

CRYOLIFE INC  
Form 10-Q  
October 28, 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 **September 30, 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 required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes

No

Edgar Filing: CRYOLIFE INC - Form 10-Q

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

Yes  No

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

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

Class	Outstanding at October 23, 2014
Common Stock, \$.01 par value per share	27,942,146 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)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
	<b>(Unaudited)</b>		<b>(Unaudited)</b>	
<b>Revenues:</b>				
Products	\$ 20,405	\$ 18,833	\$ 60,210	\$ 56,824
Preservation services	16,664	17,417	47,280	48,411
Other				71
<b>Total revenues</b>	<b>37,069</b>	<b>36,250</b>	<b>107,490</b>	<b>105,306</b>
<b>Cost of products and preservation services:</b>				
Products	4,167	3,544	12,099	10,730
Preservation services	9,103	9,357	26,735	26,472
<b>Total cost of products and preservation services</b>	<b>13,270</b>	<b>12,901</b>	<b>38,834</b>	<b>37,202</b>
<b>Gross margin</b>	<b>23,799</b>	<b>23,349</b>	<b>68,656</b>	<b>68,104</b>
<b>Operating expenses:</b>				
General, administrative, and marketing	18,882	16,532	55,116	51,441
Research and development	1,902	2,252	6,607	5,976
<b>Total operating expenses</b>	<b>20,784</b>	<b>18,784</b>	<b>61,723</b>	<b>57,417</b>
<b>Operating income</b>	<b>3,015</b>	<b>4,565</b>	<b>6,933</b>	<b>10,687</b>
Interest expense	65	55	110	159
Interest income	(1)	(1)	(49)	(3)
Other expense (income), net	4	(121)	(206)	120
<b>Income before income taxes</b>	<b>2,947</b>	<b>4,632</b>	<b>7,078</b>	<b>10,411</b>
Income tax expense	621	1,463	1,532	3,265

Edgar Filing: CRYOLIFE INC - Form 10-Q

<b>Net income</b>	<b>\$ 2,326</b>	<b>\$ 3,169</b>	<b>\$ 5,546</b>	<b>\$ 7,146</b>
<b>Income per common share:</b>				
<b>Basic</b>	<b>\$ 0.08</b>	<b>\$ 0.11</b>	<b>\$ 0.20</b>	<b>\$ 0.26</b>
<b>Diluted</b>	<b>\$ 0.08</b>	<b>\$ 0.11</b>	<b>\$ 0.19</b>	<b>\$ 0.25</b>
<b>Dividends declared per common share</b>	<b>\$ 0.0300</b>	<b>\$ 0.0275</b>	<b>\$ 0.0875</b>	<b>\$ 0.0800</b>
<b>Weighted-average common shares outstanding:</b>				
Basic	27,367	26,985	27,414	26,857
Diluted	28,268	27,699	28,345	27,499
<b>Net income</b>	<b>\$ 2,326</b>	<b>\$ 3,169</b>	<b>\$ 5,546</b>	<b>\$ 7,146</b>
Other comprehensive (loss) income	(80)	17	(73)	38
<b>Comprehensive income</b>	<b>\$ 2,246</b>	<b>\$ 3,186</b>	<b>\$ 5,473</b>	<b>\$ 7,184</b>

See accompanying Notes to Summary Consolidated Financial Statements.

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

	September 30, 2014	December 31, 2013
	(Unaudited)	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 29,823	\$ 37,643
Restricted cash and securities	923	5,350
Receivables, net	21,595	18,307
Deferred preservation costs	25,869	27,297
Inventories	13,162	9,771
Deferred income taxes	5,767	5,162
Prepaid expenses and other	5,491	2,797
<b>Total current assets</b>	<b>102,630</b>	<b>106,327</b>
Property and equipment, net	12,160	12,171
Restricted cash	5,000	
Goodwill	11,365	11,365
Patents, net	1,892	1,934
Trademarks and other intangibles, net	19,453	19,985
Notes receivable	2,000	2,000
Deferred income taxes	16,183	16,885
Other	4,478	4,016
<b>Total assets</b>	<b>\$ 175,161</b>	<b>\$ 174,683</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 5,389	\$ 5,514
Accrued compensation	4,528	4,886
Accrued procurement fees	4,874	5,427
Accrued expenses and other	4,795	4,579
Deferred income	410	316
<b>Total current liabilities</b>	<b>19,996</b>	<b>20,722</b>
Contingent consideration	1,392	1,884
Other	6,911	7,330

<b>Total liabilities</b>	<b>28,299</b>	<b>29,936</b>
<b>Commitments and contingencies</b>		
<b>Shareholders equity:</b>		
Preferred stock		
Common stock (issued shares of 29,027 in 2014 and 28,244 in 2013)	290	282
Additional paid-in capital	133,143	128,585
Retained earnings	21,835	18,741
Accumulated other comprehensive (loss) income	(66)	7
Treasury stock at cost (shares of 991 in 2014 and 413 in 2013)	(8,340)	(2,868)
<b>Total shareholders equity</b>	<b>146,862</b>	<b>144,747</b>
<b>Total liabilities and shareholders equity</b>	<b>\$ 175,161</b>	<b>\$ 174,683</b>

See accompanying Notes to Summary Consolidated Financial Statements.

**CRYOLIFE, INC. AND SUBSIDIARIES**

**SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(IN THOUSANDS)**

	<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
	(Unaudited)	
<b>Net cash flows from operating activities:</b>		
Net income	\$ 5,546	\$ 7,146
<b>Adjustments to reconcile net income to net cash from operating activities:</b>		
Depreciation and amortization	4,468	4,413
Non-cash compensation	2,736	2,357
Deferred income taxes	97	960
Other non-cash adjustments to income	(641)	1,133
<b>Changes in operating assets and liabilities:</b>		
Receivables	(3,288)	(4,143)
Deferred preservation costs and inventories	(2,123)	570
Prepaid expenses and other assets	(3,156)	(745)
Accounts payable, accrued expenses, and other liabilities	(306)	(384)
<b>Net cash flows provided by operating activities</b>	<b>3,333</b>	<b>11,307</b>
<b>Net cash flows from investing activities:</b>		
Capital expenditures	(3,225)	(3,241)
Other	(1,582)	(159)
<b>Net cash flows used in investing activities</b>	<b>(4,807)</b>	<b>(3,400)</b>
<b>Net cash flows from financing activities:</b>		
Cash dividends paid	(2,452)	(2,202)
Proceeds from exercise of stock options and issuance of common stock	1,409	852
Repurchases of common stock	(4,584)	(1,523)
Other	(677)	(407)
<b>Net cash flows used in financing activities</b>	<b>(6,304)</b>	<b>(3,280)</b>
Effect of exchange rate changes on cash	(42)	43

<b>(Decrease) increase in cash and cash equivalents</b>	<b>(7,820)</b>	<b>4,670</b>
Cash and cash equivalents, beginning of period	37,643	13,009
<b>Cash and cash equivalents, end of period</b>	<b>\$ 29,823</b>	<b>\$ 17,679</b>

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 and nine months ended September 30, 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 and nine months ended September 30, 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):

<b>September 30, 2014</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Cash equivalents:</b>				
Money market funds	\$ 7,018	\$	\$	\$ 7,018
U.S. Treasury debt securities	15,000			15,000
<b>Restricted securities:</b>				
Money market funds	923			923
<b>Total assets</b>	\$ 22,941	\$	\$	\$ 22,941
<b>Long-term liabilities:</b>				
Contingent consideration	\$	\$	\$ (1,392)	\$ (1,392)
<b>Total liabilities</b>	\$	\$	\$ (1,392)	\$ (1,392)
<b>December 31, 2013</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Cash equivalents:</b>				
Money market funds	\$ 5,349	\$	\$	\$ 5,349
Certificates of deposit	749			749
<b>Restricted securities:</b>				
Money market funds	350			350

<b>Total assets</b>	\$	6,448	\$	\$	\$	6,448
<b>Long-term liabilities:</b>						
Contingent consideration	\$		\$	\$	(1,884)	(1,884)
<b>Total liabilities</b>	\$		\$	\$	(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, U.S. Treasury debt securities, and certificates of deposit. 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):

	<b>Contingent Consideration</b>
Balance as of December 31, 2013	\$ 1,884
Gain on remeasurement of contingent consideration	(492)
Balance as of September 30, 2014	\$ 1,392

### 3. Cash Equivalents and Restricted Cash and Securities

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

<b>September 30, 2014</b>	<b>Cost Basis</b>	<b>Unrealized Holding Gains</b>	<b>Estimated Market Value</b>
Cash equivalents:			
Money market funds	\$ 7,018	\$	\$ 7,018
U.S. Treasury debt securities	15,000		15,000
Restricted cash and securities:			
Cash	5,000		5,000
Money market funds	923		923

<b>December 31, 2013</b>	<b>Cost Basis</b>	<b>Unrealized Holding Gains</b>	<b>Estimated Market Value</b>
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 September 30, 2014 and December 31, 2013 \$923,000 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 September 30, 2014 \$5.0 million of the Company's cash was designated as long-term restricted cash due to a financial covenant requirement under the Company's amended and restated credit agreement with General Electric Capital Corporation (GE Capital), as discussed in Note 11. This restriction lapses upon expiration of the credit agreement with GE Capital on September 26, 2019. As of December 31, 2013 \$5.0 million of the Company's cash was designated as short-term restricted cash under the Company's credit agreement with GE Capital prior to the September 26, 2014 amendment.

There were no gross realized gains or losses on cash equivalents in the three and nine months ended September 30, 2014 and 2013. As of September 30, 2014 \$273,000 of the Company's restricted securities had a maturity date within three months and \$650,000 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 had a maturity

date between three months and one year. As of September 30, 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.

In accordance with the terms of the HJ Agreement, 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. 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, which it received in the first half of 2014, and additional inventory. Additional inventory becomes available for distribution as it is manufactured and following Hancock Jaffe's receipt of U.S. Food and Drug Administration ( FDA ) approval of the Premarket Approval Supplement associated with its new manufacturing facility, which it received on September 29, 2014. Subsequent to this initial inventory purchase, CryoLife can purchase additional units from Hancock Jaffe at an agreed upon transfer price.

As of September 30, 2014 the Company had made payments of \$1.7 million to Hancock Jaffe, and the Company began limited distribution of ProCol in the second quarter of 2014.

## **5. Hemosphere Acquisition**

On May 16, 2012 CryoLife acquired Hemosphere, which the Company now operates as a wholly owned subsidiary. Hemosphere 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 Hemosphere acquisition date, CryoLife recorded a contingent consideration liability of \$1.8 million in long-term liabilities on its Summary Consolidated Balance Sheet, representing the estimated fair value of the contingent consideration expected to be paid to the former shareholders of Hemosphere upon the achievement of certain revenue-based milestones. The acquisition agreement provides for a maximum of \$4.5 million in future consideration payments through December 2015 based on specified sales targets.

The fair value of the contingent consideration liability was based on unobservable inputs, including management's 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 expense (income), net on the Company's Summary Consolidated Statement of Operations and Comprehensive Income. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the timing and amount of Company revenue estimates.

The Company recorded gains of \$196,000 and \$492,000 in the three and nine months ended September 30, 2014, respectively, and a gain of \$32,000 and a loss of \$46,000 in the three and nine months ended September 30, 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 \$1.4 million as of September 30, 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 September 30, 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 expected life of the loan facility. The Company advanced \$2.0 million to ValveXchange under this loan in 2012. The \$2.0 million advance is recorded as long-term notes receivable on the Company's Summary Consolidated Balance Sheets as of September 30, 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 September 30, 2014 ValveXchange had raised \$1.7 million under the Series B. ValveXchange continues to seek additional funding 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. Specifically, ValveXchange will need to expand its clinical trial in order to obtain approval to distribute its product in Europe. ValveXchange does not currently have the funds necessary to finance this expansion, and without this expansion, ValveXchange is not expected to be able to generate revenues. 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 of such adequacy. ValveXchange's current liquidity position is critical, and without additional funding, ValveXchange will likely be required to cease operations during the fourth quarter of 2014. If ValveXchange is forced to cease operations or seek reorganization in bankruptcy, the Company may be unable to secure full repayment of 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 ) and subsidiaries 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. In October 2014 the Company received the first of these additional payments, totaling \$530,000, which will be recorded as a gain in the fourth quarter of 2014. Subsequent payments will be recorded as an additional gain if, and when, received by the Company.

***Legal Action***

CryoLife received a letter from Medafor in September 2012 stating that PerClot<sup>®</sup>, 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.



In April 2014 the Company filed a declaratory judgment lawsuit against Bard and certain of its subsidiaries, including Medafor (collectively, Defendants), in the U.S. District Court for the District of Delaware (the Court). CryoLife requested 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 any valid claim of the patent held by Bard and/or that the Bard patent is invalid.

In June 2014 CryoLife filed an amended complaint, and the Defendants filed a counterclaim for infringement in August 2014. The Defendants also filed various motions to dismiss; the Court has not ruled on these motions.

On September 19, 2014 the Defendants filed with the Court a motion for a preliminary injunction, asking the Court to enjoin CryoLife's marketing and sale of PerClot in the U.S. Discovery with respect to this motion has commenced, and the Court has set a hearing date of January 23, 2015. See also Part II, Item 1, Legal Proceedings of this Form 10-Q.

## 8. Deferred Preservation Costs and Inventories

Deferred preservation costs at September 30, 2014 and December 31, 2013 are comprised of the following (in thousands):

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Cardiac tissues	\$ 11,372	\$ 12,239
Vascular tissues	14,497	15,058
Total deferred preservation costs	\$ 25,869	\$ 27,297

Inventories at September 30, 2014 and December 31, 2013 are comprised of the following (in thousands):

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Raw materials and supplies	\$ 7,548	\$ 5,706
Work-in-process	1,265	767
Finished goods	4,349	3,298
Total inventories	\$ 13,162	\$ 9,771

## 9. Goodwill and Other Intangible Assets

### *Indefinite Lived Intangible Assets*

As of September 30, 2014 and December 31, 2013 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Goodwill	\$ 11,365	\$ 11,365
Procurement contracts and agreements	2,013	2,013
Trademarks	851	841

Based on its experience with similar agreements, the Company believes that its acquired procurement contracts and 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 September 30, 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 September 30, 2014 and December 31, 2013 the gross carrying values, accumulated amortization, and approximate amortization period of the Company's definite lived intangible assets are as follows (in thousands):

	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Amortization Period</b>
<b>September 30, 2014</b>			
Acquired technology	\$ 14,020	\$ 3,530	11 - 16 Years
Patents	4,325	2,433	17 Years
Distribution and manufacturing rights and know-how	4,059	914	15 Years
Customer lists and relationships	3,370	753	13 - 17 Years
Non-compete agreement	381	295	10 Years
Other	467	216	1 - 5 Years

	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Amortization Period</b>
<b>December 31, 2013</b>			
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):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Amortization expense	\$ 504	\$ 493	\$ 1,503	\$ 1,515

As of September 30, 2014 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	<b>Remainder of 2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>
Amortization expense	\$ 504	\$ 1,987	\$ 1,980	\$ 1,926	\$ 1,917	\$ 1,911

**10. Income Taxes****Income Tax Expense**

Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company's effective income tax rate was approximately 21% and 22% for the three and nine months ended September 30, 2014, respectively, as compared to 32% and 31% for the three and nine months ended September 30, 2013, respectively.

The Company's income tax rate for the three and nine months ended September 30, 2014 was favorably affected by the reduction of uncertain tax positions and by favorable deductions taken on the Company's 2013 federal tax return, which was filed in the third quarter of 2014. To a lesser extent, the Company's income tax rate was unfavorably affected by its inability to claim 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.

In June 2014 the Internal Revenue Service completed a limited scope examination of certain of the Company's federal income tax returns. At the resolution of this examination, the Company reevaluated its liabilities for uncertain tax positions, primarily related to its research and development tax credits and credit carryforwards, and, based on revised estimates and the settlement of the examination, reversed \$748,000 in uncertain tax liabilities and tax expense.

### ***Deferred Income Taxes***

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generates deferred tax assets primarily as a result of 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 Corporation 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 September 30, 2014 the Company had 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 \$22.0 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***

On September 26, 2014 CryoLife amended and restated its credit agreement with GE Capital, extending the expiration date and amending other terms, which are discussed further below. CryoLife's amended and restated credit agreement with GE Capital (the "GE Credit Agreement") provides revolving credit for working capital, permitted acquisitions, and general corporate purposes. The GE Credit Agreement has aggregate commitments of \$20.0 million for revolving loans, including swing loans subject to a sublimit and letters of credit, and expires on September 26, 2019. The commitments may be reduced from time to time pursuant to the terms of the GE Credit Agreement. The GE Credit Agreement also permits CryoLife to request a term loan in an aggregate amount of up to \$25.0 million to finance the purchase price of a permitted acquisition.

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, based on the Company's election, at either LIBOR or GE Capital's base rate plus the respective applicable margins. All swing loans will, however, bear interest at the base loan rate. Commitment fees are paid based on the unused portion of the facility. If an event of default occurs, the applicable interest rate will increase by 2.0% per annum. The aggregate interest rate was 4.75% and 6.5% as of September 30, 2014 and December 31, 2013, respectively. As of September 30, 2014 and December 31, 2013 the outstanding balance of the GE Credit Agreement was zero, and the remaining availability was \$20.0 million.

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 and (ii) maintain minimum earnings subject to defined adjustments as of specified dates. The agreement also (i) limits the payment of cash dividends, up to specified maximums and subject to satisfaction of specified conditions, (ii) requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined within the agreement, of at least \$20.0 million, (iii) limits acquisitions or mergers except for certain permitted acquisitions, (iv) sets specified limits on the amount the Company can pay to purchase or redeem CryoLife common stock pursuant to a stock repurchase program and to fund estimated tax liabilities incurred by officers, directors, and employees as a result of awards of stock or stock equivalents, and (v) includes customary conditions on incurring new

indebtedness. As of September 30, 2014 the Company was in compliance with the covenants of the GE Credit Agreement.

As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as long-term restricted cash as of September 30, 2014 on the Company's Summary Consolidated Balance Sheet, as they are restricted for the term of the GE Credit Agreement. As of December 31, 2013 \$5.0 million of the Company's cash was designated as short-term restricted cash on the Company's Summary Consolidated Balance Sheet under the Company's credit agreement with GE Capital prior to the September 26, 2014 amendment.

### ***Interest Expense***

Interest expense was \$65,000 and \$110,000 for the three and nine months ended September 30, 2014, respectively. Interest expense was \$55,000 and \$159,000 for the three and nine months ended September 30, 2013, respectively. Interest expense in all periods included interest on debt and uncertain tax positions. Interest expense for the nine months ended September 30, 2014 was favorably affected by the reversal of interest expense related to a reduction in liability for uncertain tax positions.

## **12. Commitments and Contingencies**

### ***Leases***

In October 2014 the Company signed an agreement to lease approximately 25,000 square feet of additional office space near the Company's headquarters in suburban Atlanta, Georgia. The lease is expected to commence in February 2015 for an initial term of approximately 11 years, which the Company can renew for up to two five-year renewal periods. Payments due under this lease will total approximately \$4.4 million during the initial term, after consideration of expected rent abatements and construction and moving allowances.

### ***Liability Claims***

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. At September 30, 2014 and December 31, 2013 the Company's estimated unreported loss liability was \$1.5 million. The related recoverable insurance amounts were \$610,000 and \$580,000 as of September 30, 2014 and December 31, 2013, respectively. Further analysis indicated that the liability as of September 30, 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 Agreements***

In July 2014 the Company's Board of Directors appointed Mr. James P. Mackin as President and Chief Executive Officer ( CEO ), and the Company and Mr. Mackin entered into an employment agreement, which became effective September 2, 2014. The employment agreement has an initial three-year term. Beginning on the second anniversary of the effective date, and subject to earlier termination pursuant to the agreement, the employment term will, on a daily basis, automatically extend by one day. In accordance with the agreement, on September 2, 2014, Mr. Mackin received a one-time signing bonus of \$200,000, a grant of 400,000 stock options, and a performance stock award grant of 250,000 shares. The agreement also provides for a severance payment, which would become payable upon the occurrence of certain employment termination events, including termination by the Company without cause.

The Company's employment agreement, as amended, with its former President and CEO, and current Executive Chairman, Mr. Steven G. Anderson, confers benefits, which become payable upon the occurrence of certain events, including the voluntary retirement of Mr. Anderson or termination of his employment in conjunction with certain change in control events. As of both September 30, 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 Mr. Anderson's voluntary retirement, for which he is currently eligible. Mr. Anderson's employment agreement took effect on January 1, 2013 and terminates on December 31, 2016.

## **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 nine months ended September 30, 2014 the Company purchased approximately 488,000 shares for an aggregate purchase price of \$4.6 million. As of September 30, 2014 the Company had \$8.9 million in remaining authorizations 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 Sheets.



### *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 to \$0.0275 per share of common stock outstanding in the second quarter of 2013. In May 2014 the Board of Directors approved an increase in the quarterly cash dividend to \$0.03 per share of common stock outstanding for the second quarter 2014. The Company paid dividend payments of \$842,000 and \$2.5 million from cash on hand for the three and nine months ended September 30, 2014, respectively, and \$759,000 and \$2.2 million for the three and nine months ended September 30, 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 ), performance stock awards ( PSAs ), restricted stock units ( RSUs ), performance stock units ( PSUs ), and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder-approved Employee Stock Purchase Plan (the ESPP ) for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period.

### *Equity Grants*

During the nine months ended September 30, 2014 the Compensation Committee of the Company's Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee directors, RSUs to certain employees, and RSAs, PSUs, and PSAs to certain Company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 655,000 shares and had an aggregate grant date market value of \$6.6 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 earnings, 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 it will reevaluate this likelihood on a quarterly basis. The performance component of PSA award granted in 2014 is based upon attaining specified levels of adjusted earnings over any four consecutive calendar quarters during a three-year employment period, as defined in the PSA grant documents. The Company currently believes that achievement of the performance component is probable, and it will reevaluate this likelihood on a quarterly basis.

During the nine months ended September 30, 2013 the Compensation Committee of the Company's Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee directors, 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 395,000 shares of common stock and had an aggregate grant date market value of \$2.4 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 562,000 and 162,000 shares to certain Company officers during the nine months ended September 30, 2014 and 2013, respectively. The exercise prices of the options were equal to the stock prices on their respective grant dates.

Employees purchased common stock totaling 111,000 and 97,000 shares in the nine months ended September 30, 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:

	<b>Three Months Ended September 30, 2014</b>		<b>Nine Months Ended September 30, 2014</b>	
	<b>Stock Options</b>	<b>ESPP Options</b>	<b>Stock Options</b>	<b>ESPP Options</b>
Expected life of options	4.20 Years	.50 Years	4.21 Years	.50 Years
Expected stock price volatility	0.55	0.38	0.55	0.34
Dividends	1.18%	1.30%	1.16%	0.99%
Risk-free interest rate	1.41%	0.07%	1.34%	0.10%

	<b>Three Months Ended September 30, 2013</b>		<b>Nine Months Ended September 30, 2013</b>	
	<b>Stock Options</b>	<b>ESPP Options</b>	<b>Stock Options</b>	<b>ESPP Options</b>
Expected life of options	N/A	.50 Years	4.25 Years	.50 Years
Expected stock price volatility	N/A	0.35	0.60	0.43
Dividends	N/A	1.74%	1.91%	1.61%
Risk-free interest rate	N/A	0.10%	0.70%	0.16%

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
RSA, PSA, RSU, and PSU expense	\$ 944	\$ 628	\$ 2,357	\$ 1,891
Stock option and ESPP option expense	219	225	590	632
Total stock compensation expense	\$ 1,163	\$ 853	\$ 2,947	\$ 2,523

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, PSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the Company's ESPP. These amounts were recorded as stock compensation expense and were subject to the Company's normal allocation of expenses to deferred preservation costs and inventory costs. The Company capitalized \$71,000 and \$54,000 in the three months ended September 30, 2014 and 2013, respectively, and \$211,000 and \$166,000 in the nine months ended September 30, 2014 and 2013, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

Edgar Filing: CRYOLIFE INC - Form 10-Q

As of September 30, 2014 the Company had total unrecognized compensation costs of \$6.7 million related to RSAs, PSAs, RSUs, and PSUs and \$2.4 million related to unvested stock options, before considering the effect of expected forfeitures. As of September 30, 2014 this expense is expected to be recognized over a weighted-average period of 2.43 years for stock options, 2.92 years for PSAs, 1.55 years for RSUs, 1.34 years for RSAs, and 0.98 years for PSUs.

**15. Income Per Common Share**

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b><u>Basic income per common share</u></b>				
Net income	\$ 2,326	\$ 3,169	\$ 5,546	\$ 7,146
Net income allocated to participating securities	(53)	(72)	(112)	(163)
Net income allocated to common shareholders	\$ 2,273	\$ 3,097	\$ 5,434	\$ 6,983
Basic weighted-average common shares outstanding	27,367	26,985	27,414	26,857
Basic income per common share	\$ 0.08	\$ 0.11	\$ 0.20	\$ 0.26
<b><u>Diluted income per common share</u></b>				
Net income	\$ 2,326	\$ 3,169	\$ 5,546	\$ 7,146
Net income allocated to participating securities	(52)	(70)	(110)	(160)
Net income allocated to common shareholders	\$ 2,274	\$ 3,099	\$ 5,436	\$ 6,986
Basic weighted-average common shares outstanding	27,367	26,985	27,414	26,857
Effect of dilutive stock options and awards <sup>a</sup>	901	714	931	642
Diluted weighted-average common shares outstanding	28,268	27,699	28,345	27,499
Diluted income per common share	\$ 0.08	\$ 0.11	\$ 0.19	\$ 0.25

<sup>a</sup> 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 352,000 shares and 239,000 shares for the three and nine months ended September 30, 2014, respectively, and 1.1 million shares and 1.2 million shares for the three and nine months ended September 30, 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<sup>®</sup> Surgical Adhesive ( BioGlue ), BioFoam<sup>®</sup> Surgical Matrix ( BioFoam ), PerClot, revascularization technologies, HeRO Graft, and other products. 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 services, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Revenues:</b>				
Medical devices	\$ 20,405	\$ 18,833	\$ 60,210	\$ 56,824
Preservation services	16,664	17,417	47,280	48,411
Other <sup>a</sup>				71
<b>Total revenues</b>	<b>37,069</b>	<b>36,250</b>	<b>107,490</b>	<b>105,306</b>
<b>Cost of products and preservation services:</b>				
Medical devices	4,167	3,544	12,099	10,730
Preservation services	9,103	9,357	26,735	26,472
<b>Total cost of products and preservation services</b>	<b>13,270</b>	<b>12,901</b>	<b>38,834</b>	<b>37,202</b>
<b>Gross margin:</b>				
Medical devices	16,238	15,289	48,111	46,094
Preservation services	7,561	8,060	20,545	21,939
Other <sup>a</sup>				71
<b>Total gross margin</b>	<b>\$ 23,799</b>	<b>\$ 23,349</b>	<b>\$ 68,656</b>	<b>\$ 68,104</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Products:</b>				
BioGlue and BioFoam	\$ 15,116	\$ 14,232	\$ 45,745	\$ 43,238
PerClot	998	882	3,057	2,686
Revascularization technologies	2,306	2,353	6,074	6,837
HeRO Graft	1,984	1,366	5,304	4,063
Other products	1		30	
<b>Total products</b>	<b>20,405</b>	<b>18,833</b>	<b>60,210</b>	<b>56,824</b>

Edgar Filing: CRYOLIFE INC - Form 10-Q

Preservation services:				
Cardiac tissue	8,337	8,572	21,981	22,035
Vascular tissue	8,327	8,845	25,299	26,376
Total preservation services	16,664	17,417	47,280	48,411
Other <sup>a</sup>				71
Total revenues	\$ 37,069	\$ 36,250	\$ 107,490	\$ 105,306

<sup>a</sup> 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. (Hemosphere), 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 the quarter ended September 30, 2014 CryoLife reported third quarter revenues of \$37.1 million, a 2% increase over the quarter ended September 30, 2013, and a new quarterly record. This increase was primarily due to an increase in BioGlue revenues, despite the seasonal decline in demand typically experienced in third quarter BioGlue sales, and due to record HeRO Graft revenues. These increases were partially offset by decreases in cardiac and vascular preservation services revenues.

See the Results of Operations section below for additional analysis of the three and nine months ended September 30, 2014.

#### Recent Events

##### *Appointment of Mr. James P. Mackin as President and CEO*

On September 2, 2014 Mr. James P. Mackin became the President and Chief Executive Officer (CEO) of CryoLife and Mr. Steven G. Anderson, the former President and CEO, continued employment with the Company and assumed the role of Executive Chairman. Mr. Mackin previously worked at Medtronic, Inc. (Medtronic), where he most recently served as President of Cardiac Rhythm Disease Management, Medtronic's largest operating division. Mr. Mackin is a highly respected professional with more than 20 years of medical device industry experience. Mr. Mackin was appointed to the Company's Board of Directors in October 2014.

##### *Regulatory Activity*

In January 2013 CryoLife received a warning letter (Warning Letter) from the U.S. Food and Drug Administration (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 to the 2014 CryoLife Form 483 on April 10, 2014 and provided periodic updates during the second and third quarters of 2014. 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 restricted the distribution of certain cardiac and vascular tissues during the second quarter of 2014 while it performed a review of its internal training programs. The Company gradually resumed shipments of tissues during the second quarter of 2014, in accordance with its procedures, as it completed its training program review. The Company continues to review and modify its procedures as part of its ongoing compliance efforts. Preservation services revenues were negatively impacted during the second and third quarters as a result of reduced tissue availability due to these efforts. Some of these procedural modifications resulted in additional costs to the Company during the second and third quarters of 2014. These efforts and additional costs are ongoing and are expected to continue at least through the end of 2014. See the Results of Operations section below for additional discussion of preservation services revenues for the three and nine months ended September 30, 2014.

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. In addition to the efforts discussed above, it is possible that actions that the FDA may take, or that the Company may be required to take, in response to the 2014 CryoLife Form 483 could materially, adversely affect the Company's revenues, financial condition, profitability, and/or cash flows in future periods.

### ***Regulatory Status of the CryoValve SGPV***

On February 20, 2003 the Company received a letter from the FDA stating that a 510(k) premarket notification should be filed for the Company's decellularized CryoValve SGPV. On November 3, 2003 the Company filed a 510(k) premarket notification, which was cleared by the FDA on February 7, 2008. At the time of the clearance, the CryoValve SGPV was categorized by the FDA as an "unclassified" medical device. At the FDA's request, CryoLife committed to conducting a post-clearance study to collect long-term clinical data for the CryoValve SGPV. The follow-up study will include a minimum of 800 cumulative patient years. The Company anticipates submitting the favorable results of this study to the FDA by December 31, 2014.

On October 9, 2014 the FDA convened an advisory committee meeting to consider the FDA's recommendation to classify more than minimally manipulated (MMM) allograft heart valves from an unclassified medical device to a class III medical device. The class of MMM allograft heart valves includes CryoLife's CryoValve SGPV. At the meeting a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves should be classified as a class III product. CryoLife expects that the FDA will issue a proposal for classification of MMM allograft heart valves, which would be subject to a public comment period before finalization. After publication of the reclassification rule, CryoLife expects it would have thirty months to submit for a Premarket Approval (PMA), after which the FDA would determine if, and for how long, CryoLife could continue to provide these tissues to customers. The Company currently plans to continue to process and ship its CryoValve SGPV tissues. If the FDA ultimately classifies CryoLife's CryoValve SGPV as a class III medical device, the Company anticipates it will request a meeting with the FDA to determine the specific requirements to file for and obtain a PMA, and will determine an appropriate course of action in light of these requirements. The costs associated with obtaining such a PMA and the potential impact upon the Company's tissue revenues, if there were delays in obtaining the PMA or if the Company were unsuccessful in obtaining the PMA, could materially, adversely affect the Company's revenues, financial condition, profitability, and/or cash flows in future periods.

### **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 September 30, 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**

In May 2014 the Financial Accounting Standards Board issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an

amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard is effective for annual and interim reporting periods beginning after December 15, 2016, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2014-09 to have a material impact on its financial position, results of operations, or cash flows.

## Results of Operations

(Tables in thousands)

### Revenues

	Revenues as a Percentage of			
	Revenues for the		Total Revenues for the	
	Three Months Ended		Three Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Products:				
BioGlue and BioFoam	\$ 15,116	\$ 14,232	41%	39%
PerClot	998	882	3%	2%
Revascularization technologies	2,306	2,353	6%	7%
HeRO Graft	1,984	1,366	5%	4%
Other products	1		%	%
Total products	20,405	18,833	55%	52%
Preservation services:				
Cardiac tissue	8,337	8,572	23%	24%
Vascular tissue	8,327	8,845	22%	24%
Total preservation services	16,664	17,417	45%	48%
Other			%	%
Total	\$ 37,069	\$ 36,250	100%	100%

	Revenues as a Percentage of			
	Revenues for the		Total Revenues for the	
	Nine Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Products:				
BioGlue and BioFoam	\$ 45,745	\$ 43,238	42%	41%

Edgar Filing: CRYOLIFE INC - Form 10-Q

PerClot	3,057	2,686	3%	3%
Revascularization technologies	6,074	6,837	6%	6%
HeRO Graft	5,304	4,063	5%	4%
Other products	30		%	%
<b>Total products</b>	<b>60,210</b>	<b>56,824</b>	<b>56%</b>	<b>54%</b>
Preservation services:				
Cardiac tissue	21,981	22,035	20%	21%
Vascular tissue	25,299	26,376	24%	25%
<b>Total preservation services</b>	<b>47,280</b>	<b>48,411</b>	<b>44%</b>	<b>46%</b>
Other		71	%	%
<b>Total</b>	<b>\$ 107,490</b>	<b>\$ 105,306</b>	<b>100%</b>	<b>100%</b>

Revenues increased 2% for both the three and nine months ended September 30, 2014, as compared to the three and nine months ended September 30, 2013, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2014 is presented below.

***Products***

Revenues from products increased 8% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. Revenues from products increased 6% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. These increases were primarily due to increases in BioGlue and HeRO Graft 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, increased 6% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. This increase was primarily due to a 6% increase in the volume of milliliters sold, which increased revenues by 4%, and an increase in average sales prices, which increased revenues by 2%.

Revenues from the sale of surgical sealants increased 6% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. This increase was primarily due to a 4% increase in the volume of milliliters sold, which increased revenues by 3%, an increase in average sales prices, which increased revenues by 2%, and the favorable effect of foreign currency exchange, which increased revenues by 1%.

The increase in sales volume of surgical sealants for the three months ended September 30, 2014 was primarily due to an increase in shipments of BioGlue in international markets, largely Japan, Western Europe, and Brazil. The increase in sales volume of surgical sealants for the nine months ended September 30, 2014 was due to an increase in shipments of BioGlue in both international and domestic markets, primarily Western Europe, including sales for neurological indications, and the U.S.

The increase in average sales prices for the three and nine months ended September 30, 2014 was primarily due to list price increases in domestic markets and due to the routine negotiation of pricing contracts with certain customers.

Revenues from shipments to Japan were \$1.4 million and \$1.1 million for the three months ended September 30, 2014 and 2013, respectively, and \$3.9 million and \$4.0 million for the nine months ended September 30, 2014 and 2013, respectively. 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 is expected to 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% of total BioGlue revenues for both the three and nine months ended September 30, 2014, and 58% and 56% of total BioGlue revenues for the three and nine months ended September 30, 2013, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for each of the three and nine months ended September 30, 2014 and 2013. BioFoam is currently approved for sale in certain international markets.

#### *PerClot*

Revenues from the sale of PerClot increased 13% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. This increase was primarily due to a 4% increase in the volume of grams sold, which increased revenues by 11%, an increase in average selling prices, which increased revenues by 1%, and the favorable effect of foreign currency exchange, which increased revenues 1%.

Revenues from the sale of PerClot increased 14% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. This increase was primarily due to a 19% increase in the volume of grams sold, which increased revenues by 16%, and the favorable effect of foreign currency exchange, which increased revenues 2%, partially offset by a decrease in average selling prices, which decreased revenues 4%.

Revenues during these periods were largely for sales in certain international markets, as PerClot was only recently approved for limited domestic distribution for topical indications, as discussed below. These increases were primarily due to increased sales in the Company's direct markets in Europe, partially due to volume growth and new surgical indications.

In March 2014 CryoLife received approval of its investigational device exemption ( 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 first quarter of 2015 and currently expects to receive PMA from the FDA during 2017. In April 2014 CryoLife received 510(k) clearance for PerClot Topical from the FDA, which allowed CryoLife to



begin commercialization of PerClot Topical in the U.S. The Company began shipping PerClot Topical in August 2014 and is currently in the initial stages of this product launch.

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.

#### *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 2% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013.

Revenues from the sale of laser consoles were \$87,000 and \$379,000 for the three months ended September 30, 2014 and 2013, respectively. Revenues from the sale of handpieces increased 13% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. This increase was primarily due to a 12% increase in unit shipments of handpieces, which increased revenues by 11%, and an increase in average sales prices, which increased revenues by 2%.

Revenues from revascularization technologies decreased 11% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. Revenues from the sale of laser consoles were \$144,000 and \$462,000 for the nine months ended September 30, 2014 and 2013, respectively. Revenues from the sale of handpieces decreased 8% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. This decrease was primarily due to a 10% decrease in unit shipments of handpieces, which decreased revenues by 10%, and an increase in average sales prices, which increased revenues by 2%.

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. Handpiece revenues increased 33% for the three months ended June 30, 2014, as compared to the three months ended March 31, 2014, and increased 6% for the three months ended September 30, 2014, as compared to the three months ended June 30, 2014. Management believes that handpiece sales in the fourth quarter of 2014 will increase over the prior year fourth quarter.

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 increased 45% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. HeRO Graft revenues increased 31% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. The increase in HeRO Graft revenues was primarily due to an increase in the volume of kits sold as a result of increases in procedure volume and in the number of implanting physicians.

Management expects that HeRO Graft revenues will increase in the fourth quarter of 2014, as compared to the same period in 2013. Although HeRO Graft revenues are subject to variability quarter-to-quarter due to the timing of surgical cases, the Company believes that this variability will continue to decrease as the Company broadens its base of implanting physicians.

*Preservation Services*

Revenues from preservation services decreased 4% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. Revenues from preservation services decreased 2% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. The decrease in preservation services revenues was primarily due to a decrease in vascular tissue service revenues, and, to a lesser extent, due to a decrease in cardiac tissue services revenues.

During the second quarter of 2014 the Company voluntarily restricted the distribution of certain cardiac and vascular tissues while it performed a review of its internal training programs. The Company gradually resumed shipments of tissues during the second quarter of 2014, in accordance with its procedures, as it completed its training program review. The Company continues to review and modify its procedures as part of its ongoing compliance efforts. Preservation services revenues were negatively impacted during the second and third quarters of 2014 as a result of reduced tissue availability due to these efforts. These efforts

are ongoing and are expected to continue at least through the end of 2014. 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 and nine months ended September 30, 2014 below.

#### *Cardiac Preservation Services*

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, decreased 3% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. This decrease was primarily due to an 8% decrease in unit shipments of cardiac tissues, which decreased revenues by 8%, partially offset by an increase in average service fees, which increased revenues by 5%.

Revenues from cardiac preservation services decreased slightly for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. This decrease was primarily due to a 4% decrease in unit shipments of cardiac tissues, which decreased revenues 6%, largely offset by an increase in average service fees, which increased revenues by 6%.

The decrease in volume for the three and nine months ended September 30, 2014 was primarily due to a decrease in volume of cardiac valve shipments in domestic markets and due to a significant decrease in cardiac shipments in Europe, as discussed further below, partially offset by an increase in shipments of cardiac patches in domestic markets. The decrease in cardiac valve shipments in domestic markets was due to the timing of tissue releases, which were unfavorably impacted by reduced tissue availability as discussed above, as compared to the prior year periods. The Company ceased the routine distribution of tissues into Europe as of March 31, 2014, although a limited number of tissues have shipped and may continue to be shipped through a special regulatory process. During the nine months ended September 30, 2014 the Company's revenues from shipments of cardiac tissues into Europe were \$182,000, as compared to \$891,000 in the corresponding period in 2013.

The increase in average service fees for the three and nine months ended September 30, 2014 was primarily due to list fee increases in domestic markets that took effect in July 2014 and 2013 and due to the routine negotiation of pricing contracts with certain customers.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 69% and 64% of total cardiac preservation services revenues for the three and nine months ended September 30, 2014, respectively, and 52% and 51% of total cardiac preservation services revenues for the three and nine months ended September 30, 2013, respectively. Domestic revenues accounted for 96% of total cardiac preservation services revenues for both the three and nine months ended September 30, 2014, and 91% and 93% of total cardiac preservation services revenues for the three and nine months ended September 30, 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 cardiac preservation services revenues in the fourth quarter of 2014 will be comparable to or increase slightly from revenues in the fourth quarter of 2013, notwithstanding the cessation of routine tissue shipments to Europe.

*Vascular Preservation Services*

Revenues from vascular preservation services decreased 6% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. This decrease was primarily due to a 9% decrease in unit shipments of vascular tissues, which decreased revenues by 13%, partially offset by an increase in average service fees, which increased revenues by 7%.

Revenues from vascular preservation services decreased 4% for the nine months ended September 30, 2014, as compared to revenues for the nine months ended September 30, 2013. This decrease was primarily due to a 9% decrease in unit shipments of vascular tissues, which decreased revenues by 11%, partially offset by an increase in average service fees, which increased revenues by 7%.

The decrease in volume for the three and nine months ended September 30, 2014 was primarily due to decreases in shipments of saphenous veins, and to a lesser extent, decreases in shipments of arterial tissues, both of which were impacted by reduced tissue availability as discussed above.

The increase in average service fees for the three and nine months ended September 30, 2014 was primarily due to list fee increases in domestic markets that took effect in July 2014 and 2013, fee differences due to physical characteristics of vascular tissues, and the routine negotiation of pricing contracts with certain customers.

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.

The Company expects that vascular preservation services revenues in the fourth quarter of 2014 will decrease from revenues in the fourth quarter of 2013 due to reduced availability of vascular tissues.

## Cost of Products and Preservation Services

### *Cost of Products*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cost of products	\$ 4,167	\$ 3,544	\$ 12,099	\$ 10,730

Cost of products increased 18% and 13% for the three and nine months ended September 30, 2014, respectively, as compared to the three and nine months ended September 30, 2013, respectively. Cost of products in 2014 and 2013 includes costs related to BioGlue, BioFoam, PerClot, revascularization technologies, HeRO Grafts, and other products.

The increase in cost of products in the three and nine months ended September 30, 2014 was primarily due to an increase in the volume of products sold, 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, and, to a lesser extent, due to the increase in the cost of manufacturing BioGlue. Cost of products for the nine months ended September 30, 2013 includes \$487,000 in additional costs for revascularization technologies handpieces that were made obsolete by the Company's decision to exclusively distribute the new handpiece design, which was approved by the FDA in June 2013.

### *Cost of Preservation Services*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Cost of preservation services	\$ 9,103	\$ 9,357	\$ 26,735	\$ 26,472

Cost of preservation services decreased 3% and increased 1% for the three and nine months ended September 30, 2014, respectively, as compared to the three and nine months ended September 30, 2013, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services decreased in the three months ended September 30, 2014 primarily due to a decrease in volume of tissues shipped during the period, partially offset by an increase in the per unit cost of processing tissues, as a result of lower processing throughput of tissues, increased compliance and personnel costs, and an increase in the cost of materials. Cost of preservation services increased in the nine months ended September 30, 2014 due to an increase in the per unit cost of processing tissue, as discussed above, largely offset by a decrease in volume of tissues shipped during the period. The higher per unit cost of processing tissues is expected to continue through the end of 2014 and into 2015.

***Gross Margin***

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Gross margin	\$ 23,799	\$ 23,349	\$ 68,656	\$ 68,104
Gross margin as a percentage of total revenues	64%	64%	64%	65%

Gross margin increased 2% and 1% for the three and nine months ended September 30, 2014, respectively, as compared to the three and nine months ended September 30, 2013, respectively. Gross margin as a percentage of total revenues in the three and nine months ended September 30, 2014 was comparable to the three and nine months ended September 30, 2013, respectively.

## Operating Expenses

### *General, Administrative, and Marketing Expenses*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
General, administrative, and marketing expenses	\$ 18,882	\$ 16,532	\$ 55,116	\$ 51,441
General, administrative, and marketing expenses as a percentage of total revenues	51%	46%	51%	49%

General, administrative, and marketing expenses increased 14% for the three months ended September 30, 2014, as compared to the three months ended September 30, 2013. General, administrative, and marketing expenses increased 7% for the nine months ended September 30, 2014, as compared to the nine months ended September 30, 2013. The increase in general, administrative, and marketing expenses in the current year periods was due to \$1.0 million and \$1.4 million for the three and nine months ended September 30, 2014, respectively, in compensation charges related to personnel changes, including the appointment of Mr. Mackin as President and CEO in the third quarter of 2014 and one-time expenses associated with certain employee departures. In addition, the increase was due to higher legal and professional fees, and higher expenses to support the Company's increasing revenue base, international expansion, new product offerings, and increasing employee headcount.

The Company expects that its general, administrative, and marketing expenses will increase for the fourth quarter 2014, as compared to 2013 due to the factors discussed above. In addition, the effects of business development expenses or legal fees could further increase expenses. As discussed in Part II, Item 1, Legal Proceedings, in the second quarter of 2014 the Company filed a declaratory judgment action against C.R. Bard, Inc. ( Bard ) and certain of its subsidiaries. Management expects this litigation to be protracted and the costs associated with it during the fourth quarter of 2014 and into 2015 to be material.

### *Research and Development Expenses*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development expenses	\$ 1,902	\$ 2,252	\$ 6,607	\$ 5,976
Research and development expenses as a percentage of total revenues	5%	6%	6%	6%

Research and development expenses decreased 16% and increased 11% for the three and nine months ended September 30, 2014, respectively, as compared to the three and nine months ended September 30, 2013, respectively. 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 2015, due to planned increases in spending on PerClot clinical studies.

## Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Income before income taxes	\$ 2,947	\$ 4,632	\$ 7,078	\$ 10,411
Income tax expense	621	1,463	1,532	3,265
Net income	\$ 2,326	\$ 3,169	\$ 5,546	\$ 7,146
Diluted income per common share	\$ 0.08	\$ 0.11	\$ 0.19	\$ 0.25
Diluted weighted-average common shares outstanding	28,268	27,699	28,345	27,499



Income before income taxes decreased 36% and 32% for the three and nine months ended September 30, 2014, respectively, as compared to the three and nine months ended September 30, 2013, respectively. The decrease in income before income taxes for the three and nine months ended September 30, 2014 was primarily due to an increase in general, administrative, and marketing expenses, as discussed above, partially offset by increased revenues.

The Company's effective income tax rate was approximately 21% and 22% for the three and nine months ended September 30, 2014, respectively, as compared to 32% and 31% for the three and nine months ended September 30, 2013, respectively.

In June 2014 the Internal Revenue Service completed a limited scope examination of certain of the Company's federal income tax returns. At the resolution of this examination, the Company reevaluated its liabilities for uncertain tax positions, primarily related to its research and development tax credits and credit carryforwards, and, based on revised estimates and the settlement of the examination, reversed \$748,000 in uncertain tax liabilities and tax expense.

The Company's income tax rate for the three and nine months ended September 30, 2014 was favorably affected by the reduction of uncertain tax positions and by favorable deductions taken on the Company's 2013 federal tax return, which was filed in the third quarter of 2014. To a lesser extent, the Company's income tax rate in 2014 was unfavorably affected by its inability to claim 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 and nine months ended September 30, 2014, as compared to the three and nine months ended September 30, 2013, respectively, primarily due to the decrease in income before income taxes, as discussed above, partially offset by the favorable effect of the decrease in income tax expense, 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 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 that 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 September 30, 2014 net working capital (current assets of \$102.6 million less current liabilities of \$20.0 million) was \$82.6 million, with a current ratio (current assets divided by current liabilities) of 5 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 nine months ended September 30, 2014 was cash for general working capital needs, as certain of the Company's current asset balances increased significantly from December 31, 2013. These increases are primarily due to increases in purchased finished goods and raw materials inventory, payment of the Company's annual insurance policy renewals, and cash advances related to the Company's new ProCol Vascular Bioprosthesis ( ProCol ) product line. In addition, the Company's other cash requirements included common stock repurchases, capital expenditures, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves and its operating activities, which generated cash during the period.

On September 26, 2014 CryoLife amended and restated its credit agreement with General Electric Capital Corporation ( GE Capital ), extending the expiration date and amending other terms, which are discussed further below. CryoLife's amended and restated credit agreement with GE Capital (the GE Credit Agreement ) provides revolving credit for working capital, acquisitions, and general corporate purposes. The GE Credit Agreement has a borrowing capacity of \$20.0 million (including a letter of credit subfacility and a swingline subfacility) and expires on September 26, 2019. The commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. The GE Credit Agreement also permits CryoLife to request a term loan in an aggregate amount of up to \$25.0 million to finance or refinance the purchase price of a permitted acquisition. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company's liquidity needs during the term of the GE Credit Agreement and, as such, have been recorded as long-term restricted cash on the Company's Summary Consolidated Balance Sheets. Also, the GE Credit Agreement requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined in the agreement, of at least \$20.0 million. As of September 30, 2014 the outstanding balance under the GE Credit Agreement was zero, and \$20.0 million was available for borrowing.

In the nine months ended September 30, 2014 the Company purchased approximately 488,000 shares of its common stock for an aggregate purchase price of \$4.6 million. As of September 30, 2014 the Company had \$8.9 million in remaining authorizations under common stock repurchase programs authorized by the Company's Board of Directors, which expire 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.

As of September 30, 2014 approximately 8% 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, Inc. ( 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 that are measurable through June 2015. In October 2014 the Company received the first of these additional payments, totaling \$530,000, which will be recorded as a gain in the fourth quarter of 2014. Subsequent payments will be recorded as an additional gain if, and when, 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 any valid claim of the patent held by Bard and/or that the Bard patent is invalid. In June 2014 CryoLife filed an amended complaint, and Bard filed a counterclaim for infringement in August 2014. Bard filed various motions to dismiss; the Court has not ruled on these motions. On September 19, 2014 Bard filed with the Court a motion for a preliminary injunction, asking the Court to enjoin CryoLife's marketing and sale of PerClot in the U.S. Discovery, with respect to this motion, has commenced, and the Court has set a hearing date of January 23, 2015. See also Part II, Item 1, Legal Proceedings of this Form 10-Q. Management expects this litigation to be protracted and the costs associated with it during the fourth quarter of 2014 and into 2015 will be material.

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 first quarter of 2015. Management believes that the costs of this clinical trial will be material in 2015. In April 2014 CryoLife received 510(k) clearance from the FDA to market PerClot Topical, a version of the Company's PerClot product, which allowed CryoLife to begin commercialization of PerClot Topical in the U.S. The Company began shipping PerClot Topical in August 2014 and is currently in the initial stages of this product launch. As a result of this recent approval and clearance, CryoLife paid \$1.0 million to SMI 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 Laboratories, Inc. ( 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. As of September 30, 2014 the Company had made payments of \$1.7 million to Hancock Jaffe, and it began limited distribution of ProCol in the second 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. ValveXchange will continue to need additional funds to support its short-term and long-term operations, as it is currently not selling any product. Specifically, ValveXchange will need to expand its clinical trial in order to obtain approval to distribute its product in Europe. ValveXchange does not currently have the funds necessary to fund this expansion, and without this expansion, ValveXchange is not expected to be able to generate revenues. 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 of such adequacy. ValveXchange s current liquidity position is critical, and without additional funding, ValveXchange will likely be required to cease operations during the fourth quarter of 2014. If ValveXchange is forced to cease operations or to seek reorganization in bankruptcy, the Company may be unable to secure full repayment of the Loan.

The Company believes that its 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 startup of the PerClot clinical trials, to fund the declaratory judgment action against Bard, 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 and in 2015. The Company may seek additional borrowing capacity or financing, pursuant to its current or any future 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 or 2015, it may need to finance such activities by drawing down monies under the GE Credit Agreement, obtaining additional debt financing, or using a 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 provided by operating activities was \$3.3 million for the nine months ended September 30, 2014, as compared to \$11.3 million for the nine months ended September 30, 2013. The decrease in net cash provided was primarily due to a decrease in net income, as discussed in Results of Operations above, and an increase in working capital needs, as discussed further below.

The Company uses the indirect method to prepare its cash flow statement and, accordingly, the operating cash flows are based on the Company s net income, which is then adjusted to remove non-cash items and for changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2014 these non-cash items included a favorable \$4.5 million in depreciation and amortization expenses and \$2.7 million in non-cash compensation.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2014 these changes included unfavorable adjustments of \$3.3 million due to the timing differences between the recording of receivables and the receipt of cash, and increased balances of \$2.1 million in deferred preservation costs and inventories and \$3.2 million in prepaid expenses and other assets, for which payments have already been made.

***Net Cash Flows from Investing Activities***

Net cash used in investing activities was \$4.8 million for the nine months ended September 30, 2014, as compared to \$3.4 million for the nine months ended September 30, 2013. The current year cash used was primarily due to \$3.2 million in capital expenditures.

**Net Cash Flows from Financing Activities**

Net cash used in financing activities was \$6.3 million for the nine months ended September 30, 2014, as compared to \$3.3 million for the nine months ended September 30, 2013. The current year cash used was primarily due to \$4.6 million in purchases of treasury stock related to the Company's publicly announced stock repurchase plan and \$2.5 million in cash dividends paid.

**Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

**Capital Expenditures**

Capital expenditures were \$3.2 million for both the nine months ended September 30, 2014 and 2013. Capital expenditures in the nine months ended September 30, 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; leasehold improvements needed to support the Company's business; computer software; and computer and office equipment.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of September 30, 2014 were as follows (in thousands):

	<b>Total</b>	<b>Remainder of 2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>Thereafter</b>
Operating leases	\$ 23,164	\$ 537	\$ 3,241	\$ 3,173	\$ 3,062	\$ 3,026	\$ 10,125
Purchase commitments	4,777	1,421	1,695	1,661			
Contingent payments	3,500			2,500	1,000		
Compensation payments	1,985				1,985		
Research obligations	2,254	1,217	948	89			
<b>Total contractual obligations</b>	<b>\$ 35,680</b>	<b>\$ 3,175</b>	<b>\$ 5,884</b>	<b>\$ 7,423</b>	<b>\$ 6,047</b>	<b>\$ 3,026</b>	<b>\$ 10,125</b>

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 2016, which assumes that the Company receives FDA approval for PerClot in the first half of 2017. 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 up to \$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 may 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 Mr. Steven G. Anderson, the Company's former President and CEO and current Executive Chairman. The timing of Mr. Anderson's post-employment benefits is based on the December 2016 expiration date of the his current employment agreement; however, payment of these benefits may be accelerated upon the occurrence of certain events, including Mr. Anderson's voluntary retirement, for which he is currently eligible, or his termination in conjunction with certain change in control events.

The Company's research obligations represent commitments for ongoing studies and payments to support research and development activities and largely represent commitments related to the PerClot pivotal clinical trial.



The schedule of contractual obligations above excludes (i) obligations related to the Company's new operating lease dated October 2014, as this was not an obligation of the Company as of September 30, 2014, (ii) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation and (iii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$1.9 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.

### 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;

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 continuing material effect on the Company;

Expected timing and results of the Company's CryoValve SG pulmonary valve post-clearance study submission to the FDA;

The potential impact of the FDA review of the classification of CryoValve SG pulmonary valve tissue and the FDA advisory committee's vote in favor of classifying such tissue as a class III device;

Potential benefits and additional applications of the Company's products;

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;

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 the Company's 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, the Company's intellectual property protections;

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

Expectations about whether, and when, the Company 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;

Expectations that research and development expenses will increase materially in 2015;

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 litigation with Bard and certain of its subsidiaries during the fourth quarter of 2014 and into 2015 will be material;

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, HeRO Grafts, 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 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;

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, and/or product liability lawsuits;

The FDA has expressed an intent to reevaluate the classification of CryoValve SG pulmonary valve tissue, and its advisory committee has voted in favor of classification of such tissue as a class III medical device. If CryoValve SG pulmonary valve tissue were to be reclassified as a class III medical device, we would be required to obtain a PMA. If we were unable to obtain a PMA, issuance of the PMA were delayed, or the attendant investment were to make pursuit of a PMA infeasible, we would be unable to distribute CryoValve SG pulmonary valve tissue to our customers, which would materially, adversely impact our revenues, liquidity, and net income;

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 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 litigation with Bard and certain of its subsidiaries will continue to 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;

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;

Certain of our key production inputs are sourced from single suppliers. Should those suppliers experience production or other disruptions or temporarily suspend or discontinue their business operations or relevant product lines or configurations, or should we be unable to successfully negotiate agreements with them for continued supply, our production output could be reduced or halted, which 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 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 \$29.8 million and restricted cash of \$5.0 million and interest paid on the Company's variable rate line of credit as of September 30, 2014. A 10% adverse change in interest rates, as compared to the rates experienced by the Company in the nine months ended September 30, 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 and PerClot 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, Euros, Swiss Francs, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 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 nine months ended September 30, 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 September 30, 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 September 30, 2014, the Company is using the 1992 Framework. During the quarter ended September 30, 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 (the Original Complaint ) against C.R. Bard, Inc. ( Bard ), Davol, Inc., and Medafor, Inc. (collectively, Defendants ), 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 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 infringe the 461 Patent when used in accordance with the method published in CryoLife s literature and with the instructions for use. CryoLife received FDA 510(k) clearance for the sale of PerClot Topical in April 2014, began distributing PerClot Topical in September 2014, and received approval for an IDE in late March 2014 to begin clinical trials for PerClot in certain surgical indications.

In June 2014 CryoLife filed an amended complaint, and the Defendants filed a counterclaim for infringement in August 2014. The Defendants filed various motions to dismiss; the Court has not yet ruled on those motions.

On September 19, 2014 the Defendants filed with the Court a motion for a preliminary injunction, asking the Court to enjoin CryoLife s marketing and sale of PerClot in the U.S. Discovery with respect to such motion has commenced, and the Court has set a hearing date of January 23, 2015.

### **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 September 30, 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**

<b>Period</b>	<b>Total Number of Common Shares and Common Stock Units Purchased</b>	<b>Average Price Paid per Common Share</b>	<b>Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs</b>
07/01/14-07/31/14	64,200	\$ 8.89	64,200	\$ 10,899,487
08/01/14-08/31/14	100,555	10.33	97,200	9,896,165
09/01/14-09/30/14	104,411	10.10	99,316	8,892,877
<b>Total</b>	<b>269,166</b>	<b>9.89</b>	<b>260,716</b>	

In February 2013 the Company announced that its Board of Directors had authorized the purchase of up to \$15.0 million of its common stock through October 31, 2014. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions. For the quarter ended September 30, 2014, the Company purchased 261,000 shares of its common stock through this authorization for an aggregate purchase price of approximately \$2.6 million.

Under the Company's amended and restated 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. The Company is also entitled to repurchase up to approximately \$14.0 million of common stock under the February 2013 authorization without obtaining its lender's consent.

The Company purchased 8,000 common shares during the quarter ended September 30, 2014 that 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.

<b>Exhibit Number</b>	<b>Description</b>
3.1*	Amended and Restated Articles of Incorporation of the Company.
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	Employment Agreement, dated as of July 7, 2014, between CryoLife, Inc. and James P. Mackin. (Incorporated herein by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed July 11, 2014.)
10.2*	Separation and Release Agreement, dated as of August 28, 2014, between CryoLife, Inc. and Jeffrey W. Burris.
10.3*	Stock Option Grant Agreement, dated September 2, 2014, by and between CryoLife, Inc. and James P. Mackin.
10.4*	Restricted Stock Award Agreement, dated as of September 2, 2014, by and between CryoLife, Inc. and James P. Mackin.
10.5	Second Amendment, dated as of September 3, 2014, to the Employment Agreement, dated as of October 23, 2012, by and between CryoLife, Inc. and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed September 9, 2014.)
10.6*	Second Amended and Restated Credit Agreement, dated September 26, 2014, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner.
10.7*	First Amendment to the Distribution Agreement between CryoLife, Inc. and Starch Medical, Inc., dated May 18, 2011. (Redacted version filed with Registrant's current Report on Form 8-K filed January 30, 2012.)
31.1*	Certification by James P. Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document

Edgar Filing: CRYOLIFE INC - Form 10-Q

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.



**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/ JAMES P. MACKIN  
JAMES P. MACKIN

President and Chief Executive Officer

(Principal Executive Officer)

October 28, 2014  
DATE

/s/ D. ASHLEY LEE  
D. ASHLEY LEE

Executive Vice President, Chief Operating

Officer, and Chief Financial Officer

(Principal Financial and Accounting Officer)