

CRYOLIFE INC  
Form 10-Q  
October 29, 2013

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2013**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number: 1-13165**

**CRYOLIFE, INC.**

**(Exact name of registrant as specified in its charter)**

**Florida**  
**(State or other jurisdiction of**  
**incorporation or organization)**

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

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

**30144**  
**(Zip Code)**

**(770) 419-3355**

**(Registrant's telephone number, including area code)**

**Not Applicable**

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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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.

<b>Class</b>	<b>Outstanding at October 24, 2013</b>
Common Stock, \$.01 par value per share	27,610,551 Shares

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
	(Unaudited)		(Unaudited)	
<b>Revenues:</b>				
Products	\$ 18,833	\$ 16,893	\$ 56,824	\$ 50,043
Preservation services	17,417	16,399	48,411	48,371
Other		137	71	504
<b>Total revenues</b>	<b>36,250</b>	<b>33,429</b>	<b>105,306</b>	<b>98,918</b>
<b>Cost of products and preservation services:</b>				
Products	3,544	3,114	10,730	8,300
Preservation services	9,357	9,005	26,472	26,645
<b>Total cost of products and preservation services</b>	<b>12,901</b>	<b>12,119</b>	<b>37,202</b>	<b>34,945</b>
<b>Gross margin</b>	<b>23,349</b>	<b>21,310</b>	<b>68,104</b>	<b>63,973</b>
<b>Operating expenses:</b>				
General, administrative, and marketing	16,532	16,533	51,441	48,374
Research and development	2,252	1,829	5,976	5,192
<b>Total operating expenses</b>	<b>18,784</b>	<b>18,362</b>	<b>57,417</b>	<b>53,566</b>
<b>Operating income</b>	<b>4,565</b>	<b>2,948</b>	<b>10,687</b>	<b>10,407</b>
Interest expense	55	42	159	159
Interest income	(1)	(1)	(3)	(4)
Other (income) expense, net	(121)	283	120	442
<b>Income before income taxes</b>	<b>4,632</b>	<b>2,624</b>	<b>10,411</b>	<b>9,810</b>
Income tax expense	1,463	1,086	3,265	3,947
<b>Net income</b>	<b>\$ 3,169</b>	<b>\$ 1,538</b>	<b>\$ 7,146</b>	<b>\$ 5,863</b>
<b>Income per common share:</b>				
<b>Basic</b>	<b>\$ 0.11</b>	<b>\$ 0.06</b>	<b>\$ 0.26</b>	<b>\$ 0.21</b>

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<b>Diluted</b>	\$	<b>0.11</b>	\$	<b>0.06</b>	\$	<b>0.25</b>	\$	<b>0.21</b>
<b>Dividends declared per share</b>	\$	<b>0.0275</b>	\$	<b>0.0250</b>	\$	<b>0.0800</b>	\$	<b>0.0250</b>
<b>Weighted-average common shares outstanding:</b>								
Basic		26,985		26,810		26,857		26,951
Diluted		27,699		27,210		27,499		27,329
<b>Net income</b>	\$	<b>3,169</b>	\$	<b>1,538</b>	\$	<b>7,146</b>	\$	<b>5,863</b>
Other comprehensive income		17		20		38		28
<b>Comprehensive income</b>	\$	<b>3,186</b>	\$	<b>1,558</b>	\$	<b>7,184</b>	\$	<b>5,891</b>

See accompanying Notes to Summary Consolidated Financial Statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	September 30, 2013	December 31, 2012
	(Unaudited)	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 17,679	\$ 13,009
Restricted securities	321	323
Receivables, net	20,663	16,520
Deferred preservation costs	27,201	27,954
Inventories	10,206	10,557
Deferred income taxes	5,651	6,100
Prepaid expenses and other	3,172	3,040
<b>Total current assets</b>	<b>84,893</b>	<b>77,503</b>
Property and equipment, net	11,917	11,667
Investment in equity securities	5,908	5,908
Restricted cash	5,000	5,000
Goodwill	11,365	11,365
Patents, net	1,969	2,114
Trademarks and other intangibles, net	20,406	21,968
Notes receivable	2,000	2,000
Deferred income taxes	16,053	16,564
Other	3,680	3,067
<b>Total assets</b>	<b>\$ 163,191</b>	<b>\$ 157,156</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 4,939	\$ 3,775
Accrued compensation	4,036	5,055
Accrued procurement fees	5,515	4,762
Accrued expenses and other	5,426	6,437
Deferred income	311	1,401
<b>Total current liabilities</b>	<b>20,227</b>	<b>21,430</b>
Contingent consideration liability	1,958	1,912
Other	6,467	5,702
<b>Total liabilities</b>	<b>28,652</b>	<b>29,044</b>
<b>Commitments and contingencies</b>		
<b>Shareholders equity:</b>		
Preferred stock		

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Common stock (issued shares of 27,928 in 2013 and 27,486 in 2012)	279	275
Additional paid-in capital	125,727	122,414
Retained earnings	10,480	5,536
Accumulated other comprehensive loss	(1)	(39)
Treasury stock at cost (shares of 322 in 2013 and 14 in 2012)	(1,946)	(74)
<b>Total shareholders equity</b>	<b>134,539</b>	<b>128,112</b>
<b>Total liabilities and shareholders equity</b>	<b>\$ 163,191</b>	<b>\$ 157,156</b>

See accompanying Notes to Summary Consolidated Financial Statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Nine Months Ended	
	September 30,	
	2013	2012
	(Unaudited)	
<b>Net cash flows from operating activities:</b>		
Net income	\$ 7,146	\$ 5,863
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	4,413	4,176
Non-cash compensation	2,357	2,251
Deferred income taxes	960	1,636
Other non-cash adjustments to income	1,133	1,054
Changes in operating assets and liabilities:		
Receivables	(4,143)	(790)
Deferred preservation costs and inventories	570	(1,365)
Prepaid expenses and other assets	(745)	(792)
Accounts payable, accrued expenses, and other liabilities	(384)	(1,025)
<b>Net cash flows provided by operating activities</b>	<b>11,307</b>	<b>11,008</b>
<b>Net cash flows from investing activities:</b>		
Acquisition of Hemosphere, net of cash acquired		(17,040)
Advances under notes receivable		(1,000)
Capital expenditures	(3,241)	(2,210)
Other	(159)	(760)
<b>Net cash flows used in investing activities</b>	<b>(3,400)</b>	<b>(21,010)</b>
<b>Net cash flows from financing activities:</b>		
Cash dividends paid	(2,202)	(686)
Proceeds from exercise of stock options and issuance of common stock	852	302
Repurchases of common stock	(1,523)	(3,463)
Other	(407)	(74)
<b>Net cash flows used in financing activities</b>	<b>(3,280)</b>	<b>(3,921)</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>4,627</b>	<b>(13,923)</b>
Effect of exchange rate changes on cash	43	8
Cash and cash equivalents, beginning of period	13,009	21,705



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<b>Cash and cash equivalents, end of period</b>	<b>\$ 17,679</b>	<b>\$ 7,790</b>
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See accompanying Notes to Summary Consolidated Financial Statements.

## CRYOLIFE, INC. AND SUBSIDIARIES

## NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

**1. Basis of Presentation**

The accompanying summary consolidated financial statements include the accounts of CryoLife, Inc. and its subsidiaries (CryoLife, the Company, we, or us). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Summary Consolidated Balance Sheet as of December 31, 2012 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of and for the three and nine months ended September 30, 2013 and 2012 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2012.

**2. Financial Instruments**

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

<b>September 30, 2013</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Cash equivalents:				
Money market funds	\$ 1,312	\$	\$	\$ 1,312
Certificates of deposit	2,748			2,748
Restricted securities:				
Money market funds	321			321
<b>Total assets</b>	\$ 4,381	\$	\$	\$ 4,381

Long-term liabilities:				
Contingent consideration	\$	\$	\$ (1,958)	\$ (1,958)
<b>Total liabilities</b>	\$	\$	\$ (1,958)	\$ (1,958)

<b>December 31, 2012</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Cash equivalents:				
Money market funds	\$ 1,319	\$	\$	\$ 1,319
Restricted securities:				
Money market funds	323			323
<b>Total assets</b>	\$ 1,642	\$	\$	\$ 1,642

Long-term liabilities:				
Contingent consideration	\$	\$	\$ (1,912)	\$ (1,912)

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<b>Total liabilities</b>	\$	\$	\$ (1,912)	\$ (1,912)
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The Company used prices quoted from its investment management companies to determine the Level 1 valuation of its investments in money market funds, certificates of deposit, and securities. The Company has changed the presentation of its December 31, 2012 money market funds to Level 1 from Level 2, consistent with its current year presentation. The Company recorded a contingent consideration liability, classified as Level 3, as a result of its acquisition of Hemosphere, Inc. ( Hemosphere ) in May 2012. Refer to Note 4 for further discussion of the Level 3 contingent consideration liability.

Changes in fair value of Level 3 liabilities are listed below (in thousands):

	Contingent Consideration
Balance as of December 31, 2012	\$ 1,912
Loss on remeasurement of contingent consideration	46
Balance as of September 30, 2013	\$ 1,958

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

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

	Cost Basis	Unrealized Holding Loss	Estimated Market Value
<b>September 30, 2013</b>			
Cash equivalents:			
Money market funds	\$ 1,312	\$	\$ 1,312
Certificates of deposit	2,750	(2)	2,748
Restricted cash and securities:			
Cash	5,000		5,000
Money market funds	321		321
<b>December 31, 2012</b>			
Cash equivalents:			
Money market funds	\$ 1,319	\$	\$ 1,319
Restricted cash and securities:			
Cash	5,000		5,000
Money market funds	323		323

As of September 30, 2013 and December 31, 2012 \$321,000 and \$323,000, respectively, of the Company's money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating to international tax obligations. As of September 30, 2013 and December 31, 2012 \$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 credit agreement with General Electric Capital Corporation (GE Capital), as discussed in Note 11. This restriction lapses upon expiration of the credit agreement with GE Capital on October 28, 2014.

There were no gross realized gains or losses on cash equivalents in the three and nine months ended September 30, 2013 and 2012. Differences between the cost basis and market value listed above, consisting of a net unrealized holding loss of \$2,000 at September 30, 2013, are included as a separate component of accumulated other comprehensive income (loss) in the shareholders' equity section of the Summary Consolidated Balance Sheet and are included in other comprehensive income (loss) on the Summary Consolidated Statements of Operations and Comprehensive Income. As of September 30, 2013 \$321,000 of restricted securities had a maturity date of between three months and one year. As of December 31, 2012 \$323,000 of restricted securities had a maturity date within three months. As of September 30, 2013 and December 31, 2012 \$5.0 million of the Company's restricted cash had no maturity date.

### 4. Hemisphere Acquisition

#### Overview

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

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operates Hemosphere as a wholly owned subsidiary.

Hemosphere is the developer and marketer of the Hemodialysis Reliable Qutflow Graft ( HeR<sup>®</sup>Graft ), a proprietary graft-based solution for end-stage renal disease hemodialysis patients with limited access options and central venous obstruction.

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### ***Contingent Consideration***

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

The fair value of the contingent consideration liability was based on unobservable inputs, including management estimates and assumptions about future revenues, and is, therefore, classified as Level 3 within the fair value hierarchy presented in Note 2. The Company will remeasure this liability at each reporting date and will record changes in the fair value of the contingent consideration 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 a gain of \$32,000 and a loss of \$37,000 in the three months ended September 30, 2013 and 2012, respectively, and losses of \$46,000 and \$62,000 in the nine months ended September 30, 2013 and 2012, 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 \$2.0 million as of September 30, 2013 and \$1.9 million as of December 31, 2012.

### ***Accounting for the Transaction***

The Company recorded an allocation of the \$22.0 million purchase price to Hemosphere's tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of May 16, 2012. Goodwill was recorded based on the amount by which the purchase price exceeded the fair value of the net assets acquired, and is not deductible for tax purposes. Goodwill from this transaction has been allocated to the Company's medical devices segment. The purchase price allocation was finalized as of December 31, 2012.

CryoLife incurred transaction and integration costs related to the acquisition of approximately \$2.4 million for the year ended December 31, 2012. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on the Company's Summary Consolidated Statement of Operations and Comprehensive Income. The Company incurred integration costs during the three and nine months ended September 30, 2013 related to the transfer of manufacturing operations. The Company does not expect to continue to incur significant transaction or integration costs in the fourth quarter of 2013.

## **5. 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. The Company's carrying value of this investment includes the purchase price and certain transaction costs, and CryoLife's investment represents an approximate 19% equity ownership in ValveXchange based on ValveXchange's current capitalization. As ValveXchange's stock is not actively traded on any public stock exchange and as the Company's investment is in preferred stock, the Company accounts for this investment using the cost method. The Company recorded its investment as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

### ***Loan Agreement***

In July 2011 the Company entered into an agreement with ValveXchange, as amended, to make available up to \$2.0 million to ValveXchange in debt financing through a revolving credit facility (Loan). The Loan includes various affirmative and negative covenants, including financial covenant requirements, and expires on July 30, 2018, unless terminated earlier. Amounts loaned under the Loan will earn interest at an 8% annual rate and are secured by substantially all of the tangible and intangible assets of ValveXchange. The Company incurred loan origination costs, net of fees charged to ValveXchange, of approximately \$117,000, which are being expensed on a straight-line basis over the life of the loan facility. The Company advanced \$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, 2013 and December 31, 2012.

On July 22, 2013 CryoLife notified ValveXchange that ValveXchange was in default of certain loan covenants, due to factors including ValveXchange's failure to obtain CryoLife's consent for a certain convertible note financing that ValveXchange obtained in July 2013. CryoLife

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and ValveXchange are continuing to work to resolve this event of default, which was ongoing as of October 24, 2013.

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***Investment and Loan Analysis***

During the quarter ended September 30, 2013 the Company determined that available information, including ValveXchange's financial condition and cash position, indicated that it should reevaluate its investment in ValveXchange preferred stock for impairment. However, based on this updated analysis, the Company does not believe that its investment in ValveXchange was impaired in the third quarter of 2013. If the Company subsequently determines that the value of its ValveXchange stock has been impaired, if ValveXchange issues additional shares at a valuation materially different than the carrying value of the Company's shares, or if the Company decides to sell its ValveXchange Preferred Stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in ValveXchange could be material. The carrying value of the Company's 2.4 million shares of ValveXchange preferred stock was \$3.2 million as of September 30, 2013 and December 31, 2012.

ValveXchange is currently attempting to raise additional funds to support its short-term and long-term operations. However, even if ValveXchange is able to secure some additional financing, if it is unable to obtain additional amounts and cannot meet its obligations, CryoLife may need to foreclose on the related collateral to secure repayment of the Loan. Although CryoLife currently believes that the value of the collateral is adequate to repay the Loan, there is no guarantee that the security for the notes will be sufficient to repay the Loan. In addition, if CryoLife is forced to foreclose on the Loan, it may materially, adversely affect the value of CryoLife's preferred stock investment in ValveXchange. The Company may decide to allow ValveXchange to issue shares in payment of some or all of the outstanding debt balance in connection with a future round of financing.

***Option Agreement***

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

**6. CardioFocus Settlement**

On June 14, 2012 CryoLife's subsidiary, Cardiogenesis Corporation (Cardiogenesis), entered into a settlement agreement with respect to its litigation with CardioFocus, Inc. (CardioFocus). Pursuant to the terms of the settlement agreement, Cardiogenesis paid \$4.5 million in cash to CardioFocus. Cardiogenesis and CardioFocus agreed and acknowledged that each party would bear its own costs and expenses, including attorneys' fees, incurred in or as a result of the litigation. On June 14, 2012 the parties filed a stipulation of dismissal with prejudice in the U.S. District Court for the District of Massachusetts.

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

**7. Medafor Matters**

***Investment in Medafor Common Stock***

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

In connection with its purchase of Medafor common stock, the Company entered into agreements with the sellers that could have required CryoLife to make additional payments to the sellers if CryoLife acquired or merged with Medafor within a specified time period. The Company accounted for these provisions as an embedded derivative. The last of these provisions expired in June 2013, and as of September 30, 2013 a derivative no longer exists. As of December 31, 2012 the value of this derivative was zero.





**C.R. Bard's Acquisition of Medafor**

On October 1, 2013 C.R. Bard, Inc. 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 will record 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 an additional \$8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to approximately \$575,000, if released, would be received in late 2014, although this amount is subject to possible offsets. These payments will be recorded as an additional gain when and if received by the Company.

**Investment Analysis**

During the quarter ended September 30, 2013 the Company reviewed available information, including the pending acquisition, and determined that no factors were present indicating that the Company should evaluate the carrying value of its cost method investment in Medafor common stock for impairment. The carrying value of the Company's 2.4 million shares of Medafor common stock was approximately \$2.6 million as of both September 30, 2013 and December 31, 2012.

**Distribution Agreement and Legal Action**

CryoLife distributed a powdered hemostat for Medafor from 2008 to 2010. CryoLife filed a lawsuit against Medafor in 2009 in the U.S. District Court for the Northern District of Georgia ( Georgia Court ). In 2010 Medafor filed counterclaims against CryoLife in the same case. The litigation related to an exclusive distribution agreement that the parties entered into in April 2008.

In June 2012 the parties entered into a settlement agreement. Per the settlement, Medafor paid \$3.5 million in cash to CryoLife in the third quarter of 2012. On June 29, 2012 the parties jointly filed stipulated dismissals with prejudice with the Georgia Court. As a result of the settlement, CryoLife recorded a gain of \$4.7 million as a reduction in general, administrative, and marketing expenses on its Summary Consolidated Statement of Operations and Comprehensive Income in the second quarter of 2012 and recorded a reduction in accounts payable of \$1.2 million to write off a payable for previous inventory purchases, which was discharged pursuant to the settlement agreement.

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

**8. Deferred Preservation Costs and Inventories**

Deferred preservation costs at September 30, 2013 and December 31, 2012 are comprised of the following (in thousands):

	September 30, 2013	December 31, 2012
Cardiac tissues	\$ 12,072	\$ 11,950
Vascular tissues	15,129	16,004
<b>Total deferred preservation costs</b>	<b>\$ 27,201</b>	<b>\$ 27,954</b>

Inventories at September 30, 2013 and December 31, 2012 are comprised of the following (in thousands):

September 30, 2013	December 31, 2012
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Raw materials and supplies	\$	6,644	\$	5,836
Work-in-process		899		830
Finished goods		2,663		3,891
Total inventories	\$	10,206	\$	10,557

**9. Goodwill and Other Intangible Assets*****Indefinite Lived Intangible Assets***

As of September 30, 2013 and December 31, 2012 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	September 30, 2013	December 31, 2012
Goodwill	\$ 11,365	\$ 11,365
Procurement contracts and agreements	2,013	2,013
Trademarks	839	870
Other		250

Based on its experience with similar agreements, the Company believes that its acquired contracts and procurement agreements have an indefinite useful life, as the Company expects to continue to renew these contracts for the foreseeable future. The Company believes that its trademarks 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, 2013 and December 31, 2012 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, 2012.

***Definite Lived Intangible Assets***

As of September 30, 2013 and December 31, 2012 the gross carrying values, accumulated amortization, and approximate amortization period of the Company's definite lived intangible assets are as follows (in thousands):

<b>September 30, 2013</b>	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Amortization Period</b>
Acquired technology	\$ 14,020	\$ 2,392	11 -16 Years
Patents	4,316	2,347	17 Years
Distribution and manufacturing rights and know-how	3,559	654	15 Years
Customer lists and relationships	3,370	511	13 -17 Years
Non-compete agreement	381	257	10 Years
Other	198	160	1 - 3 Years

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

***Amortization Expense***

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

Three Months Ended September 30,	Nine Months Ended September 30,
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	2013	2012	2013	2012
Amortization expense	\$ 493	\$ 521	\$ 1,515	\$ 1,454

As of September 30, 2013 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	<b>Remainder of 2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
Amortization expense	\$ 491	\$ 1,948	\$ 1,905	\$ 1,898	\$ 1,850	\$ 1,844

#### 10. Income Taxes

The Company's effective income tax rate was approximately 32% and 31% for the three and nine months ended September 30, 2013, respectively, as compared to 41% and 40% for the three and nine months ended September 30, 2012, respectively. The Company's income tax rate for the nine months ended September 30, 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. The Company's income tax rate in 2012 was negatively affected by the absence of a research and development tax credit, which was not enacted for the 2012 tax year during 2012.

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generates deferred tax assets primarily as a result of book write-downs, reserves, or impairments which are not immediately deductible for tax return purposes. The Company acquired significant deferred tax assets, primarily net operating loss carryforwards, from its acquisitions of Hemosphere and Cardiogenesis in the second quarters of 2012 and 2011, respectively. The Company currently estimates that a portion of its state net operating loss carryforwards will not be recoverable and has, therefore, recorded a valuation allowance against these state net operating loss carryforwards.

As of September 30, 2013 the Company maintained a total of \$2.3 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$21.7 million. As of December 31, 2012 the Company had a total of \$2.3 million in valuation allowances against deferred tax assets and a net deferred tax asset of \$22.7 million.

#### 11. Debt

##### *GE Credit Agreement*

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

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings subject to defined adjustments as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. The agreement also limits the payment of cash dividends, up to a maximum of \$3.5 million per year, subject to satisfaction of specified conditions. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as restricted cash as of September 30, 2013 and December 31, 2012 on the Company's Summary Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement. Also, the GE Credit Agreement requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined within the agreement, of at least \$20.0 million. The GE Credit Agreement includes customary conditions on incurring new indebtedness. Commitment fees are paid based on the unused portion of the facility. As of September 30, 2013 the Company was in compliance with the covenants of the GE Credit Agreement.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest as determined by GE Capital at either LIBOR, with a minimum rate of 4.25%, or GE Capital's base rate, with a minimum rate of 3.25% each, plus the applicable margin. As of September 30, 2013 and December 31, 2012 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate was 6.50%, and the remaining availability was \$20.0 million.

**Other**

Interest expense was \$55,000 and \$159,000 for the three and nine months ended September 30, 2013, respectively, and \$42,000 and \$159,000 for the three and nine months ended September 30, 2012, respectively, which included interest on debt and uncertain tax positions.

**12. Commitments and Contingencies****Liability Claims**

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

	September 30, 2013	December 31, 2012
Short-term liability	\$ 820	\$ 895
Long-term liability	734	755
<b>Total liability</b>	<b>1,554</b>	<b>1,650</b>
Short-term recoverable	304	320
Long-term recoverable	294	300
<b>Total recoverable</b>	<b>598</b>	<b>620</b>
<b>Total net unreported loss liability</b>	<b>\$ 956</b>	<b>\$ 1,030</b>

Further analysis indicated that the liability as of September 30, 2013 could be estimated to be as high as \$2.9 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

**Employment Agreement**

The Company has an employment agreement with its Chief Executive Officer ( CEO ) that confers benefits which become payable upon the occurrence of certain events, including the voluntary retirement of the CEO or termination of the CEO s employment in conjunction with certain change in control events. As of both September 30, 2013 and December 31, 2012 the Company had \$2.1 million in accrued expenses and other current liabilities on the Summary Consolidated Balance Sheets representing benefits payable upon the CEO s voluntary retirement, for which he is currently eligible. The CEO s current employment agreement took effect on January 1, 2013 and terminates on December 31, 2015. A payment of \$100,000 was made to the CEO in January 2013 in accordance with the terms of the new employment agreement.

**13. Shareholders Equity****Common Stock Repurchase**

On November 1, 2011 the Company announced that its Board of Directors had authorized the Company s purchase of \$15.0 million of its common stock; this program expired on December 31, 2012. In February 2013 the Company s Board of Directors authorized the purchase of up to \$15.0 million of its common stock through October 31, 2014.

In the nine months ended September 30, 2013 the Company purchased approximately 253,000 shares for an aggregate purchase price of \$1.5 million. As of September 30, 2013 the Company had \$13.5 million in remaining authorizations under the repurchase program. For the year ended December 31, 2012 the Company purchased approximately 639,000 shares for an aggregate purchase price of \$3.3 million. These shares were recorded, at cost, as part of treasury stock on the Company s Summary Consolidated Balance Sheets.





### ***Treasury Stock***

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

### ***Cash Dividends***

On August 21, 2012 the Company announced that its Board of Directors had approved the initiation of a quarterly cash dividend of \$0.025 per share of common stock outstanding. In May 2013 the Company announced that its Board of Directors approved a 10% increase in the quarterly cash dividend beginning in the second quarter of 2013 from \$0.025 to \$0.0275 per share of common stock outstanding. The Company paid dividend payments from cash on hand of \$759,000 and \$2.2 million for the three and nine months ended September 30, 2013, respectively, and \$686,000 for both the three and nine months ended September 30, 2012. The dividend payments were recorded as a reduction to retained earnings on the Company's Summary Consolidated Balance Sheets.

## **14. Stock Compensation**

### ***Overview***

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of restricted stock awards ( RSAs ), restricted stock units ( RSUs ), performance stock units ( PSUs ), and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP ) for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period.

### ***Equity Grants***

The Compensation Committee of the Company's Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee directors, RSUs to certain employees, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 395,000 shares and had an aggregate market value of \$2.4 million during the nine months ended September 30, 2013. The PSUs granted in 2013 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 2013 is based on attaining specified levels of adjusted EBITDA, as defined in the grant, for the 2013 calendar year. The Company currently believes that achievement of the performance component is probable and will reevaluate this likelihood on a quarterly basis.

The Compensation Committee of the Company's Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee directors and RSAs and PSUs to certain Company officers which, counting PSUs at target levels, together totaled 387,000 shares of common stock and had an aggregate market value of \$2.1 million during the nine months ended September 30, 2012. The PSUs granted in 2012 earned approximately 125% of the target number of shares.

The Compensation Committee of the Company's Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers totaling 162,000 and 159,000 shares during the nine months ended September 30, 2013 and 2012, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Employees purchased common stock totaling 97,000 and 72,000 shares in the nine months ended September 30, 2013 and 2012, respectively, through the Company's ESPP.

**Stock Compensation Expense**

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

	Three Months Ended September 30, 2013		Nine Months Ended September 30, 2013	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	0.50 Years	4.25 Years	0.50 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%

	Three Months Ended September 30, 2012		Nine Months Ended September 30, 2012	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	0.50 Years	4.25 Years	0.50 Years
Expected stock price volatility	N/A	0.44	0.60	0.54
Risk-free interest rate	N/A	0.16%	0.71%	0.06%

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

	Three Months Ended		Nine Months Ended	
	September 30, 2013	September 30, 2012	September 30, 2013	September 30, 2012
RSA, RSU, and PSU expense	\$ 628	\$ 513	\$ 1,891	\$ 1,533
Stock option and ESPP option expense	225	295	632	875
<b>Total stock compensation expense</b>	<b>\$ 853</b>	<b>\$ 808</b>	<b>\$ 2,523</b>	<b>\$ 2,408</b>

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the Company's ESPP. These amounts were recorded as stock compensation expense and were subject to the Company's normal allocation of expenses to deferred preservation costs and inventory costs. The Company capitalized \$54,000 and \$53,000 in the three months ended September 30, 2013 and 2012, respectively, and \$166,000 and \$157,000 in the nine months ended September 30, 2013 and 2012, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

As of September 30, 2013 the Company had total unrecognized compensation costs of \$730,000 related to unvested stock options and \$2.8 million related to RSAs, RSUs, and PSUs, before considering the effect of expected forfeitures. As of September 30, 2013 this expense is expected to be recognized over a weighted-average period of 1.39 years for stock options, 1.17 years for RSAs, 1.51 years for RSUs, and 1.06 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):

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<b><u>Basic income per common share</u></b>	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Net income	\$ 3,169	\$ 1,538	\$ 7,146	\$ 5,863
Net income allocated to participating securities	(72)	(36)	(163)	(133)
Net income allocated to common shareholders	\$ 3,097	\$ 1,502	\$ 6,983	\$ 5,730
Basic weighted-average common shares outstanding	26,985	26,810	26,857	26,951
Basic income per common share	\$ 0.11	\$ 0.06	\$ 0.26	\$ 0.21

<u>Diluted income per common share</u>	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Net income	\$ 3,169	\$ 1,538	\$ 7,146	\$ 5,863
Net income allocated to participating securities	(70)	(36)	(160)	(131)
Net income allocated to common shareholders	\$ 3,099	\$ 1,502	\$ 6,986	\$ 5,732
Basic weighted-average common shares outstanding	26,985	26,810	26,857	26,951
Effect of dilutive stock options and awards <sup>a</sup>	714	400	642	378
Diluted weighted-average common shares outstanding	27,699	27,210	27,499	27,329
Diluted income per common share	\$ 0.11	\$ 0.06	\$ 0.25	\$ 0.21

<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 1.1 million shares for the three months ended and 1.2 million shares for the nine months ended September 30, 2013 and 1.7 million shares for both the three and nine months ended September 30, 2012 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, and HeRO Graft. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

The primary measure of segment performance, as viewed by the Company's management, is segment gross margin, or net external revenues less cost of products and preservation services. The Company does not segregate assets by segment; therefore, asset information is excluded from the segment disclosures below.

The following table summarizes revenues, cost of products and services, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Revenues:				
Medical devices	\$ 18,833	\$ 16,893	\$ 56,824	\$ 50,043
Preservation services	17,417	16,399	48,411	48,371
Other <sup>a</sup>		137	71	504
Total revenues	36,250	33,429	105,306	98,918

Cost of products and preservation services:

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Medical devices	3,544	3,114	10,730	8,300
Preservation services	9,357	9,005	26,472	26,645
<b>Total cost of products and preservation services</b>	<b>12,901</b>	<b>12,119</b>	<b>37,202</b>	<b>34,945</b>
Gross margin:				
Medical devices	15,289	13,779	46,094	41,743
Preservation services	8,060	7,394	21,939	21,726
Other <sup>a</sup>		137	71	504
<b>Total gross margin</b>	<b>\$ 23,349</b>	<b>\$ 21,310</b>	<b>\$ 68,104</b>	<b>\$ 63,973</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
<b>Products:</b>				
BioGlue and BioFoam	\$ 14,232	\$ 12,725	\$ 43,238	\$ 39,858
PerClot	882	734	2,686	2,069
Revascularization technologies	2,353	2,060	6,837	6,107
HeRO Graft	1,366	1,374	4,063	2,009
<b>Total products</b>	<b>18,833</b>	<b>16,893</b>	<b>56,824</b>	<b>50,043</b>
<b>Preservation services:</b>				
Cardiac tissue	8,572	8,239	22,035	22,662
Vascular tissue	8,845	8,160	26,376	25,709
<b>Total preservation services</b>	<b>17,417</b>	<b>16,399</b>	<b>48,411</b>	<b>48,371</b>
Other <sup>a</sup>		137	71	504
<b>Total revenues</b>	<b>\$ 36,250</b>	<b>\$ 33,429</b>	<b>\$ 105,306</b>	<b>\$ 98,918</b>

<sup>a</sup> The Other designation includes grant revenue.

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## PART I - FINANCIAL INFORMATION

### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### Overview

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

For the quarter ended September 30, 2013 CryoLife reported all-time record quarterly revenues of \$36.3 million, largely driven by strong sales of BioGlue, in what is typically a slower sales period for the Company's surgical sealants. The Company's BioGlue, PerClot, and revascularization technologies product lines and vascular preservation services all had the highest revenues recorded by the Company during a third quarter. The Company's cardiac preservation services reported a quarterly all-time record, reaching \$8.6 million for the first time. The Company's HERO Graft product line showed a small decrease in revenues during the quarter both in comparison to the third quarter of 2012 and the second quarter of 2013. The Company generated \$7.3 million in operating cash during the quarter for a total of \$11.3 million in operating cash generated in the first nine months of 2013.

In September 2013 the Company hosted its first Aortic Valve and Root Boot Camp training session. This training was attended by residents from official cardiothoracic surgery training programs and focused on aortic root anatomy, aortic valve and root, annulus enlargement, and myectomy; aortic repair and valve-sparing; aortic root replacement; and pulmonary autograft replacement, commonly known as the Ross Procedure.

See the Results of Operations section below for additional analysis of the nine months ended September 30, 2013.

#### Recent Events

##### *C.R. Bard's Acquisition of Medafor*

On October 1, 2013 C.R. Bard, Inc. 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 will record 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 an additional \$8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to approximately \$575,000, if released, would be received in late 2014, although this amount is subject to possible offsets. These payments will be recorded as an additional gain when and if received by the Company.

#### *Regulatory Activity*



On January 30, 2013 CryoLife received a warning letter ( Warning Letter ) dated January 29, 2013 from the U.S. Food and Drug Administration ( FDA ). The Warning Letter followed a Form 483, Notice of Inspectional Observations from the FDA ( Form 483 ), related to the Company s processing, preservation, and distribution of human tissue and the manufacture of medical devices. The Form 483 followed a routine quality system inspection of the Company s facilities by the FDA during the period September 17, 2012 to October 16, 2012. The Warning Letter relates to certain observations from the Form 483 that the FDA believes were either inadequately addressed by the Company s responses or for which the FDA required further information to fully assess the Company s corrective actions. The Company responded to the FDA s requests and implemented corrective actions. During the second quarter of 2013 the Company received verbal communication from the FDA indicating that these corrective actions appear satisfactory in addressing the issues raised in the Warning Letter; however, the FDA will need to conduct an inspection to verify these corrective actions. CryoLife believes that this inspection may occur in the fourth quarter of 2013 or in 2014. The Company believes that these corrective actions have adequately addressed the FDA s notice of violations contained in the Warning Letter; however, it is possible that the Company s actions ultimately may not be satisfactory to the FDA. The

Company is awaiting re-inspection by the FDA. The Company believes that the Warning Letter and its actions regarding the Warning Letter and Form 483 will not have a material effect on the Company. However, it is possible that further actions the Company may be required to take in response to the Form 483 and Warning Letter could materially, adversely affect the availability of the Company's tissues and products and cost structure, which could affect the Company's revenues, financial condition, profitability, or cash flows.

Following the receipt of the Warning Letter, CryoLife received a letter from the Human Tissue Authority (HTA) in London, U.K., on March 28, 2013, which governs the distribution of tissues by the Company's subsidiary, CryoLife Europa, Ltd. (Europa), into markets in Europe. The letter temporarily suspended Europa's license to import human tissue, due to concerns the HTA had related to the FDA Warning Letter, and directed Europa to issue a recall for tissues previously distributed which have not been implanted. The HTA subsequently issued a variance to allow Europa to continue to import tissue into Europe under certain circumstances for critically ill patients; however, this variance could be revoked at any time without further warning. In August the HTA reinstated Europa's license but placed certain conditions on the processing of tissue, which Europa has appealed. If the HTA does not reverse its decision related to these processing conditions, the Company may be unable to ship tissues into Europe. The suspension and subsequent activity has decreased and may continue to decrease European preservation services revenues, which totaled \$2.3 million in 2012 and \$1.1 million in the nine months ended September 30, 2013, \$444,000 of which was recorded prior to the HTA suspension, and were primarily related to the shipment of cardiac tissues. However, due to the low fees and high costs of distributing tissues into Europe, CryoLife does not believe that this suspension, including the related recall expenses, will have a material, adverse effect on the Company's financial condition, profitability, or cash flows.

On May 23, 2013 CryoLife received a Form 483 related to the Company's subsidiary Cardiogenesis (Cardiogenesis Form 483). The Cardiogenesis Form 483 followed a quality system inspection of the Company's facilities by the FDA in May 2013. The Cardiogenesis Form 483 contains certain observations including observations concerning labeling, complaint handling, and field actions. The Company has responded to the FDA's requests and has implemented changes that it believes will 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. The Company believes that the Cardiogenesis Form 483 will not have a material effect on the Company. However, it is possible that actions the Company may be required to take in response to the Cardiogenesis Form 483 could materially, adversely affect the Company's revascularization technologies revenues, financial condition, profitability, or cash flows. Subsequent to receipt of the Cardiogenesis Form 483, as discussed above, Cardiogenesis received Premarket Approval (PMA) supplement approval from the FDA for its redesigned Sologrip and PEARL handpieces.

### **Critical Accounting Policies**

A summary of the Company's significant accounting policies is included in Note 1 of the Notes to Consolidated Financial Statements, contained in the Company's Form 10-K for the year ended December 31, 2012. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company's operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require the Company to make estimates and assumptions. The Company did not experience any significant changes during the quarter ended September 30, 2013 in any of its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2012.

### **New Accounting Pronouncements**

In January 2013 the Company adopted Accounting Standards Update (ASU), 2012-02, Intangibles-Goodwill and Other (Topic 350): *Testing Indefinite-Lived Intangible Assets for Impairment*, which gives entities testing indefinite-lived intangible assets for impairment the option of performing a qualitative assessment before performing

the quantitative impairment test as well as the option to bypass the qualitative assessment in any period and proceed directly to performing the quantitative impairment test. The adoption of ASU 2012-02 did not have a material effect on the Company's financial condition, profitability, or cash flows.

In February 2013 the Company adopted ASU 2013-02, Comprehensive Income (Topic 220): *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, which requires separate presentation of the components that are reclassified out of accumulated other comprehensive income either on the face of the financial statements or in the notes to the financial statements. This update also requires companies to disclose the income statement line items affected by any significant reclassifications. The adoption of ASU 2013-02 did not have a material effect on the Company's financial disclosures.

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

	Revenues for the Three Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Three Months Ended September 30,	
	2013	2012	2013	2012
	Products:			
BioGlue and BioFoam	\$ 14,232	\$ 12,725	39%	38%
PerClot	882	734	2%	2%
Revascularization technologies	2,353	2,060	7%	6%
HeRO Graft	1,366	1,374	4%	5%
Total products	18,833	16,893	52%	51%
Preservation services:				
Cardiac tissue	8,572	8,239	24%	25%
Vascular tissue	8,845	8,160	24%	24%
Total preservation services	17,417	16,399	48%	49%
Other		137	%	%
Total	\$ 36,250	\$ 33,429	100%	100%

	Revenues for the Nine Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2013	2012	2013	2012
	Products:			
BioGlue and BioFoam	\$ 43,238	\$ 39,858	41%	40%
PerClot	2,686	2,069	3%	2%
Revascularization technologies	6,837	6,107	6%	6%
HeRO Graft	4,063	2,009	4%	2%
Total products	56,824	50,043	54%	50%
Preservation services:				
Cardiac tissue	22,035	22,662	21%	23%
Vascular tissue	26,376	25,709	25%	26%
Total preservation services	48,411	48,371	46%	49%

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Other	71	504	%	1%
Total	\$ 105,306	\$ 98,918	100%	100%

Revenues increased 8% and 6% for the three and nine months ended September 30, 2013, respectively, as compared to the three and nine months ended September 30, 2012, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2013 is presented below.

**Products**

Revenues from products increased 11% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. Revenues from products increased 14% for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012. These increases were primarily due to an increase in BioGlue revenues. The increase for the nine months ended September 30, 2013 was also due to the addition of HeRO Graft revenues as a result of the Company's acquisition of Hemosphere in the second quarter of 2012. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot; revascularization technologies; and HeRO Graft 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 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 12% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. This increase was primarily due to a 10% increase in the volume of milliliters sold, which increased revenues by 8%, an increase in average sales prices, which increased revenues by 3%, and the favorable effect of foreign currency exchange, which increased revenues less than 1%.

Revenues from the sale of surgical sealants increased 8% for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012. This increase was primarily due to an 8% increase in the volume of milliliters sold, which increased revenues by 6%, and by an increase in average sales prices, which increased revenues by 2%.

The increase in sales volume of surgical sealants for the three months ended September 30, 2013 was primarily due to an increase in shipments of BioGlue in certain international markets, and, to a lesser extent, an increase in the Company's domestic markets. The increase in sales volume of surgical sealants for the nine months ended September 30, 2013 was due to an increase in shipments of BioGlue in certain international markets, partially offset by a volume decrease in the Company's domestic markets.

The increase in average sales prices for the three and nine months ended September 30, 2013 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 \$1.1 million for both the three months ended September 30, 2013 and 2012, and \$4.0 million and \$3.4 million for the nine months ended September 30, 2013 and 2012, respectively. Management believes that BioGlue sales will be positively affected by increased shipments to Japan for the full year 2013 as compared to 2012, although this increase will be less than the increase experienced in 2012 over 2011. 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.

Management believes that the decrease in BioGlue shipments in its domestic markets for the nine months ended September 30, 2013 is a result of various factors, including: continued economic pressures on hospitals and the resulting attempts by hospitals to control costs by reducing spending on consumable items such as BioGlue, the efforts of some large competitors in imposing and enforcing contract purchasing requirements for competing non-CryoLife products, and the U.S. market introduction of sealant products with approved indications for use in clinical applications in which BioGlue has been used off-label previously. However, the Company has seen the effect of these factors on its domestic BioGlue shipments slow in recent quarters. In the third quarter of 2013 domestic shipments showed a 2% increase in the volume of milliliters sold over the same quarter in 2012. Management believes that BioGlue sales volume in domestic markets could continue to be affected by the factors discussed above, which may cause a decrease in BioGlue sales volume in future quarters.

Domestic revenues accounted for 58% and 56% of total BioGlue revenues for the three and nine months ended September 30, 2013, respectively, and 60% of total BioGlue revenues for both the three and nine months ended September 30, 2012. BioFoam sales accounted for less than 1% of surgical sealant sales for each of the three and nine months ended September 30, 2013 and 2012. BioFoam is currently approved for sale in certain international markets.

*PerClot*

Revenues from the sale of PerClot increased 20% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. This increase was primarily due to a 29% increase in the volume of grams sold, which increased revenues by 26% and the favorable effect of foreign currency exchange, which increased revenues 2%, partially offset by a decrease in average selling prices, which decreased revenues 8%.

Revenues from the sale of PerClot increased 30% for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012. This increase was primarily due to a 36% increase in the volume of grams sold, which increased revenues by 32% and the favorable effect of foreign currency exchange, which increased revenues 1%, partially offset by a decrease in average selling prices, which decreased revenues 3%.

Revenues during these three and nine month periods were for sales in certain international markets, as PerClot is not yet approved for domestic distribution or widespread international distribution. These increases were primarily due to increased sales in the Company's markets in Europe, partially due to growth in both new geographies and new surgical indications.

In June 2013 CryoLife received conditional approval of its investigational device exemption ( IDE ) for PerClot from the FDA. IDE approval would allow the Company to begin clinical trials for the purpose of obtaining PMA to distribute PerClot in the U.S. As part of the conditional approval for the PerClot IDE, the Company must make certain revisions to the investigational study protocol, clinical product labeling, and Patient Informed Consent forms. The Company refiled the IDE submission on September 27, 2013. The Company expects to obtain FDA approval to begin enrollment in the pivotal trial late in the fourth quarter of 2013 or in the first quarter of 2014.

Management believes that PerClot revenues will be flat or show a slight decrease in the fourth quarter of 2013 as compared to the fourth quarter of 2012 as the Company's revenues in the fourth quarter of 2012 were favorably affected by a large stocking order from an international distributor. However, management believes that PerClot revenues will increase for the full year of 2013 as compared to the full year of 2012. Continued weak economic conditions and their constraining effect on hospital budgets are expected to drive continued pricing pressures, especially due to the many hemostatic agents currently competing for market share in Europe.

#### *Revascularization Technologies*

Revenues from revascularization technologies include revenues related primarily to the sale of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from revascularization technologies increased 14% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. Revenues from the sale of laser consoles were \$379,000 and zero for the three months ended September 30, 2013 and 2012, respectively. Revenues from the sale of handpieces decreased 2% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. This decrease was primarily due to an 11% decrease in unit shipments of handpieces, which decreased revenues by 10%, partially offset by an increase in average sales prices, which increased revenues by 8%.

Revenues from revascularization technologies increased 12% for the nine months ended September 30, 2013 as compared to nine months ended September 30, 2012. Revenues from the sale of laser consoles were \$462,000 and \$279,000 for the nine months ended September 30, 2013 and 2012, respectively. Revenues from the sale of handpieces increased 13% for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012. This increase was primarily due to a 5% increase in unit shipments of handpieces, which increased revenues by 5%, and an increase in average sales prices, which increased revenues by 8%.

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. The decrease in handpiece volume for the three months ended September 30, 2013 was primarily due to delays in receiving sufficient inventory from the Company's third party supplier to meet demand for the new design. The Company has received additional shipments of inventory subsequent to the end of the third quarter and does not anticipate that availability of inventory will affect handpiece sales in the fourth quarter of 2013. The increase in handpiece volume for the nine months ended September 30, 2013 was primarily due to the Company's strategy to focus on increasing procedure volume.

Revascularization technologies revenues for the 2013 and 2012 periods discussed above consisted primarily of handpiece sales. The amount of revenues from console sales can vary significantly from quarter-to-quarter due to the long lead time required to generate sales of capital equipment. Revenues from laser consoles have been affected by the current economic environment, which makes hospitals reluctant to invest in large capital purchases.



*HeRO Graft*

HeRO Graft revenues for the three months ended September 30, 2013 decreased 1% when compared to the three months ended September 30, 2012. Revenues from HeRO Grafts for the nine months ended September 30, 2013 increased significantly over the corresponding period in 2012 as HeRO Grafts were not marketed by the Company for the full prior year period. The Company began marketing HeRO Grafts following its acquisition of Hemosphere in May 2012. HeRO Graft revenues for the nine months ended September 30, 2013 increased 1% when compared to the combined pre- and post-acquisition revenues for the nine months ended September 30, 2012.

Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. HeRO Grafts are primarily distributed in domestic markets as a solution for end-stage renal disease in certain hemodialysis patients.

As the HeRO Graft implant is currently performed by a relatively small number of surgeons, HeRO Graft revenues are subject to more variability quarter-to-quarter due to the timing of surgical cases. As the population of implanting doctors increases, the Company expects this variability in revenues will decrease.

### *Preservation Services*

Revenues from preservation services increased 6% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. Revenues from preservation services for the nine months ended September 30, 2013 were comparable to revenues for the nine months ended September 30, 2012. The increase in revenues for the three month period was primarily due to an increase in vascular tissue service revenues during the period, and, to a lesser extent, due to an increase in cardiac tissue service revenues. 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. The Company currently believes that preservation services revenues for the fourth quarter and full year of 2013 will be comparable to revenues for fourth quarter and full year of 2012; however, if CryoLife is unable to resolve the issues identified by the HTA, preservation services revenues could decrease slightly for the fourth quarter and full year of 2013 as compared to the corresponding periods in 2012. Only 4% of the Company's preservation services revenues in 2012 were from tissues shipped into Europe, and due to the low fees and high costs of distributing tissues into Europe, CryoLife does not believe that the HTA suspension will have a material, adverse effect on the Company's financial condition, profitability, or cash flows. See further discussion of any specific items affecting cardiac and vascular preservation services revenues for the three and nine months ended September 30, 2013 below.

### *Cardiac Preservation Services*

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 4% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. This increase was primarily due to an increase in average service fees, which increased revenues by 4%.

Revenues from cardiac preservation services decreased 3% for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012. This decrease was primarily due to a 7% decrease in unit shipments of cardiac tissues, which decreased revenues 6%, partially offset by an increase in average service fees, which increased revenues by 3%.

The increase in average service fees for the three and nine months ended September 30, 2013 was primarily due to list fee increases in domestic markets in November 2012 and July 2013, and due to the routine negotiation of pricing contracts with certain customers.

The decrease in volume for the nine months ended September 30, 2013 was primarily due to a decrease in volume of cardiac valve shipments, largely as a result of the timing of tissue releases for shipments to domestic markets as compared to the prior year periods, which can vary as discussed above, and a decrease in shipments into Europe in the second quarter of 2013 as a result of the HTA's letter suspending CryoLife's license to distribute tissue in Europe.

During the three months ended September 30, 2013 the Company's revenues from shipments of cardiac tissues into Europe under the special access variance allowed by the HTA were \$501,000 as compared to \$456,000 in the

corresponding period in 2012. The Company is not certain if this volume will continue throughout the fourth quarter of 2013, as the variance could be revoked by the HTA at any time. The Company expects that cardiac preservation services revenues for the full year of 2013 will be negatively affected by the HTA's letter suspending CryoLife's license to distribute tissue in Europe, primarily due to reduced shipments in the second quarter of 2013, as discussed above.

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.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 52% and 51% of total cardiac preservation services revenues for the three and nine months ended September 30, 2013, respectively, and 49% and 45% of total cardiac preservation services revenues for the three and nine months ended September 30, 2012, respectively. Domestic revenues accounted for 91% and 93% of total cardiac preservation services revenues for the three and nine months ended September 30, 2013, respectively, and 91% and 90% of total cardiac preservation services revenues for the three and nine months ended September 30, 2012, respectively.

*Vascular Preservation Services*

Revenues from vascular preservation services increased 8% for the three months ended September 30, 2013 as compared to the three months ended September 30, 2012. This increase was primarily due to an increase in average service fees, which increased revenues by 12%, partially offset by a 6% decrease in unit shipments of vascular tissues, which decreased revenues by 4%.

Revenues from vascular preservation services for the nine months ended September 30, 2013 increased 3% as compared to revenues for the nine months ended September 30, 2012. This increase was primarily due to an increase in average service fees, which increased revenues by 6%, partially offset by a 5% decrease in unit shipments of vascular tissues, which decreased revenues by 3%.

The increase in average service fees for the three and nine months ended September 30, 2013 was primarily due to list fee increases in domestic markets in November 2012 and July 2013, fee differences due to physical characteristics of vascular tissues, and the routine negotiation of pricing contracts with certain customers.

The decrease in vascular volume for the three and nine months ended September 30, 2013 was primarily due to decreases in shipments of saphenous veins and, to a lesser extent, femoral veins. The Company believes that the decrease in unit shipments of veins was primarily due to the timing of tissue releases for shipments to domestic markets as compared to the prior year periods, which can vary as discussed above.

The majority of the Company's vascular preservation services revenues are related to shipments of saphenous veins, which are mainly used in peripheral vascular reconstruction surgeries to avoid limb amputations. These tissues are primarily distributed in domestic markets.

**Cost of Products and Preservation Services***Cost of Products*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Cost of products	\$ 3,544	\$ 3,114	\$ 10,730	\$ 8,300

Cost of products increased 14% and 29% for the three and nine months ended September 30, 2013, respectively, as compared to the three and nine months ended September 30, 2012, respectively. Cost of products in 2013 and 2012 includes costs related to BioGlue, BioFoam, PerClot, revascularization technologies, and HeRO Grafts.

Cost of products for the three and nine months ended September 30, 2013 includes \$53,000 and \$487,000, respectively, 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.

The increase in cost of products in the three and nine months ended September 30, 2013 was primarily due to the increase in sales volume of BioGlue. To a lesser extent, the increase in cost of products in the three months ended September 30, 2013 was also due to the increase in sales volume of PerClot and in the nine months ended September 30, 2013 by the increase in sales volume of revascularization technologies and PerClot.

*Cost of Preservation Services*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Cost of preservation services	\$ 9,357	\$ 9,005	\$ 26,472	\$ 26,645

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Cost of preservation services increased 4% and decreased 1% for the three and nine months ended September 30, 2013, respectively, as compared to the three and nine months ended September 30, 2012, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three months ended September 30, 2013 primarily due to an increase in the per unit cost of processing tissues primarily as a result of a change in vascular tissue mix. Cost of preservation services decreased in the nine months ended September 30, 2013 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 primarily as a result of a change in vascular tissue mix and write-down of certain cardiac tissues distributed in international markets in the first half of 2013, which are not expected to ship prior to the expiration date of their packaging.

### Gross Margin

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Gross margin	\$ 23,349	\$ 21,310	\$ 68,104	\$ 63,973
Gross margin as a percentage of total revenues	64%	64%	65%	65%

Gross margin increased 10% and 6% for the three and nine months ended September 30, 2013, respectively, as compared to the three and nine months ended September 30, 2012, respectively. Gross margin increased primarily due to an increase in product revenues during the 2013 periods. To a lesser extent, gross margins for the three months ended September 30, 2013 were favorably affected by increases in fees on preservation services. Gross margin as a percentage of total revenues in the three and nine months ended September 30, 2013 was comparable to the three and nine months ended September 30, 2012, respectively.

### Operating Expenses

#### General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
General, administrative, and marketing expenses	\$ 16,532	\$ 16,533	\$ 51,441	\$ 48,374
General, administrative, and marketing expenses as a percentage of total revenues	46%	49%	49%	49%

General, administrative, and marketing expenses for the three months ended September 30, 2013 were comparable to the three months ended September 30, 2012. General, administrative, and marketing expenses increased 6% for the nine months ended September 30, 2013, as compared to the nine months ended September 30, 2012.

General, administrative, and marketing expenses for the nine months ended September 30, 2013 included marketing expenses of the expanded sales staff and costs related to the transfer of HeRO Graft manufacturing operations which was not present in the full corresponding prior year period, due to the acquisition of Hemosphere in May 2012. Medical device excise taxes were \$265,000 and \$767,000 for the three and nine months ended September 30, 2013, respectively, and zero for both the three and nine months ended September 30, 2012.

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

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



**Research and Development Expenses**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Research and development expenses	\$ 2,252	\$ 1,829	\$ 5,976	\$ 5,192
Research and development expenses as a percentage of total revenues	6%	5%	6%	5%

Research and development expenses increased 23% and 15% for the three and nine months ended September 30, 2013, respectively, as compared to the three and nine months ended September 30, 2012, respectively. Research and development spending in these periods was primarily focused on PerClot, the Company's tissue processing, revascularization technologies, and BioGlue and BioFoam. Due to increases in spending on clinical studies related to PerClot in the first nine months of 2013 and anticipated increases in the fourth quarter of 2013 and in 2014, the Company expects that research and development spending for the full year of 2013 will increase compared to the full year of 2012 and that research and development spending for 2014 will increase significantly as compared to 2013.

**Earnings**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Income before income taxes	\$ 4,632	\$ 2,624	\$ 10,411	\$ 9,810
Income tax expense	1,463	1,086	3,265	3,947
Net income	\$ 3,169	\$ 1,538	\$ 7,146	\$ 5,863
Diluted income per common share	\$ 0.11	\$ 0.06	\$ 0.25	\$ 0.21
Diluted weighted-average common shares outstanding	27,699	27,210	27,499	27,329

Income before income taxes increased 77% and 6% for the three and nine months ended September 30, 2013, respectively, as compared to the three and nine months ended September 30, 2012, respectively. The increase in income before income taxes for the three and nine months ended September 30, 2013 was primarily due to an increase in product revenues, which increased margins, partially offset by an increase in operating expenses, as discussed above.

The Company's effective income tax rate was approximately 32% and 31% for the three and nine months ended September 30, 2013, respectively, as compared to 41% and 40% for the three and nine months ended September 30, 2012, respectively. The Company's income tax rate for the nine months ended September 30, 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. The Company's income tax rate in 2012 was negatively affected by the unfavorable tax treatment of certain acquisition related expenses due to the acquisition of Hemosphere and by the research and development tax credit, which was not enacted for the 2012 tax year during 2012.

Net income and diluted income per common share increased for the three and nine months ended September 30, 2013 as compared to the three and nine months ended September 30, 2012, primarily due to the increase in income before income taxes, as discussed above.

The Company anticipates that net income and diluted income per common share will increase significantly in the fourth quarter and full year of 2013 over the corresponding prior year periods due to the expected gain of approximately \$12.7 million from the sale of the Company's investment in Medafor common stock due to C.R. Bard, Inc.'s acquisition of Medafor on October 1, 2013.



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Diluted income per common share could be unfavorably affected in future periods by the issuance of additional shares of common stock and favorably affected by the Company's repurchase of its common stock. Stock repurchases are influenced by many factors, including: stock price, available funds, and competing demands for such funds, and as a result, may be suspended or discontinued at any time.

## **Seasonality**

The Company believes the demand for BioGlue is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to the summer holiday season in Europe and in the U.S. The Company's market for BioGlue in Japan is still in a growth phase, however, the Company believes that demand for BioGlue in Japan may continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by the slower summer holiday season in Japan.

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

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

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

The Company's demand for its cardiac preservation services has traditionally been seasonal, with peak demand generally occurring in the third quarter. Management believes this trend for cardiac preservation services is primarily due to the high number of surgeries scheduled during the summer months for school-aged patients. Based on experience in recent years, management believes that this trend is lessening as the Company is distributing a higher percentage of its tissues to adult populations.

The Company believes the demand for its vascular preservation services is seasonal, with lowest demand generally occurring in the fourth quarter. Management believes this trend for vascular preservation services is primarily due to fewer vascular surgeries being scheduled during the winter holiday months.

## **Liquidity and Capital Resources**

### ***Net Working Capital***

At September 30, 2013 net working capital (current assets of \$84.9 million less current liabilities of \$20.2 million) was \$64.7 million, with a current ratio (current assets divided by current liabilities) of 4 to 1, compared to net working capital of \$56.1 million and a current ratio of 4 to 1 at December 31, 2012.

### ***Overall Liquidity and Capital Resources***

The Company's largest cash requirement for the nine months ended September 30, 2013 was cash for general working capital needs, as the Company's accounts receivable balance increased significantly from December 31, 2012. The accounts receivable increase was due to the Company's recent sales, which have not yet been converted to cash, along with the fact that accounts receivable as of December 31, 2012 was lower than normal due to timing of payments. In addition, the Company's other cash requirements included capital expenditures, repurchases of the Company's common stock, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves and its operating activities, which generated cash during the period.

CryoLife's credit agreement with General Electric Capital Corporation (the "GE Credit Agreement") provides revolving credit for working capital, acquisitions, and other corporate purposes. The borrowing capacity under the GE Credit Agreement is \$20.0 million (including a letter of credit subfacility), and the GE Credit Agreement expires October 28, 2014. The borrowing capacity may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash

equivalents of at least \$5.0 million in accounts in which General Electric Capital Corporation has a first priority perfected lien. As a result, these funds will not be available to meet the Company's liquidity needs during the term of the GE Credit Agreement and, as such, have been recorded as restricted cash and securities on the Company's 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, 2013 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, 2013 the Company purchased approximately 253,000 shares of its common stock for an aggregate purchase price of \$1.5 million. As of September 30, 2013 the Company had \$13.5 million in remaining authorizations under common stock repurchase programs authorized by the Company's Board of Directors. The Company is entitled to repurchase approximately \$8.7 million in additional common stock without obtaining its lender's consent. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions.

As of September 30, 2013 approximately 5% of the Company's cash and cash equivalents were held in foreign jurisdictions.

On October 1, 2013 C.R. Bard, Inc. 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 will record 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 an additional \$8.4 million upon the release of funds held in escrow and the satisfaction of certain contingent milestones, measurable through June 2015. The first of these additional payments, which the Company believes could be up to approximately \$575,000, if released, would be received in late 2014, although this amount is subject to possible offsets. These payments will be recorded as an additional gain when and if received by the Company.

As discussed elsewhere in this 10-Q, in September 2012, CryoLife received a letter from Medafor stating that PerClot, when introduced in the U.S., will, when used in accordance with the method published in CryoLife's literature and with the instructions for use, infringe Medafor's U.S. patent. CryoLife does not believe that it will infringe Medafor's patent. There have been no further communications between CryoLife and Medafor, or CryoLife and C.R. Bard related to the September letter. In the event that patent infringement litigation were to commence between CryoLife and Medafor in 2014, the costs of this litigation in 2014 would likely be material.

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. On July 22, 2013 CryoLife notified ValveXchange that ValveXchange was in default of certain loan covenants, due to factors including ValveXchange's failure to obtain CryoLife's consent for a certain convertible note financing that ValveXchange obtained in July 2013. CryoLife and ValveXchange are continuing to work to resolve this event of default, which was ongoing as of October 24, 2013. However, even if ValveXchange is able to secure some additional financing, if it is unable to obtain additional amounts and cannot meet its obligations, CryoLife may need to foreclose on the related collateral to secure repayment of the Loan. Although CryoLife currently believes that the value of the collateral is adequate to repay the Loan, there is no guarantee that the security for the notes will be sufficient to repay the Loan. If CryoLife is forced to foreclose on the Loan, it may materially, adversely affect the value of CryoLife's preferred stock investment in ValveXchange. The Company may decide to allow ValveXchange to issue shares in payment of some or all of the outstanding debt balance in connection with a future round of financing.

The Company believes that its anticipated cash from operations and existing cash and cash equivalents will enable the Company to meet its current operational liquidity needs for at least the next twelve months. The Company's future cash requirements are expected to include cash to fund the PerClot clinical trials, to repurchase the Company's common stock, to fund the cash dividend to common shareholders, to fund additional research and development expenditures, to fund business development activities, to purchase license agreements, 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 fourth quarter of 2013 and during 2014. The Company may seek additional borrowing capacity or financing pursuant to its shelf registration statement, for general corporate purposes, or to fund other future cash requirements. If the Company undertakes further significant business development activity in 2013 or 2014, it may need to finance such activities by drawing down monies under the GE Credit Agreement, obtaining additional debt financing, or using its shelf registration statement to sell equities.

The Company acquired net operating loss carryforwards from its acquisitions of Hemosphere and Cardiogenesis that the Company believes will reduce required cash payments for federal income taxes by approximately \$1.5 million for the 2013 tax year.

#### ***Net Cash Flows from Operating Activities***

Net cash provided by operating activities was \$11.3 million for the nine months ended September 30, 2013 as compared to \$11.0 million for the nine months ended September 30, 2012.

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, 2013 these non-cash items included a favorable \$4.4 million in depreciation and amortization expenses, \$2.4 million in non-cash compensation, and \$960,000 in deferred income taxes.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2013 these changes included unfavorable adjustments of \$4.1 million due to the timing differences between the recording of receivables and the receipt of cash.

**Net Cash Flows from Investing Activities**

Net cash used in investing activities was \$3.4 million for the nine months ended September 30, 2013 as compared to \$21.0 million for the nine months ended September 30, 2012. The current year cash used was primarily due to \$3.2 million in capital expenditures. The prior year cash used was primarily due to the acquisition of Hemosphere.

**Net Cash Flows from Financing Activities**

Net cash used in financing activities was \$3.3 million for the nine months ended September 30, 2013 as compared to \$3.9 million for the nine months ended September 30, 2012. The current year cash used was primarily due to \$2.2 million in cash dividends paid and \$1.5 million in purchases of treasury stock related to the Company's publicly announced stock repurchase plan.

**Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

**Scheduled Contractual Obligations and Future Payments**

Scheduled contractual obligations and the related future payments as of September 30, 2013 are as follows (in thousands):

	Total	Remainder of 2013	2014	2015	2016	2017	Thereafter
Operating leases	\$ 25,951	\$ 497	\$ 3,123	\$ 3,098	\$ 3,012	\$ 3,050	\$ 13,171
Purchase commitments	6,878	3,401	1,819	1,658			
Contingent payments	4,500	500	500	3,500			
Compensation payments	1,985				1,985		
Research obligations	2,028	475	1,427	97	29		
Total contractual obligations	\$ 41,342	\$ 4,873	\$ 6,869	\$ 8,353	\$ 5,026	\$ 3,050	\$ 13,171

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

The Company's purchase commitments include minimum purchase requirements for PerClot related to the Company's transaction with SMI. These minimum purchases are included through 2015, as the Company expects to receive FDA approval for PerClot in late 2015. Upon FDA approval, the Company may terminate its minimum purchase requirements, per the terms of the agreements between the parties, which the Company expects to do. However, if the Company does not terminate this provision, it will have minimum purchase obligations of \$1.75 million per year through the end of the contract term in 2025. The Company's purchase commitments also include obligations from agreements with suppliers.

The contingent payment obligations include obligations related to the Company's acquisition of Hemosphere and transaction with SMI. The contingent payment obligation for Hemosphere represents the payments that the Company will make if certain revenue milestones are achieved. The schedule includes one contingent milestone payment for \$2.5 million that the Company believes it is likely to pay in 2015, although the timing of this payment may change. The schedule excludes one Hemosphere contingent milestone payment of up to \$2.0 million, as the Company cannot make a reasonably reliable estimate of when this future payment may be made, if at all. The contingent payment obligation for PerClot represents the payments that the Company will make if certain FDA regulatory approvals and other commercial milestones are achieved. The schedule excludes one PerClot contingent milestone payment of \$500,000, as the Company cannot make a reasonably reliable estimate of timing of this future payment.

The Company's compensation payment obligations represent estimated payments for post-employment benefits for the Company's Chief Executive Officer (CEO). The timing of the CEO's post-employment benefits is based on the December 2015 expiration date of the CEO's employment agreement; however, payment of this benefit may be accelerated upon the occurrence of certain events, including the voluntary retirement of the CEO or termination of the CEO's employment in conjunction with certain change in control events.

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

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$2.7 million, because the Company cannot make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made for specific litigation or by any taxing authorities.

### **Capital Expenditures**

Capital expenditures for the nine months ended September 30, 2013 were \$3.2 million compared to \$2.2 million for the nine months ended September 30, 2012. Capital expenditures in the nine months ended September 30, 2013 were primarily related to the routine purchases of manufacturing and tissue processing equipment, including support for the Company's HeRO Graft and PerClot product lines; revascularization technologies lasers; computer and office equipment; computer software; and leasehold improvements needed to support the Company's business.

### Forward-Looking Statements

This Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. Forward-looking statements give the Company's current expectations or forecasts of future events. The words could, may, might, will, would, shall, should, potential, pending, intend, believe, expect, anticipate, estimate, plan, future, and other similar expressions identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Risks and Uncertainties and elsewhere in this Form 10-Q.

All statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

Expectations regarding the accounting treatment and costs of certain transactions;

Expectations regarding transaction and integration costs related to the acquisition of Hemosphere;

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

Expectations regarding additional payments that the Company could receive as a result of C.R. Bard, Inc.'s acquisition of Medafor;

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

Expectations regarding the renewal of certain contracts;

Anticipated cash flow contributions of the Company's trademarks;

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

Expectations regarding the attainment of the performance component of 2013 equity grants, and the recognition of expenses related to equity grants;



Expectations regarding the timing of the FDA inspection to verify the Company's corrective actions;

The Company's belief that its corrective actions have adequately addressed the FDA's notice of violations in the Warning Letter, and the Company's belief regarding the effect on the Company of the Warning Letter and the Company's actions regarding the Warning Letter and Form 483;

Expectations regarding the effect of the processing conditions imposed by the HTA on the Company's ability to ship tissues into Europe and the factors that could affect the volume of shipments of cardiac tissues into Europe during the fourth quarter of 2013;

Expectations regarding the effect of the suspension imposed by the HTA, along with subsequent activity, on the Company's European preservation services revenues and cardiac preservation services revenues;

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

The Company's beliefs regarding its ability to address the FDA's Observations in the Cardiogenesis Form 483, and the effect on the Company from the Cardiogenesis Form 483 and the Company's actions regarding the Cardiogenesis Form 483;

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

Management's plans for BioGlue in Japan and China and management's beliefs regarding international growth opportunities for BioGlue;

The Company's expectation that it will obtain FDA approval to begin enrollment in the pivotal PerClot clinical trial late in the fourth quarter of 2013 or in the first quarter of 2014;

Management's beliefs regarding PerClot sales in the remainder of 2013, and the factors expected to drive continued pricing pressures;

The Company's anticipation that availability of inventory will not affect handpiece sales in the fourth quarter of 2013;

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

The Company's beliefs regarding preservation services revenues for the fourth quarter and full year of 2013, and the factors effecting such revenues;

Expectations regarding the timing of shipments of certain cardiac tissues;

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

Expectations regarding costs related to the transfer of HeRO Graft manufacturing operations;

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

The Company's expectations regarding research and development expenses for the full years of 2013 and 2014, and the factors effecting such expenses, including anticipated increases in spending on clinical studies related to PerClot;

The Company's expectation that net income and diluted income per common share will increase significantly in the fourth quarter and full year of 2013, and the factors causing such increase;

The Company's beliefs regarding the seasonal nature of the demand for BioGlue and its cardiac and vascular preservation services;

The Company's belief 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's belief that if it needs to foreclose on the ValveXchange Loan, the value of the related collateral is adequate to repay the Loan;

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

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

The Company's belief that further significant business development activity in 2013 or 2014 may require the Company to draw down monies on its credit facility, obtain additional debt financing, or sell equity under its shelf registration statement, and the Company's belief that it may seek additional borrowing capacity or financing for general corporate purposes or to fund other future cash requirements;

The Company's expectations that it will receive FDA approval for PerClot in 2015 and that it will terminate its minimum purchase requirements for PerClot after the product receives FDA approval;

Expectations regarding payments to former shareholders of Hemosphere upon the achievement of certain revenue-based milestones, management's estimates and assumptions regarding the achievement of such milestones, expectations regarding obligations for certain contingent payments and purchase commitments related to asset purchases and acquisitions, and the timing of such payments and purchases;

Estimated liability for uncertain tax positions and interest and penalties;

Anticipated affect on the Company of changes in interest rates and foreign currency exchange rates; and

Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risk factors set forth under Part I, Item 1A of the Company's Form 10-K for the year ended December 31, 2012, and other factors, many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

### **Risks and Uncertainties**

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

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

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

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

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

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

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

Upon its inspection, the FDA may determine that our corrective actions have not adequately addressed the issues raised in the Warning Letter. If we have failed to respond to the notice of violations in the Warning Letter to the FDA's satisfaction, then we may be subject to additional regulatory action by the FDA, including recalls, injunctions, and/or civil money penalties, and the demand for our products and services could be negatively impacted by adverse publicity with respect to the Warning Letter. In addition, further actions required to be taken in response to the Warning Letter could impact the availability of our products and tissues and our cost structure;

The HTA could revoke the special access variance granted to Europa at any time without warning. If the HTA does not reverse its decision to impose certain processing conditions upon Europa, then the Company may be unable to ship tissues into Europe other than pursuant to the variance, and our preservation services revenues could be adversely impacted;

We may fail to address the FDA's observations in the Cardiogenesis Form 483 to the FDA's satisfaction, and as a result, we may be subject to additional regulatory action by the FDA. In addition, actions required to be taken in response to the Cardiogenesis Form 483 could adversely impact our revascularization technologies 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 be unable to obtain the FDA's approval to begin enrollment in the PerClot clinical trial in our expected timeframe, if at all. In addition we may ultimately be unsuccessful in our 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;

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

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

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

As a result of the funding issues that have been affecting ValveXchange, our preferred stock investment in ValveXchange may be further impaired, or our Loan to ValveXchange may become uncollectible, which could have a material, adverse impact on our business. Even if ValveXchange is able to secure additional financing, it may nonetheless default on the Loan in the future, and 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. If we foreclose on the Loan, it may adversely impact the value of our preferred stock investment in ValveXchange;

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

Intense competition may impact our ability to operate profitably;

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

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

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

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

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

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

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

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

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

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

We are dependent on our key personnel.

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### **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 \$17.7 million and restricted cash of \$5.0 million and interest paid on the Company's variable rate line of credit as of September 30, 2013. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the nine months ended September 30, 2013, affecting the Company's cash and cash equivalents, restricted cash and securities, and line of credit would not have a material effect on the Company's financial position, profitability, or cash flows.

#### **Foreign Currency Exchange Rate Risk**

The Company has balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency denominated balances are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of cash or funds that the Company will receive in payment for assets or that the Company would have to pay to settle liabilities. As a result, the Company could be required to record these changes as gains or losses on foreign currency translation.

The Company has revenues and expenses that are denominated in foreign currencies. Specifically, a significant portion of the Company's international BioGlue revenues are denominated in British Pounds and Euros, and a portion of the Company's general, administrative, and marketing expenses are denominated in British Pounds and Euros. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2013 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, 2013 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 (the "Exchange Act" ). 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, 2013 the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

During the quarter ended September 30, 2013 there were no other changes in the Company's internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company's internal control over financial reporting.

## **Part II - OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

None.

### **Item 1A. Risk Factors.**

The risk relating to our investment in Medafor described in Part I, Item 1A, "Risk Factors" under the heading "Our Investment In Medafor Has Been Impaired, And Our Investment Could Be Further Impaired By Risks Associated With Medafor's Business Or By Medafor's Actions, Which Could Have A Material, Adverse Impact On Our Financial Condition And Profitability," in our Form 10-K for the year ended December 31, 2012 is no longer applicable because of the acquisition of Medafor by C.R. Bard, Inc. and the related payments made to us in the fourth quarter of 2013 for our Medafor stock as described elsewhere in this Form 10-Q.

**Although We Have Received \$15.4 Million For C.R. Bard's Acquisition Of Medafor And May Receive Additional Cash Of Up To \$8.4 Million In The Future Related To Medafor's Earnout And Release Of Escrow Funds, It Is Possible We May Not Receive Any Additional Monies Or The Amount Of The Additional Monies Received Could Be Significantly Less Than \$8.4 Million.**

As discussed elsewhere in this Form 10-Q, we received approximately \$15.4 million for our shares of Medafor common stock, due to C.R. Bard's acquisition of Medafor. We could receive up to an estimated additional \$8.4 million from this transaction in the future. This number is based on information provided by Medafor and C.R. Bard as part of the transaction. Based on the information that was provided to all shareholders of Medafor by Medafor and C.R. Bard, it appears that we owned approximately 9.2% of Medafor's stock at the closing of their transaction with C.R. Bard. Therefore, it appears that we would be entitled to approximately 9.2% of each of the following amounts:

#### ***Potential Escrow Amounts***

In the fourth quarter of 2014, either: (a) \$6.25 million of the effective \$18.5 million escrow will be released, or (b) if the remaining escrow amount is less than \$6.25 million, the remaining escrow amount less any pending indemnification claims owed by Medafor to C.R. Bard;

In the second quarter of 2015, the remaining escrow not previously paid will be released, except for (a) amounts held for pending indemnification claims owed by Medafor to C.R. Bard and (b) \$2 million, adjusted for certain tax indemnification claims, if any, that have been made or similar amounts recovered; and

In the fourth quarter of 2017, the remaining amounts of the escrow, if any, plus all interest accumulated from the acquisition date will be released minus any indemnification claims owed by

Medafor to C.R. Bard.

***Potential Earnout Amounts***

In either the second or third quarter of 2015, based on whether Medafor and C.R. Bard disagree regarding the calculations of the net sales of Medafor products from the period of July 1, 2014 until June 30, 2015 ( Net Sales ), a milestone payment of up to \$80 million will occur, as follows

\$20 million, if the Net Sales are between \$60 million and \$64,999,999;

\$35 million, if the Net Sales are between \$65 million and \$69,999,999;

\$55 million, if the Net Sales are between \$70 million and \$74,999,999; or

\$80 million, if the Net Sales are equal to or greater than \$75 million

However, 15% of any of these payments are subject to offset to pay any indemnification claims that might arise which are owed by Medafor to C.R. Bard

We do not have any control over or visibility regarding any claims that may have been or will be made against the escrow, whether these escrow amounts will be released, whether Medafor products will meet the sales requirements that would pay the

earn out amounts, or whether any setoffs will occur. Additionally, we may not be aware of any of these issues until we receive payments, if any, because of our lack of visibility. As a result, the amount of additional monies that could be paid to us may be significantly less than the \$8.4 million that Medafor has indicated that we could potentially receive.

**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, 2013 of equity securities that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934:

**Issuer Purchases of Equity Securities**

**Common Stock and Common Stock Units**

<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>
07/01/13 - 07/31/13	10,799	\$ 7.11		\$ 13,622,333
08/01/13 - 08/31/13				13,622,333
09/01/13 - 09/30/13	23,512	6.20	23,512	13,476,633
Total	34,311	6.48	23,512	13,476,633

In February 2013 the Company announced that its Board of Directors had authorized the purchase of up to \$15.0 million of its common stock through October 31, 2014. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions, on such terms as management deems appropriate, and will be dependent upon various factors, including: price, regulatory requirements, and other market conditions. For the quarter ended September 30, 2013, the Company purchased 24,000 shares of its common stock through this authorization for an aggregate purchase price of approximately \$146,000.

Under the Company's credit agreement with General Electric Capital Corporation, the Company is required, after giving effect to stock repurchases, to maintain liquidity, as defined within the agreement, of at least \$20.0 million. The Company is entitled to repurchase up to approximately \$8.7 million of common stock under the February 2013 authorization without obtaining its lender's consent.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.



**Item 6. Exhibits.**

The exhibit index can be found below.

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form S-3 filed February 22, 2012.)
3.2	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed July 27, 2011.)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
4.2	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.)
10.1*	Second Amendment to the Distribution Agreement between the Company and Starch Medical, Inc., dated September 20, 2013.
10.2*	Third Amendment, dated September 20, 2013, to the Amended and Restated Credit Agreement, dated October 28, 2011, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, General Electric Capital Corporation, as lender, swingline lender, as letter of credit issuer, and as the agent for all lenders, and GE Capital Markets, Inc., as sole lead arranger and bookrunner.
31.1*	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\* Furnished herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CRYOLIFE, INC.

(Registrant)

/s/ STEVEN G. ANDERSON

/s/ D. ASHLEY LEE

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

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

October 29, 2013

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DATE