs and Inventories

Deferred preservation costs at March 31, 2014 and December 31, 2013 are comprised of the following (in thousands):

	March 31, 2014	December 31, 2013
Cardiac tissues	\$ 11,681	\$ 12,239
Vascular tissues	14,534	15,058
Total deferred preservation costs	\$ 26,215	\$ 27,297

Inventories at March 31, 2014 and December 31, 2013 are comprised of the following (in thousands):

	March 31, 2014	December 31, 2013
Raw materials and supplies	\$ 6,213	\$ 5,706
Work-in-process	807	767
Finished goods	4,469	3,298
Total inventories	\$ 11,489	\$ 9,771

9. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of March 31, 2014 and December 31, 2013 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	March 31, 2014	December 31, 2013
Goodwill	\$ 11,365	\$ 11,365
Procurement contracts and agreements	2,013	2,013
Trademarks	846	841

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 have an indefinite useful life as the Company currently anticipates that these trademarks will contribute to cash flows of the Company indefinitely.

As of March 31, 2014 and December 31, 2013 the Company's entire goodwill balance is related to its Medical Devices segment, and there has been no change from the balance recorded as of December 31, 2013.

Definite Lived Intangible Assets

As of March 31, 2014 and December 31, 2013 the gross carrying values, accumulated amortization, and approximate amortization periods of the Company's definite lived intangible assets are as follows (dollars in thousands):

March 31, 2014	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	\$ 14,020	\$ 2,961	11-16 Years
Patents	4,236	2,384	17 Years
Distribution and manufacturing rights and know-how	3,559	776	15 Years
Customer lists and relationships	3,370	632	13-17 Years

Edgar Filing: CRYOLIFE INC - Form 10-Q

Non-compete agreement	381	276	10 Years
Other	470	185	1-5 Years

	Gross Carrying Value	Accumulated Amortization	Amortization Period
<u>December 31, 2013</u>			
Acquired technology	\$ 14,020	\$ 2,677	11-16 Years
Patents	4,348	2,414	17 Years
Distribution and manufacturing rights and know-how	3,559	714	15 Years
Customer lists and relationships	3,370	572	13-17 Years
Non-compete agreement	381	267	10 Years
Other	202	171	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,	
	2014	2013
Amortization expense	\$ 496	\$ 514

As of March 31, 2014 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2014	2015	2016	2017	2018	2019
Amortization expense	\$ 1,499	\$ 1,968	\$ 1,960	\$ 1,904	\$ 1,895	\$ 1,847

10. Income Taxes

The Company's effective income tax rate was approximately 39% for the three months ended March 31, 2014, as compared to 28% for the three months ended March 31, 2013. The Company's income tax rate for the three months ended March 31, 2014 was unfavorably affected by the research and development tax credit, which has not yet been enacted for the 2014 tax year. The Company's income tax rate in 2013 was favorably affected 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.

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, 2014 the Company maintained a total of \$1.5 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$22.1 million. As of December 31, 2013 the Company had a total of \$1.5 million in valuation allowances against deferred tax assets and a net deferred tax asset of \$22.0 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 provides for 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. 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, 2014 and December 31, 2013 on the Company's Summary Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement. The GE Credit Agreement allows the payment of cash dividends up to a maximum of \$3.5 million per year, subject to satisfaction of specified conditions. 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, 2014 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%, plus the applicable margin. As of March 31, 2014 and December 31, 2013 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.

In April 2014 the Company and GE Capital amended the GE Credit Agreement to increase to \$14.0 million the maximum amount that the Company may spend, from the date of the amendment through the end of the term of the GE Credit Agreement, to purchase or redeem common stock of the Company pursuant to a stock repurchase program. The \$14.0 million maximum is sufficient to cover the remaining amount under the stock repurchase program approved by the Company's Board of Directors in February 2013, of approximately \$13.5 million, as discussed further in Note 13.

Interest Expense

Interest expense was \$61,000 and \$50,000 for the three months ended March 31, 2014 and 2013, respectively, which included interest on debt and uncertain tax positions.

12. Commitments and Contingencies

Liability Claims

At March 31, 2014 and December 31, 2013 the Company's estimated unreported loss liability was \$1.5 million. The related recoverable insurance amounts were \$595,000 and \$580,000 as of March 31, 2014 and December 31, 2013, respectively. The Company accrues its estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and records the related recoverable insurance amount as a component of other long-term assets, as appropriate. Further analysis indicated that the liability as of March 31, 2014 could have been estimated to be as high as \$2.7 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 his voluntary retirement or termination of his employment in conjunction with certain change in control events. As of both March 31, 2014 and December 31, 2013 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.

13. Shareholders' Equity

Common Stock Repurchase

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.

In the three months ended March 31, 2014 the Company did not purchase common stock under the repurchase program. For the year ended December 31, 2013 the Company purchased approximately 253,000 shares for an aggregate purchase price of \$1.5 million. These shares were recorded, at cost, as part of treasury stock on the Company's Summary Consolidated Balance Sheet. As of March 31, 2014 and December 31, 2013 the Company had \$13.5 million in remaining authorizations under the repurchase program.

Cash Dividends

The Company initiated a quarterly cash dividend of \$0.025 per share of common stock outstanding in the third quarter of 2012, and increased this dividend by 10% to \$0.0275 per share of common stock outstanding in the second quarter of 2013. The Company paid dividend payments of \$772,000 and \$687,000 from cash on hand for the three months ended March 31, 2014 and

2013, respectively. The dividend payments were recorded as a reduction to retained earnings on the Company's Summary Consolidated Balance Sheets.

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 (RSAs), restricted stock units (RSUs), performance stock units (PSUs), and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP) for the benefit of its employees. The ESPP allows eligible employees 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

During the three months ended March 31, 2014 the Compensation Committee of the Company's Board of Directors authorized awards from approved stock incentive plans of RSUs to certain employees and RSAs and PSUs to certain Company officers, which assuming that performance under the PSUs were to be achieved at target levels, together totaled 326,000 shares and had an aggregate market value of \$3.3 million. The PSUs granted in 2014 represent the right to receive from 50% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2014 is based on attaining specified levels of adjusted EBITDA, as defined in the PSU grant documents, for the 2014 calendar year. The Company currently believes that achievement of the performance component is probable, and will reevaluate this likelihood on a quarterly basis.

During the three months ended March 31, 2013 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, assuming that performance under the PSUs were to be achieved at target levels, together totaled 324,000 shares of common stock and had an aggregate market value of \$1.9 million. Shares issued under the 2013 PSU awards were earned at approximately 115% of the target number of shares.

The Compensation Committee of the Company's Board of Directors authorized from approved stock incentive plans, grants of stock options to purchase a total of 162,000 shares to certain Company officers during both the three months ended March 31, 2014 and 2013. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 59,000 and 49,000 shares in the three months ended March 31, 2014 and 2013, 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		Three Months Ended	
March 31, 2014		March 31, 2013	
Stock Options	ESPP Options	Stock Options	ESPP Options

Edgar Filing: CRYOLIFE INC - Form 10-Q

Expected life of options	4.25 Years	.50 Years	4.25 Years	.50 Years
Expected stock price volatility	0.55	0.34	0.60	0.43
Dividends	1.10%	0.99%	1.91%	1.61%
Risk-free interest rate	1.19%	0.10%	0.70%	0.16%

Edgar Filing: CRYOLIFE INC - Form 10-Q

The following table summarizes total stock compensation expenses prior to the capitalization of amounts into deferred preservation and inventory costs (in thousands):

	Three Months Ended	
	March 31, 2014	2013
RSA, RSU, and PSU expense	\$ 712	\$ 635
Stock option and ESPP option expense	207	211
Total stock compensation expense	\$ 919	\$ 846

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 continued 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 \$74,000 and \$64,000 in the three months ended March 31, 2014 and 2013, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

As of March 31, 2014 the Company had total unrecognized compensation costs of \$5.3 million related to RSAs, RSUs, and PSUs, and \$1.0 million related to unvested stock options before considering the effect of expected forfeitures. As of March 31, 2014 this expense is expected to be recognized over a weighted-average period of 1.69 years for RSAs, 1.65 years for RSUs, 1.48 years for PSUs, and 2.25 years for stock options.

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):

	Three Months Ended	
	March 31,	
<u>Basic income per common share</u>	2014	2013
Net income	\$ 1,059	\$ 2,192
Net income allocated to participating securities	(21)	(50)
Net income allocated to common shareholders	\$ 1,038	\$ 2,142
Basic weighted-average common shares outstanding	27,376	26,861
Basic income per common share	\$ 0.04	\$ 0.08

	Three Months Ended	
	March 31,	
<u>Diluted income per common share</u>	2014	2013
Net income	\$ 1,059	\$ 2,192
Net income allocated to participating securities	(21)	(50)
Net income allocated to common shareholders	\$ 1,038	\$ 2,142
Basic weighted-average common shares outstanding	27,376	26,861
Effect of dilutive stock options and awards ^a	1,087	627

Diluted weighted-average common shares outstanding	28,463	27,488
Diluted income per common share	\$ 0.04	\$ 0.08

^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 131,000 shares and 1.2 million shares for the three months ended March 31, 2014 and 2013, 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.

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 preservation services, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended	
	March 31,	
	2014	2013
Revenues:		
Medical devices	\$ 19,455	\$ 19,796
Preservation services	16,276	15,677
Other ^a	--	63
Total revenues	35,731	35,536
Cost of products and preservation services:		
Medical devices	3,801	3,465
Preservation services	9,457	8,795
Total cost of products and preservation services	13,258	12,260
Gross margin:		
Medical devices	15,654	16,331
Preservation services	6,819	6,882
Other ^a	--	63
Total gross margin	\$ 22,473	\$ 23,276

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

	Three Months Ended	
	March 31,	
	2014	2013
Products:		
BioGlue and BioFoam	\$ 15,240	\$ 15,464
PerClot	916	864
Revascularization technologies	1,684	2,191
HeRO Graft	1,615	1,277
Total products	19,455	19,796
Preservation services:		
Cardiac tissue	7,190	6,645

Edgar Filing: CRYOLIFE INC - Form 10-Q

Vascular tissue	9,086	9,032
Total preservation services	16,276	15,677
Other ^a	--	63
Total revenues	\$ 35,731	\$ 35,536

^a 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) 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 PerClot®, a powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI). 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. (Hemisphere), market the Hemodialysis Reliable Outflow Graft (HeRO® Graft), which is a solution for end-stage renal disease (ESRD) 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 of which are processed using CryoLife's proprietary SynerGraft® technology.

During or shortly after the quarter ended March 31, 2014 CryoLife reported several new business developments, which are expected to help drive the future growth of the Company's medical device business. In February 2014 CryoLife announced the establishment of a new entity, CryoLife Asia Pacific Pte. Ltd. (CryoLife Asia Pacific), to expand the Company's presence in the rapidly growing Asia-Pacific medical device market. In March 2014 CryoLife entered into an exclusive agreement to distribute ProCol® Vascular Bioprosthesis (ProCol), a bioprosthetic vascular graft used to treat ESRD. Also in March 2014 CryoLife received from the U.S. Food and Drug Administration (FDA) approval of its investigational device exemption (IDE) for PerClot, which will allow the Company to begin enrollment in its pivotal U.S. PerClot clinical trial. In April 2014 CryoLife received 510(k) clearance from the FDA to market PerClot Topical, which CryoLife intends to launch in the second quarter of 2014 for use initially in ear, nose, and throat (ENT) procedures. Each of these developments is discussed further in Recent Events below. In addition, the Company hosted its third Central Venous Pathology Summit from March 25 through 27, 2014. The event examined treatment strategies for durable hemodialysis access in cases of central venous pathology, with an emphasis on treatment algorithms to both preserve and salvage central veins and a hands-on practicum. This summit underscores CryoLife's continuing commitment to the treatment of patients with ESRD.

Also during the quarter ended March 31, 2014 the Company received a Form 483, Notice of Inspectional Observations, from the FDA that included observations regarding design and process validations, environmental monitoring, product controls and handling, and employee training. See the Regulatory Activity section below for further details.

For the quarter ended March 31, 2014 CryoLife reported record first quarter revenues of \$35.7 million, a 1% increase over the quarter ended March 31, 2013. This increase was primarily due to an increase in cardiac tissue preservation services revenues, largely offset by a decrease in revascularization technologies revenues.

See the Results of Operations section below for additional analysis of the three months ended March 31, 2014.

Recent Events

CryoLife Asia Pacific

In February 2014 CryoLife announced the establishment of CryoLife Asia Pacific, a wholly owned subsidiary of CryoLife, to expand the Company's presence in the rapidly growing Asia-Pacific medical device market. To support

this new subsidiary, CryoLife relocated Mr. Rich Gridley, Vice President Sales, Canada, Asia-Pacific, and The Americas, to a new regional headquarters in Singapore. In addition to his previous responsibilities, Mr. Gridley assumed the position of general manager, CryoLife Asia Pacific. He will manage CryoLife's sales expansion, product registrations, and new product introductions in the Company's Asia-Pacific distribution network, including Japan and China.

ProCol Distribution Agreement

In March 2014 CryoLife acquired the exclusive worldwide distribution rights for ProCol, from Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). The agreement between CryoLife and Hancock Jaffe (the HJ Agreement) has an initial three-year term and is renewable for two one-year periods at CryoLife's option. Per the terms of the HJ Agreement, CryoLife has the option to acquire the ProCol product line from Hancock Jaffe beginning in March 2016.

ProCol, which is approved for sale in the U.S., is a biological graft derived from a bovine mesenteric vein that provides vascular access for ESRD hemodialysis patients. It is intended for the creation of a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft. ProCol is complementary to CryoLife's HeRO Graft, which also serves patients with ESRD. ProCol provides vascular access for earlier-stage ESRD patients, while HeRO Graft is designed for patients with limited access options and central venous obstruction.

CryoLife will make payments to Hancock Jaffe of up to \$2.3 million during 2014, with no more than \$650,000 payable in any quarter. The first payment of \$430,000 was made in the first quarter of 2014. In exchange for these payments, CryoLife will receive a designated amount of ProCol inventory for resale, including a small amount of existing commercially salable inventory and additional inventory as it is manufactured and after Hancock Jaffe receives FDA approval of the Premarket Approval (PMA) Supplement associated with its new manufacturing facilities. Subsequent to this initial inventory purchase, CryoLife can purchase additional units from Hancock Jaffe at an agreed upon transfer price.

PerClot

In March 2014 CryoLife received approval of its IDE for PerClot from the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot in the U.S. The Company plans to begin enrollment in the trial in the second quarter of 2014 and could potentially receive PMA from the FDA by the end of 2015.

The PerClot IDE is a prospective, multicenter, multidisciplinary, controlled clinical investigation. The study will include 324 patients across cardiac, general, and urological surgical specialties. The primary objective of this investigation will be to collect clinical data concerning the safety and efficacy of PerClot versus C.R. Bard, Inc.'s (Bard) Arista MPH Hemostat in multiple surgical disciplines when used as an adjunct to conventional means of achieving hemostasis such as pressure or ligature. The primary efficacy endpoint of this investigation will be achievement of hemostasis at the site of application at five minutes following application of the prescribed hemostatic agent. The secondary efficacy endpoint for this investigation will be hemostasis at the site of application evaluated at two minutes. Safety endpoints will include, but are not limited to, the incidence of reoperation due to bleeding, total hospitalization and procedure time, and the incidence of procedure complications and/or adverse events through final patient follow-up at three months.

In April 2014 CryoLife received 510(k) clearance from the FDA to market PerClot Topical in the U.S. PerClot Topical is a version of the Company's PerClot product, which will be manufactured by the Company at its headquarters and labeled for use in certain topical indications. CryoLife intends to launch PerClot Topical in the second quarter of 2014 initially for use in ENT procedures. PerClot Topical is a hemostat composed of absorbable polysaccharide granules and is intended for use as a topical dressing for the temporary treatment of mildly bleeding wounds such as surgical wounds, including post-operative, donor sites, and dermatological, cuts and lacerations, and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access, and percutaneous catheter access sites.

As discussed in Part II, Item 1, Legal Proceedings of this Form 10-Q, in April 2014, the Company filed a declaratory judgment action against Bard and certain of its subsidiaries, including Medafor, Inc., in federal court, requesting that the court confirm that CryoLife's anticipated sales of PerClot, when it is approved by the FDA, and certain of its derivative products, such as PerClot Topical, which has been cleared by the FDA, will not infringe upon the patent held by Bard and/or that the Bard patent is invalid.

Regulatory Activity

In January 2013 CryoLife received a warning letter (Warning Letter) from the FDA. The Warning Letter followed a Form 483, Notice of Inspectional Observations, from the FDA (2012 CryoLife Form 483), related to a routine quality system inspection of the Company s facilities by the FDA in September and October 2012.

In February and March 2014 the FDA re-inspected the Company to review the Company s actions and responses to the Warning Letter and to conduct a quality system inspection. Following this re-inspection, on March 20, 2014 CryoLife received a Form 483, Notice of Inspectional Observations, from the FDA (2014 CryoLife Form 483). The 2014 CryoLife Form 483 included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training.

The Company responded timely to the 2014 CryoLife Form 483 on April 10, 2014, and communications with the FDA related to these observations are ongoing. As part of the Company s response to the 2014 CryoLife Form 483, the Company voluntarily changed the expiration dating of its BioGlue 5 ml syringe from 24 months to 18 months. The Company will re-label BioGlue 5 ml product that has not reached the 18-month expiration and will replace BioGlue 5 ml product that has exceeded the 18-month expiration. The Company temporarily postponed shipments of certain cardiac and vascular tissues while it performed a voluntary review of its internal training programs.

The Company recorded an impairment to its deferred preservation costs in the first quarter of 2014 related to this review and has subsequently resumed shipments of tissues in accordance with its procedures. The Company does not believe that any of these actions will have a material impact on the Company's financial statements.

The Company believes that the changes it has implemented, and will implement, will adequately address the FDA's observations; however, it is possible that the Company may not be able to do so in a manner satisfactory to the FDA, and the FDA could issue a warning letter or take other enforcement or regulatory actions, including requiring a recall or manufacturing hold. Although the Company currently believes that the 2014 CryoLife Form 483 will not have a material effect on the Company, it is nonetheless possible that actions it may be required to take in response to the 2014 CryoLife Form 483 could materially, adversely affect the Company's revenues, financial condition, profitability, or cash flows.

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, 2013. 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, 2014 in any of its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2013.

New Accounting Pronouncements

There were no new accounting pronouncements relevant to the Company that management anticipates implementing during the year ending December 31, 2014.

Results of Operations*(Tables in thousands)***Revenues**

	Revenues for the Three Months Ended March 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended March 31,	
	2014	2013	2014	2013
Products:				
BioGlue and BioFoam	\$ 15,240	\$ 15,464	43%	44%
PerClot	916	864	2%	2%
Revascularization technologies	1,684	2,191	5%	6%
HeRO Graft	1,615	1,277	4%	4%
Total products	19,455	19,796	54%	56%
Preservation services:				
Cardiac tissue	7,190	6,645	20%	19%
Vascular tissue	9,086	9,032	26%	25%
Total preservation services	16,276	15,677	46%	44%
Other	--	63	--%	--%
Total	\$ 35,731	\$ 35,536	100%	100%

Revenues increased 1% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. A detailed discussion of the changes in product revenues and preservation services revenues for the three months ended March 31, 2014 is presented below.

Products

Revenues from products decreased 2% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. The decrease was primarily due to a decrease in revascularization technologies revenues. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot; revascularization technologies; and HeRO Graft is presented below.

The Company's sales of products 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 and/or Euro decline materially in the future, this would have a material, adverse effect on the Company's revenues denominated in these currencies.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, decreased 1% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. This decrease was primarily due to a 4% decrease in the volume of milliliters sold, which decreased revenues by 3%, partially offset by an increase in average sales prices, which increased revenues by 1%, and the favorable effect of foreign currency exchange, which increased revenues less than 1%.

The decrease in sales volume of surgical sealants for the three months ended March 31, 2014 was primarily due to a decrease in shipments of BioGlue in certain international markets, partially offset by an increase in the Company's domestic markets. The decrease in international sales of BioGlue was primarily due to decreased sales to Japan and to Latin America due to variability in ordering patterns from quarter-to-quarter.

Revenues from shipments to Japan were \$1.6 million for the three months ended March 31, 2014, as compared to \$2.4 million for the three months ended March 31, 2013. Management currently believes that BioGlue sales will be positively affected by increased shipments to Japan for the full year 2014, as compared to 2013, although this increase will be less than the increase experienced in 2013 over 2012. Management is currently seeking expanded indications for BioGlue in Japan and regulatory

approval for BioGlue in China and, if successful, believes this will provide additional international growth opportunities for BioGlue in future years.

Domestic revenues accounted for 56% and 52% of total BioGlue revenues for the three months ended March 31, 2014 and 2013, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for each of the three months ended March 31, 2014 and 2013. BioFoam is currently approved for sale in certain international markets.

PerClot

Revenues from the sale of PerClot increased 6% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. This increase was primarily due to a 19% increase in the volume of grams sold, which increased revenues by 10% and the favorable effect of foreign currency exchange, which increased revenues 2%, partially offset by a decrease in average selling prices, which decreased revenues 6%.

Revenues during these periods were for sales in certain international markets, as PerClot is not yet approved for domestic distribution, except as discussed below, or for widespread international distribution. These increases were primarily due to increased sales in the Company's markets in Europe, partially due to growth in both new geographies and new surgical indications. The Company expects that overall PerClot revenues will increase in 2014, as compared to 2013; however, revenues may show some variability from quarter-to-quarter.

In March 2014 CryoLife received approval of its IDE for PerClot from the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot in the U.S. The Company plans to begin enrollment in the trial in the second quarter of 2014 and could potentially receive PMA from the FDA by the end of 2015.

In April 2014 CryoLife received 510(k) clearance for PerClot Topical from the FDA, which allows CryoLife to begin commercialization of PerClot Topical in the U.S. The Company plans to begin shipping PerClot Topical in the second quarter of 2014.

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 decreased 23% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. Revenues from the sale of laser consoles were \$57,000 and zero for the three months ended March 31, 2014 and 2013, respectively. Revenues from the sale of handpieces decreased 28% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, primarily due to a 29% decrease in unit shipments of handpieces. Revenues from the sale of handpieces decreased 2% for the three months ended March 31, 2014, as compared to the three months ended December 31, 2013.

In June 2013 the FDA approved the Company's new handpiece design, and the Company made the decision to exclusively distribute the new handpiece beginning late in the second quarter of 2013. Following the rollout of the new handpiece, the Company's handpiece revenues decreased sequentially in the third and the fourth quarters of 2013, due to the slower than anticipated adoption of the new handpiece design. This decrease in handpiece revenues slowed in the first quarter of 2014. Management currently believes that handpiece sales will increase slightly in the second quarter of 2014, as compared to the first quarter of 2014, as the new handpiece becomes more widely used and adopted, but will decrease as compared to the second quarter of 2013.

The amount of revenues from laser console sales can vary significantly from quarter-to-quarter due to the long lead time required to generate sales of capital equipment.

HeRO Graft

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 as a solution for ESRD in certain hemodialysis patients. HeRO Graft revenues for the three months ended March 31, 2014 increased 26%, as compared to the three months ended March 31, 2013, primarily due to an increase in the volume of kits sold as a result of an increase in procedure volume and an increase in the number of implanting physicians.

Management currently expects that overall HeRO Graft revenues will increase in 2014, as compared to 2013. As the HeRO Graft implant is currently performed by a relatively small number of physicians, HeRO Graft revenues are subject to variability quarter-to-quarter due to the timing of surgical cases. As the population of implanting physicians increases, the Company expects this variability in revenues will decrease.

Preservation Services

Revenues from preservation services increased 4% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. The increase in revenues for the three month period was primarily due to an increase in cardiac tissue service revenues during the period. A detailed discussion of the changes in cardiac and vascular preservation services revenues is presented below.

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. See further discussion of any specific items affecting cardiac and vascular preservation services revenues for the three months ended March 31, 2014 below.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 8% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. This increase was primarily due to an increase in average service fees, which increased revenues by 6%, and a 4% increase in unit shipments of cardiac tissues, which increased revenues by 2%.

The increase in average service fees for the three months ended March 31, 2014 was primarily due to list price increases in domestic markets that took effect in July 2013 and due to the routine negotiation of pricing contracts with certain customers.

During the three months ended March 31, 2014 the Company's revenues from shipments of cardiac tissues into Europe were \$148,000 as compared to \$361,000 in the corresponding period in 2013. The Company ceased the distribution of tissues into Europe as of March 31, 2014.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 58% and 50% of total cardiac preservation services revenues for the three months ended March 31, 2014 and 2013, respectively. Domestic revenues accounted for 95% and 91% of total cardiac preservation services revenues for the three months ended March 31, 2014 and 2013, respectively.

The Company's cardiac valves are primarily used in cardiac replacement and reconstruction surgeries, including the Ross procedure, for patients with endocarditis or congenital heart defects.

The Company expects that overall cardiac preservation services revenues in 2014 will be comparable to the revenues in 2013, notwithstanding the cessation of shipments to Europe.

Vascular Preservation Services

Revenues from vascular preservation services increased 1% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. This increase was primarily due to an increase in average service fees, which increased revenues by 7%, largely offset by a 7% decrease in unit shipments of vascular tissues, which decreased revenues by 6%.

The increase in average service fees for the three months ended March 31, 2014 was primarily due to list fee increases in domestic markets that took effect in July 2013, fee differences due to physical characteristics of vascular tissues, and the routine negotiation of pricing contracts with certain customers.

The decrease in vascular volume for the three months ended March 31, 2014 was primarily due to decreases in shipments of saphenous veins and, to a lesser extent, femoral arteries. The Company believes that the decrease in unit shipments of veins was primarily due to the timing of tissue releases for shipments to domestic markets as compared to the prior year periods, which can vary as discussed above.

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,	
	2014	2013
Cost of products	\$ 3,801	\$ 3,465

Cost of products increased 10% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. Cost of products in 2014 and 2013 includes costs related to BioGlue, BioFoam, PerClot, revascularization technologies, and HeRO Grafts.

The increase in cost of products in the three months ended March 31, 2014 was primarily due to the increase in the per unit cost of manufacturing HeRO Grafts, as a result of the transfer of manufacturing to a new location and lower manufacturing throughput. To a lesser extent, the increase was due to an increase in the per unit costs of manufacturing BioGlue, partially offset by a decrease in the sales volume of revascularization technologies handpieces.

Cost of Preservation Services

	Three Months Ended	
	March 31,	
	2014	2013
Cost of preservation services	\$ 9,457	\$ 8,795

Cost of preservation services increased 8% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. 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, 2014 primarily due to an increase in the per unit cost of processing tissues, as a result of lower manufacturing throughput of tissues and an increase in the cost of materials.

Gross Margin

	Three Months Ended	
	March 31,	
	2014	2013
Gross margin	\$ 22,473	\$ 23,276

Gross margin as a percentage of total revenues 63% 65%

Gross margin decreased 3% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. Gross margin as a percentage of total revenues in the three months ended March 31, 2014 decreased slightly as compared to the three months ended March 31, 2013. These decreases were due to increases in costs as discussed above.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended	
	March 31,	
	2014	2013
General, administrative, and marketing expenses	\$ 18,275	\$ 17,977
General, administrative, and marketing expenses as a percentage of total revenues	51%	51%

General, administrative, and marketing expenses increased 2% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013.

The Company expects that its general, administrative, and marketing expenses will increase for the full year 2014, as compared to 2013. In addition the effects of business development expenses could further increase expenses. As discussed in Part II, Item 1, Legal Proceedings, the Company has filed a declaratory judgment action against Bard and certain of its subsidiaries, including Medafor, in federal court, requesting that the court confirm that CryoLife's anticipated sales of PerClot and certain of its derivative products, such as PerClot Topical, will not infringe upon the patent held by Bard and/or that the Bard patent is invalid. Management expects this litigation to be protracted and the costs associated with it during 2014 to be material. The Company is unable to predict at this time when and the pace at which those costs will be incurred.

Research and Development Expenses

	Three Months Ended	
	March 31,	
	2014	2013
Research and development expenses	\$ 2,502	\$ 1,988
Research and development expenses as a percentage of total revenues	7%	6%

Research and development expenses increased 26% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. Research and development spending in these periods was primarily focused on clinical and pre-clinical work with respect to PerClot, the Company's tissue processing, and BioGlue and BioFoam. The Company expects that research and development spending will increase materially in 2014 due to planned increases in spending on PerClot clinical studies.

Earnings

	Three Months Ended	
	March 31,	
	2014	2013
Income before income taxes	\$ 1,737	\$ 3,044
Income tax expense	678	852
Net income	\$ 1,059	\$ 2,192
Diluted income per common share	\$ 0.04	\$ 0.08
Diluted weighted-average common shares outstanding	28,463	27,488

Income before income taxes decreased 43% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. The decrease in income before income taxes for the three months ended March 31, 2014 was primarily due to an increase in cost of products and preservation services, which decreased margins, and an increase in research and development expenses, as discussed above, partially offset by increased revenues.

The Company's effective income tax rate was approximately 39% for the three months ended March 31, 2014, as compared to 28% for the three months ended March 31, 2013. The Company's income tax rate for the three months ended March 31, 2014 was unfavorably affected by the research and development tax credit, which has not yet been enacted for the 2014 tax year. 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.

Net income and diluted income per common share decreased for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013, primarily due to the decrease in income before income taxes, as discussed above.

Diluted income per common share could be unfavorably affected in future periods by the issuance of additional shares of common stock and favorably affected by the Company's repurchase of its common stock. Stock repurchases are influenced 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 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 continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by 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.

The Company does not believe the demand for revascularization technologies and HeRO Grafts is seasonal, as the Company's data does not indicate a significant trend.

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. Based on experience in recent years, management believes that this trend is lessening as the Company is distributing a higher percentage of its tissues for use in adult populations.

The Company's 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 vascular surgeries being scheduled during the winter holiday months.

Liquidity and Capital Resources

Net Working Capital

At March 31, 2014 net working capital (current assets of \$105.9 million less current liabilities of \$18.4 million) was \$87.5 million, with a current ratio (current assets divided by current liabilities) of 6 to 1, compared to net working capital of \$85.6 million and a current ratio of 5 to 1 at December 31, 2013.

Overall Liquidity and Capital Resources

The Company's largest cash requirement for the three months ended March 31, 2014 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, 2013. The accounts receivable increase was due to the Company's recent sales, which have not yet been converted to cash. 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 and cash dividend payments. The Company funded its cash requirements through its existing cash reserves.

CryoLife's credit agreement with General Electric Capital Corporation, as amended (the "GE Credit Agreement"), provides revolving credit for working capital, acquisitions, and other corporate purposes. The borrowing capacity under the GE Credit Agreement, which expires October 28, 2014, is \$20.0 million (including a letter of credit subfacility). 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 General Electric Capital Corporation 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 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, 2014 the outstanding balance under the GE Credit Agreement was zero, and \$20.0 million was available for borrowing.

As of March 31, 2014 the Company had \$13.5 million in remaining authorizations under common stock repurchase programs authorized by the Company's Board of Directors. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions.

As of March 31, 2014 approximately 3% of the Company's cash and cash equivalents were held in foreign jurisdictions.

On October 1, 2013 Bard completed its previously announced acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately \$15.4 million for its 2.4 million shares of Medafor common stock and recorded an initial gain of approximately \$12.7 million on the sale in the fourth quarter of 2013. The Company could receive additional payments totaling up to \$8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to

approximately \$525,000, if released, would be received in late 2014, although this amount is subject to possible offsets. These payments will be recorded as an additional gain when and if received by the Company.

As discussed elsewhere in this Form 10-Q, in September 2012, CryoLife received a letter from Medafor stating that PerClot, when introduced in the U.S and used in accordance with the method published in CryoLife's literature and with the instructions for use, will infringe Medafor's (now Bard's) U.S. patent. CryoLife does not believe that its sales of PerClot will infringe Bard's patent. Accordingly in April 2014 the Company filed a declaratory judgment action against Bard and certain of its subsidiaries, including Medafor, in federal court, requesting that the court confirm that CryoLife's anticipated sales of PerClot and certain of its derivative products, such as PerClot Topical, will not infringe upon the patent held by Bard and/or that the Bard patent is invalid. Management expects this litigation to be protracted and the costs associated with it during 2014 to be material. The Company is unable to predict at this time when and the pace at which those costs will be incurred.

In March 2014 CryoLife received approval of its IDE for PerClot from the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot in the U.S. The Company plans to begin enrollment in the trial in the second quarter of 2014. Management believes that the costs of this clinical trial will be material in 2014. In April 2014 CryoLife received 510(k) clearance from the FDA to market PerClot Topical, a version of the Company's PerClot product, which will be manufactured by the Company at its headquarters and labeled for use in certain topical indications. As a result of this recent approval and clearance, CryoLife will pay to SMI \$1.0 million in the second quarter of 2014 pursuant to the terms of the agreements between CryoLife and SMI.

In March 2014 CryoLife acquired the exclusive worldwide distribution rights for ProCol from Hancock Jaffe. CryoLife will make payments to Hancock Jaffe of up to \$2.3 million during 2014, with no more than \$650,000 payable in any quarter. The first payment of \$430,000 was made in the first quarter of 2014.

During 2012 the Company advanced a total of \$2.0 million in debt financing to ValveXchange, Inc. (ValveXchange) through a revolving credit facility (the Loan). The Loan is secured by substantially all of the tangible and intangible assets of ValveXchange. During 2013 CryoLife repeatedly notified ValveXchange that ValveXchange was in default of certain loan covenants, due to factors including ValveXchange's failure to obtain CryoLife's consent for certain convertible note financings that ValveXchange previously obtained. In April 2014, in conjunction with ValveXchange's series B preferred stock fundraising (the Series B), CryoLife and ValveXchange entered into an amendment to the Loan agreement pursuant to which CryoLife waived ValveXchange's previous Loan defaults in exchange for an agreement that 10% of any amounts raised in the Series B in excess of \$1.25 million would be paid to CryoLife. As of April 25, 2014, ValveXchange had raised \$1.4 million under the Series B. ValveXchange will continue to need additional funds to support its short-term and long-term operations, as it is currently not selling any product. However, even if ValveXchange is able to secure additional funds, if those funds are insufficient and ValveXchange cannot meet its business obligations, CryoLife may need to foreclose on the related collateral to secure repayment of the Loan. Although CryoLife currently believes that the value of the collateral is adequate to repay the Loan, there is no guarantee that the security for the notes will be sufficient to repay the Loan.

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 are expected to include cash to fund the PerClot clinical trials, to fund the PerClot declaratory judgment action, to make payments to Hancock Jaffe related to the ProCol distribution agreement, to fund business development activities, to repurchase the Company's common stock, to fund the cash dividend to common shareholders, to fund additional research and development expenditures, for general working capital needs, for capital expenditures, and for other corporate purposes. These items may have a significant effect on the Company's cash flows during the remainder of 2014. 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 2014, it may 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 2014 tax year.

Net Cash Flows from Operating Activities

Net cash used in operating activities was \$2.0 million for the three months ended March 31, 2014, as compared to \$1.2 million for the three months ended March 31, 2013.

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, 2014 these non-cash items included a favorable \$1.5 million in depreciation and amortization expenses and \$845,000 in non-cash compensation.

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, 2014 these changes included unfavorable adjustments of \$2.7 million due to the timing differences between the recording of receivables and the receipt of cash, \$1.1 million due to timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the actual payment of cash, and \$821,000 in increased balances of inventory and deferred preservation costs for which payments have already been made.

Net Cash Flows from Investing Activities

Net cash used in investing activities was \$1.7 million for the three months ended March 31, 2014, as compared to \$1.1 million for the three months ended March 31, 2013. 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 \$1.1 million for the three months ended March 31, 2014, as compared to \$2.1 million for the three months ended March 31, 2013. The current year cash used was primarily due to \$772,000 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, 2014 are as follows (in thousands):

	Total	2014	2015	2016	2017	2018	Thereafter
Operating leases	\$ 24,286	\$ 2,079	\$ 3,060	\$ 2,988	\$ 3,006	\$ 3,028	\$ 10,125
Purchase commitments	5,660	3,946	1,714	--	--	--	--
Contingent payments	4,000	500	--	3,500	--	--	--
Compensation payments	1,985	--	--	1,985	--	--	--
Research obligations	1,989	1,553	369	67	--	--	--
Total contractual obligations	\$ 37,920	\$ 8,078	\$ 5,143	\$ 8,540	\$ 3,006	\$ 3,028	\$ 10,125

The Company's operating lease obligations result from the lease of land and buildings that comprise the Company's corporate headquarters and manufacturing facilities, leases related to additional office and warehouse space, leases on Company vehicles, and leases on a variety of office equipment.

The Company's purchase commitments include minimum purchase requirements for PerClot related to the Company's transaction with SMI. These minimum purchases are included through 2015, which assumes that the Company receives FDA approval for PerClot in late 2015. Upon FDA approval, the Company may terminate its minimum purchase requirements, per the terms of the agreements between the parties, which the Company 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 to purchase ProCol from Hancock Jaffe and obligations from agreements with other suppliers.

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 2016, 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 current 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, and payment could be extended in the event the term of the CEO's employment contract is extended. The Company's Compensation Committee has entered into negotiations with our CEO regarding a one-year extension of his employment contract.

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 \$2.7 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 were \$1.0 million for both of the three month periods ended March 31, 2014 and 2013. Capital expenditures in the three months ended March 31, 2014 were primarily related to the routine purchases of manufacturing and tissue processing equipment, including support for the Company's HeRO Graft and PerClot product lines; revascularization technologies lasers; 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, potential, pending, intend, believe, expect, anticipate, estimate, plan, future, and other similar expressions 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:

Plans, costs, and expected timelines regarding clinical trials to obtain PMA to distribute PerClot in the U.S., regulatory approval for PerClot, the distribution of PerClot in certain markets after the requisite regulatory approvals are obtained, and the Company's expectation that it will terminate its minimum purchase requirements after regulatory approval of PerClot;

Plans regarding the timing, scope, and targeted indications for the launch of PerClot Topical;

Potential benefits and additional applications of the Company's surgical adhesives, sealants, hemostats, and TMR treatment;

Revenue trend estimates for the Company's products and services for 2014;

Plans related to regulatory approval in certain markets for BioFoam, and the subsequent distribution of BioFoam in those markets;

Expectations regarding growth opportunities for BioGlue in Japan and China;

Expectations regarding 2014 tissue processing revenues;

Receipt of ProCol inventory from Hancock Jaffe, and the receipt of distribution fees and profits resulting from the sale of ProCol;

Expected payments to Hancock Jaffe pursuant to the ProCol exclusive distribution agreement;

Expectations regarding 2014 HeRO Graft revenues and revenue variability;

Potential for competitive products and services to affect the market for the Company's products and services;

Anticipated payment of quarterly dividends each year;

Expectations regarding the recoverability and realizability of deferred tax assets and the anticipated benefits of net operating loss carryforwards;

Estimates of fair value of acquired assets, and its belief that the estimates are reasonable;

Expectations that the Company will continue to renew certain acquired contracts and procurement agreements for the foreseeable future;

Assumptions regarding the adequacy of, and competitive advantages conferred by, its intellectual property protections;

Plans and expectations regarding research and development of new technologies and products;

Expectations about whether and when it may receive additional payments related to its sale of Medafor stock;

Expectations that general, administrative, and marketing expenses will increase in 2014, as compared to 2013, before consideration of the effects of litigation and business development expenses;

Expectations that research and development expenses will increase materially in 2014, as compared to 2013;

The Company's belief that its sales of PerClot, upon FDA approval, and its derivative products will not infringe the patent held by Bard, that the costs associated with the declaratory judgment action against Bard and certain of its subsidiaries will be material, and that the pace at which those costs will be incurred will be unpredictable;

Expectations regarding business consolidations in the healthcare industry that could exert downward pressure on demand for Company products and the fees charged by the Company;

Expectations regarding sales of BioGlue, PerClot, handpieces, and laser consoles and the factors affecting such sales;

The Company's belief that healthcare policy and law changes may have a material adverse effect on the business;

The Company's belief that the underlying collateral is sufficient to secure the Company's \$2.0 million loan to ValveXchange;

The Company's belief regarding the sufficiency of its response to the 2014 CryoLife Form 483 and the Warning Letter, and that any issues related to the FDA's observations in the 2014 CryoLife Form 483 and the Warning Letter will not have a material effect on the Company;

Expectations regarding the impact of the re-labeling and change in expiration dating with respect to BioGlue 5ml syringes;

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

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

Estimates of contingent payments and royalties that may be paid by the Company and the timing of such payments;

The impact on cash flows of funding business development activities and the potential need to obtain additional borrowing capacity or financing;

Expectations regarding the source of any future payments related to any unreported product or tissue processing liability claims;

The anticipated impact of changes in prevailing economic conditions, interest rates, and foreign currency exchange rates;

Constraints imposed on the Company by its lender under the existing credit facility;

Plans regarding acquisition and investment opportunities of complementary product lines and companies;

Edgar Filing: CRYOLIFE INC - Form 10-Q

The anticipated effect of suppliers' /sources' inability to deliver critical raw materials or tissues and/or the Company having to source supply from an alternate supplier;

Expected impacts of issuance of additional shares and share repurchases on financial results calculated on a per-share basis;

Issues that may affect the Company's future growth, financial performance, and cash flows; 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, 2013, 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 affect 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 most of the rest of the world. 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 being subjected to 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 and additional regulatory scrutiny and inspections as a result;

The FDA may determine that our corrective actions have not, and/or proposed corrective actions will not, adequately address the issues raised in the 2014 CryoLife Form 483 and/or the Warning Letter. If we have failed to respond to the notice of violations in the 2014 CryoLife Form 483 or 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 2014 CryoLife Form 483 and/or the Warning Letter. In addition, further actions required to be taken in response to the 2014 CryoLife Form 483 and/or the Warning Letter could impact the availability of our products and tissues and our cost structure, including our revenues, financial condition, profitability, and cash flows;

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;

We will not fully realize the benefit of our distribution agreement with Hancock Jaffe unless Hancock Jaffe is able to obtain approval of a PMA with respect to its new manufacturing facility, which is beyond our control;

If Hancock Jaffe is ultimately unable to obtain approval of a PMA with respect to its new facility, we may be unable to obtain refunds of amounts previously paid to Hancock Jaffe or to obtain sufficient value from pledged collateral, and, therefore, a portion of the amounts we have paid to Hancock Jaffe may have to be written-down or impaired, and such amounts could be material;

We may ultimately be unsuccessful in our PerClot clinical trials and/or may be unable to obtain FDA approval to market and distribute PerClot in the U.S. 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;

Our declaratory judgment action against Bard and certain of its subsidiaries will be expensive, and if we lose, we may be prohibited from selling PerClot and its derivative products, such as PerClot Topical, or may have to pay substantial royalties or damages related to such sales;

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;

As a result of the funding issues that have been affecting ValveXchange, our Loan to ValveXchange may become uncollectible, which could have a material, adverse impact on our business. Even if ValveXchange is able to secure additional financing, it may nonetheless default on the Loan in the future, we may need to foreclose on the Loan, and there is no guarantee that the security for the notes will be sufficient to repay the Loan;

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 right to receive additional payments for our Medafor common stock is subject to revenue performance conditions related to the Arista product, as to which we have no control or ability to predict;

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 \$32.8 million and restricted cash of \$5.7 million and interest paid on the Company's variable rate line of credit as of March 31, 2014. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended March 31, 2014, affecting the Company's cash and cash equivalents, restricted cash and securities, and line of credit would not have a material effect 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, 2014 affecting the Company's balances denominated in foreign currencies would not have had a material effect 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, 2014 affecting the Company's revenue and expense transactions denominated in foreign currencies, would not have had a material effect 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, 2014, 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.

On May 14, 2013 the Committee of Sponsoring Organizations of the Treadway Commission (COSO) issued an updated version of its Internal Control - Integrated Framework (2013 Framework). Originally issued in 1992, (1992 Framework), the framework helps organizations design, implement, and evaluate the effectiveness of internal control concepts and simplify their use and application. The 1992 Framework will remain effective during the transition, which extends to December 15, 2014, after which time COSO will consider it as superseded by the 2013 Framework. As of March 31, 2014, the Company is using the 1992 Framework. During the quarter ended March 31, 2014 there were no changes in the Company's internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company's internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

On April 28, 2014 CryoLife filed a declaratory judgment lawsuit against C.R. Bard, Inc., Medafor, Inc., and Davol, Inc., (collectively, Bard) in the U.S. District Court for the District of Delaware (the Court). CryoLife requested that the Court declare that CryoLife's manufacture, use, offer for sale, and sale of PerClot in the U.S. does not infringe and would not infringe Bard's United States Patent No. 6,060,461 (the 461 Patent). In addition, CryoLife requested that the Court declare that the claims of the 461 Patent are invalid. As part of the relief requested, CryoLife requested injunctive relief to prohibit certain actions by Bard and an award of attorneys' fees.

The lawsuit against Bard follows the receipt by CryoLife of a letter from Medafor, Inc. 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 the 461 Patent. CryoLife received FDA 510(k) clearance for the sale of PerClot Topical in April 2014 and received approval for an IDE to begin clinical trials for PerClot in certain surgical indications in late March 2014.

As of the date of this filing, Bard has not answered the lawsuit.

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, 2013.

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, 2014 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	Average Price Paid per Common Share	Total Number of Common Shares Purchased as	Dollar Value of Common Shares That May Yet Be Purchased Under the
--------	---	---	---	--

	Units Purchased		Part of Publicly Announced Plans or Programs	Plans or Programs
01/01/14 - 01/31/14	29,694	\$ 9.79	--	\$ 13,476,633
02/01/14 - 02/28/14	99,441	9.82	--	13,476,633
03/01/14 - 03/31/14	--	--	--	13,476,633
Total	129,135	9.81	--	13,476,633

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.

Under the Company's credit agreement with General Electric Capital Corporation, the Company is required, after giving effect to stock repurchases, to maintain liquidity, as defined within the agreement, of at least \$20.0 million. In April 2014 the Company amended the agreement to allow repurchases up to approximately \$14.0 million of common stock under the February 2013 authorization without obtaining its lender's consent. As of March 31, 2014 \$13.5 million remains available under the authorization.

The common shares purchased during the quarter ended March 31, 2014 were tendered to the Company in payment of the exercise price of outstanding options and taxes on stock compensation and were not part of a publicly announced plan or program.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

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.) (File No. 001-13165)
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.) (File No. 001-13165)
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.) (File No. 001-13165)
10.1**	Exclusive Supply and Distribution Agreement, dated as of March 26, 2014, by and between CryoLife, Inc. and Hancock Jaffe Laboratories, Inc.
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.

Edgar Filing: CRYOLIFE INC - Form 10-Q

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.

+ Document is the subject of a confidential treatment request; portions of the document have been redacted and filed separately with the Securities and Exchange Commission.

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, 2014

DATE