

CRYOLIFE INC
Form 10-Q
October 27, 2015

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

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

For the quarterly period ended **September 30, 2015**

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

Edgar Filing: CRYOLIFE INC - Form 10-Q

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

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

Large accelerated filer

Accelerated filer

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

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

Yes No

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

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

Outstanding at October 22, 2015
28,454,868 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(Unaudited)		(Unaudited)	
Revenues:				
Products	\$ 19,859	\$ 20,405	\$ 59,168	\$ 60,210
Preservation services	16,844	16,664	46,892	47,280
Total revenues	36,703	37,069	106,060	107,490
Cost of products and preservation services:				
Products	4,278	4,167	13,555	12,099
Preservation services	9,443	9,103	28,302	26,735
Total cost of products and preservation services	13,721	13,270	41,857	38,834
Gross margin	22,982	23,799	64,203	68,656
Operating expenses:				
General, administrative, and marketing	17,494	18,882	55,790	55,116
Research and development	2,960	1,902	7,896	6,607
Total operating expenses	20,454	20,784	63,686	61,723
Operating income	2,528	3,015	517	6,933
Interest expense	(78)	65	(18)	110
Interest income	(14)	(1)	(29)	(49)
Gain on sale of Medafor investment	--	--	(891)	--
Other (income) expense, net	(238)	4	204	(206)

Edgar Filing: CRYOLIFE INC - Form 10-Q

Income before income taxes	2,858	2,947	1,251	7,078
Income tax expense (benefit)	713	621	(118)	1,532
Net income	\$ 2,145	\$ 2,326	\$ 1,369	\$ 5,546
Income per common share:				
Basic	\$ 0.08	\$ 0.08	\$ 0.05	\$ 0.20
Diluted	\$ 0.07	\$ 0.08	\$ 0.05	\$ 0.19
Dividends declared per common share	\$ 0.0300	\$ 0.0300	\$ 0.0900	\$ 0.0875
Weighted-average common shares outstanding:				
Basic	27,823	27,367	27,687	27,414
Diluted	28,596	28,268	28,487	28,345
Net income	\$ 2,145	\$ 2,326	\$ 1,369	\$ 5,546
Other comprehensive loss	(349)	(80)	(124)	(73)
Comprehensive income	\$ 1,796	\$ 2,246	\$ 1,245	\$ 5,473

See accompanying Notes to Summary Consolidated Financial Statements.

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

	September 30, 2015	December 31, 2014
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 38,497	\$ 33,375
Restricted securities	848	884
Receivables, net	24,443	22,863
Inventories	14,432	12,739
Deferred preservation costs	23,480	25,196
Deferred income taxes	5,729	6,210
Prepaid expenses and other	5,399	4,761
Total current assets	112,828	106,028
<hr/>		
Property and equipment, net	12,036	12,002
Restricted cash	5,000	5,000
Goodwill	11,365	11,365
Patents, net	1,446	1,784
Trademarks and other intangibles, net	17,713	19,496
Deferred income taxes	14,141	15,659
Other	5,452	4,823
Total assets	\$ 179,981	\$ 176,157
<hr/>		
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 4,637	\$ 4,543
Accrued compensation	7,952	5,406
Accrued procurement fees	4,683	4,675
Accrued expenses and other	4,596	5,583
Deferred income	362	420
Total current liabilities	22,230	20,627
<hr/>		
Other	5,858	6,845
Total liabilities	28,088	27,472

Commitments and contingencies				
Shareholders equity:				
Preferred stock		--		--
Common stock (issued shares of 29,719 in 2015 and 29,229 in 2014)		297		292
Additional paid-in capital		141,480		135,227
Retained earnings		21,584		22,768
Accumulated other comprehensive loss		(245)		(121)
Treasury stock at cost (shares of 1,265 in 2015 and 1,101 in 2014)		(11,223)		(9,481)
Total shareholders equity		151,893		148,685
Total liabilities and shareholders equity		\$ 179,981		\$ 176,157

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,	
	2015	2014
	(Unaudited)	
Net cash flows from operating activities:		
Net income	\$ 1,369	\$ 5,546
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	4,539	4,468
Non-cash compensation	3,727	2,736
Gain on sale of Medafor investment	(891)	--
Other non-cash adjustments to income	3,314	(544)
Changes in operating assets and liabilities:		
Receivables	(1,580)	(3,288)
Inventories and deferred preservation costs	(692)	(2,123)
Prepaid expenses and other assets	(1,267)	(3,156)
Accounts payable, accrued expenses, and other liabilities	1,508	(306)
Net cash flows provided by operating activities	10,027	3,333
Net cash flows from investing activities:		
Capital expenditures	(3,186)	(3,225)
Proceeds from sale of Medafor investment	891	--
Other	(508)	(1,582)
Net cash flows used in investing activities	(2,803)	(4,807)
Net cash flows from financing activities:		
Cash dividends paid	(2,553)	(2,452)
Proceeds from exercise of stock options and issuance of common stock	1,408	1,409
Repurchases of common stock	--	(4,584)
Other	(809)	(677)
Net cash flows used in financing activities	(1,954)	(6,304)
Effect of exchange rate changes on cash	(148)	(42)

Increase (decrease) in cash and cash equivalents	5,122	(7,820)
Cash and cash equivalents, beginning of period	33,375	37,643
Cash and cash equivalents, end of period	\$ 38,497	\$ 29,823

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, 2014 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, 2015 and 2014 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, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. 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, 2014.

2. Financial Instruments

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

September 30, 2015	Level 1	Level 2	Level 3	Total
Restricted securities:				
Money market funds	\$ 848	\$ --	\$ --	\$ 848
Total assets	\$ 848	\$ --	\$ --	\$ 848

December 31, 2014	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 18,213	\$ --	\$ --	\$ 18,213
Restricted securities:				
Money market funds	884	--	--	884
Total assets	\$ 19,097	\$ --	\$ --	\$ 19,097

The Company used prices quoted from its investment management companies to determine the Level 1 valuation of its investments in money market funds.

3. Cash Equivalents and Restricted Cash and Securities

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

September 30, 2015	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Restricted cash and securities:			
Cash	\$ 5,000	\$ --	\$ 5,000
Money market funds	848	--	848

December 31, 2014	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	\$ 18,213	\$ --	\$ 18,213
Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	884	--	884

As of September 30, 2015 and December 31, 2014 \$848,000 and \$884,000, respectively, of the Company's money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations. As of September 30, 2015 and December 31, 2014 \$5.0 million of the Company's cash was designated as long-term restricted cash due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation (GE Capital), as discussed in Note 11. This restriction will lapse upon expiration of the credit agreement with GE Capital on September 26, 2019.

There were no gross realized gains or losses on cash equivalents in the three and nine months ended September 30, 2015 and 2014. As of September 30, 2015 \$240,000 of the Company's restricted securities had a maturity date within three months and \$608,000 had a maturity date between three months and one year. As of December 31, 2014 \$622,000 of the Company's restricted securities had a maturity date within three months and \$262,000 had a maturity date between three months and one year. As of September 30, 2015 and December 31, 2014 \$5.0 million of the Company's long-term restricted cash had no maturity date.

4. Distribution Agreements

ProCol Distribution Agreement

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

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

In accordance with the terms of the HJ Agreement, CryoLife made payments to Hancock Jaffe of \$1.7 million during 2014 and \$576,000 in January 2015. In exchange for these payments, CryoLife obtained the right to receive a designated amount of ProCol inventory for resale, a portion of which the Company received in 2014 and 2015. Subsequent to this initial inventory purchase, CryoLife can purchase additional units from Hancock Jaffe at an agreed upon transfer price. The Company began limited distribution of ProCol in the second quarter of 2014. On September 29, 2014 Hancock Jaffe received U.S. Food and Drug Administration (FDA) approval of the Premarket Approval (PMA) Supplement associated with its new manufacturing facility, and the Company began shipping product made in this new facility in the fourth quarter of 2014.

CryoLife made additional payments of \$735,000 in the aggregate during the second and third quarters of 2015. As of September 30, 2015 CryoLife had made a total of \$3.0 million in payments to Hancock Jaffe and had received \$1.2 million in inventory. Therefore, as of September 30, 2015 CryoLife had approximately \$1.8 million in remaining prepayments on its Summary Consolidated Balance Sheet for which inventory had not yet been received. During the second quarter of 2015 CryoLife notified Hancock Jaffe that it was in breach of the HJ Agreement due to, among other things, Hancock Jaffe's failure to timely ship inventory. CryoLife believes Hancock Jaffe remains in breach of the HJ Agreement. CryoLife is currently negotiating with Hancock Jaffe an amendment to the HJ Agreement to, among other things, help ensure a continuing supply of product. If CryoLife is unable to secure full satisfaction or repayment of the amounts owed, the prepayment may become impaired in future periods.

PhotoFix Distribution Agreement

In 2014 CryoLife entered into an exclusive supply and distribution agreement with Genesee Biomedical, Inc. (GBI) to acquire the distribution rights to PhotoFix™, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix has received FDA 510(k) clearance and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure.

The agreement between CryoLife and GBI (the GBI Agreement) has an initial five-year term and is renewable for two one-year periods at CryoLife's option. Under the terms of the GBI Agreement, CryoLife is purchasing PhotoFix inventory for resale at an agreed upon transfer price and has the option, which became effective in March 2015, to acquire the PhotoFix product line from GBI. In January 2015 the Company received its initial shipments and launched its distribution of PhotoFix.

5. Hemisphere Acquisition

Overview

On May 16, 2012 CryoLife acquired Hemisphere, Inc. (Hemisphere) and its HeRO Graft product line, which the Company operated as a wholly owned subsidiary until December 31, 2014 when it was merged into the CryoLife, Inc. parent entity. The HeRO Graft is a proprietary graft-based solution for ESRD hemodialysis patients with limited access options and central venous obstruction.

Contingent Consideration

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

The fair value of the contingent consideration liability was estimated by discounting to present value the contingent payments expected to be made based on a probability-weighted scenario approach. The Company applied a risk-based estimate of the probability of achieving each scenario and then applied a cost-of-debt-based discount rate. This fair value measurement was based on unobservable inputs, including management estimates and assumptions about future revenues, and was, therefore, classified as Level 3 within the fair value hierarchy. The Company remeasured this liability at each reporting date and recorded changes in the fair value of the contingent consideration in other (income) expense on the Company's Consolidated Statements 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. As of December 31, 2014 the Company reviewed the full year revenue performance of the HeRO Graft for 2014 and 2013, and reviewed its 2015 annual budgets, which were updated in the fourth quarter of 2014. As a result of this review, as of December 31, 2014 the Company believed that achievement of the minimum revenue target to trigger payment was remote, and, therefore, estimated the fair value of the contingent consideration to be zero.

The Company recorded a gain of zero in both the three and nine months ended September 30, 2015 and gains of \$196,000 and \$492,000 in the three and nine months ended September 30, 2014, respectively, on the remeasurement of the contingent consideration liability. The gains recorded in the prior year periods were due to changes in the Company's estimates, partially offset by the effect of the passage of time on the fair value measurements. The balance of the contingent consideration liability was zero as of September 30, 2015 and December 31, 2014.

6. ValveXchange

Preferred Stock Investment

In July 2011 the Company purchased shares of series A preferred stock of ValveXchange, Inc. (ValveXchange) for approximately \$3.5 million. ValveXchange was a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic

leaflets. As ValveXchange's stock was not actively traded on any public stock exchange, and as the Company's investment was in preferred stock, the Company initially accounted for this investment using the cost method as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheet.

During the fourth quarter of 2013 the Company reevaluated its investment in ValveXchange preferred stock for impairment. Based on this analysis, the Company believed that its investment in ValveXchange was fully impaired as of December 31, 2013, and the impairment was other than temporary. As of September 30, 2015 and December 31, 2014 the carrying value of the Company's investment in ValveXchange preferred stock was zero.

Loan Agreement

In July 2011 the Company entered into an agreement with ValveXchange, as amended, to make available to ValveXchange up to \$2.0 million in debt financing through a revolving credit facility (the *Loan*). The Loan included various affirmative and negative covenants, including financial covenant requirements, and would have expired on July 30, 2018, unless terminated earlier. Amounts under the Loan earned interest at an 8% annual rate and were secured by substantially all of the tangible and intangible assets of ValveXchange. The Company advanced \$2.0 million to ValveXchange under this loan in 2012.

During the quarter ended December 31, 2014 CryoLife became aware of various factors, including ValveXchange's inability to secure additional funding, its lack of capital to continue basic operations, and the likelihood of impending default on the Loan. In December 2014 CryoLife notified ValveXchange that it was in breach of the Loan, and in January 2015, after ValveXchange failed to cure this breach, CryoLife accelerated the amounts due under the Loan. In January 2015 ValveXchange informed CryoLife management of its intent to file for bankruptcy, which created substantial uncertainty regarding the disposition of CryoLife's claim for amounts it is owed under the Loan. Given these circumstances, CryoLife believed that its Loan became fully impaired in the fourth quarter of 2014. As a result, during the three months ended December 31, 2014 the Company recorded other non-operating expense of \$2.0 million to write-down its long-term note receivable from ValveXchange. ValveXchange was dissolved in June 2015. The net carrying value of the long-term note receivable was zero as of September 30, 2015 and December 31, 2014.

7. Medafor Matters

Investment in Medafor Common Stock

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

On October 1, 2013 C.R. Bard, Inc., a developer, manufacturer, and marketer of medical technologies in the fields of vascular, urology, oncology, and surgical specialty products (*Bard*), and its subsidiaries completed its acquisition of all outstanding shares of Medafor common stock. The Company received an initial payment of approximately \$15.4 million in the fourth quarter of 2013 for its 2.4 million shares of Medafor common stock and received additional payments of \$530,000 in the fourth quarter of 2014 and \$891,000 in April 2015 related to the release of transaction consideration in escrow. Based on information provided by Medafor in its September 24, 2013 Proxy Statement, Bard was required to make additional contingent milestone payments based on the achievement of certain net revenue targets measurable through June 2015.

In September 2015 the Company received a letter from the representative of the former shareholders of Medafor, which stated that net sales were insufficient to trigger payment of additional contingent consideration by Bard. The final release of transaction consideration from escrow is expected to be received in October 2017 and is expected to be nominal. This subsequent payment will be recorded as an additional gain if, and when, received by the Company.

The Company recorded a gain on the sale of Medafor investment of zero and \$891,000 for the three and nine months ended September 30, 2015, respectively, and zero for both the three and nine months ended September 30, 2014.

Legal Action

In April 2014 CryoLife filed a declaratory judgment lawsuit against Bard, and its subsidiaries Davol, Inc. (*Davol*) and Medafor (collectively, *Defendants*), in the U.S. District Court for the District of Delaware (the *District Court*). CryoLife requested that the District Court declare that CryoLife's manufacture, use, offer for sale, and sale of PerClot

in the U.S. does not, and would not, infringe Bard's U.S. Patent No. 6,060,461 (the '461 Patent'). In addition, CryoLife requested that the District Court declare that the claims of the '461 Patent are invalid. CryoLife also requested injunctive relief and an award of attorneys' fees.

The lawsuit against the Defendants followed the receipt by CryoLife of a letter from Medafor in September 2012 stating that PerClot, when introduced in the U.S., would infringe the '461 Patent when used in accordance with the method published in CryoLife's literature and with the instructions for use. CryoLife received FDA 510(k) clearance for the sale of PerClot Topical in April 2014 and began distributing PerClot Topical in August 2014. CryoLife also received IDE approval in March 2014 to begin clinical trials for PerClot in certain surgical indications.

In August 2014 Medafor filed a counterclaim against CryoLife for infringement of the 461 Patent. In September 2014 Medafor filed a motion for a preliminary injunction, asking the District Court to enjoin CryoLife's marketing and sale of PerClot in the U.S. In March 2015 the District Court ruled that CryoLife's declaratory judgment lawsuit against Medafor may proceed but dismissed Bard and Davol from the lawsuit. The District Court also granted Medafor's motion for a preliminary injunction, which prohibits CryoLife from marketing, selling, and distributing PerClot in the U.S. while the litigation proceeds. In March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot in the U.S., including PerClot Topical, in accordance with the District Court's order. In April 2015 CryoLife appealed the District Court's ruling on the preliminary injunction motion to the U.S. Court of Appeals for the Federal Circuit. CryoLife dismissed this appeal in June 2015. The case is proceeding through the discovery phase in the District Court.

8. Inventories and Deferred Preservation Costs

Inventories at September 30, 2015 and December 31, 2014 are comprised of the following (in thousands):

	September 30, 2015	December 31, 2014
Raw materials and supplies	\$ 7,671	\$ 7,942
Work-in-process	985	1,006
Finished goods	5,776	3,791
Total inventories	\$ 14,432	\$ 12,739

Deferred preservation costs at September 30, 2015 and December 31, 2014 are comprised of the following (in thousands):

	September 30, 2015	December 31, 2014
Cardiac tissues	\$ 10,729	\$ 10,875
Vascular tissues	12,751	14,321
Total deferred preservation costs	\$ 23,480	\$ 25,196

9. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of September 30, 2015 and December 31, 2014 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

September 30, 2015	December 31, 2014
-----------------------	----------------------

Edgar Filing: CRYOLIFE INC - Form 10-Q

Goodwill	\$	11,365	\$	11,365
Procurement contracts and agreements		2,013		2,013
Trademarks		858		853

Based on its experience with similar agreements, the Company believes that its acquired procurement contracts and agreements have indefinite useful lives, as the Company expects to continue to renew these contracts for the foreseeable future. The Company believes that its trademarks have indefinite useful lives as the Company currently anticipates that these trademarks will contribute to cash flows of the Company indefinitely.

As of September 30, 2015 and December 31, 2014 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, 2014.

Definite Lived Intangible Assets

As of September 30, 2015 and December 31, 2014 the gross carrying values, accumulated amortization, and approximate amortization period of the Company's definite lived intangible assets are as follows (in thousands):

September 30, 2015	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	\$ 14,020	\$ 4,669	11 - 16 Years
Patents	4,047	2,601	17 Years
Distribution and manufacturing rights and know-how	4,059	1,173	11 - 15 Years
Customer lists and relationships	3,370	994	13 - 17 Years
Non-compete agreement	381	333	10 Years
Other	268	87	3 - 5 Years

December 31, 2014	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	\$ 14,020	\$ 3,815	11 - 16 Years
Patents	4,281	2,497	17 Years
Distribution and manufacturing rights and know-how	4,559	989	11 - 15 Years
Customer lists and relationships	3,370	813	13 - 17 Years
Non-compete agreement	381	305	10 Years
Other	461	239	1 - 5 Years

Amortization Expense

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Amortization expense	\$ 503	\$ 504	\$ 1,520	\$ 1,503

As of September 30, 2015 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2015	2016	2017	2018	2019	2020
Amortization expense	\$ 502	\$ 2,003	\$ 1,950	\$ 1,942	\$ 1,896	\$ 1,722

10. Income Taxes**Income Tax Expense**

Edgar Filing: CRYOLIFE INC - Form 10-Q

The Company's effective income tax rate was approximately 25% and -9% for the three and nine months ended September 30, 2015, respectively, as compared to 21% and 22% for the three and nine months ended September 30, 2014, respectively.

The Company's income tax rate for both the three and nine months ended September 30, 2015 was favorably affected by the reversal of \$794,000 in uncertain tax positions, primarily related to research and development tax credits for which the statute of limitations has expired. This was partially offset by the unfavorable effect of the absence of the domestic production activities deduction, as the Company does not anticipate being eligible for this deduction in 2015. The Company expects that its effective income tax rate in the fourth quarter of 2015 will be higher than that of the third quarter of 2015, as the anticipated reversal of uncertain tax positions in the fourth quarter is expected to be significantly smaller than in the third quarter.

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

examination, reversed \$748,000 in uncertain tax liabilities and tax expense. The Company's income tax rate for the three and nine months ended September 30, 2014 was favorably affected by the reduction of uncertain tax positions and by favorable deductions taken on the Company's 2013 federal tax return, which was filed in the third quarter of 2014.

The Company's income tax rates for the nine months ended September 30, 2015 and 2014 did not include an anticipated benefit from the research and development tax credit, which had not yet been enacted within the respective time periods.

Deferred Income Taxes

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

As of September 30, 2015 the Company maintained a total of \$2.1 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$19.9 million. As of December 31, 2014 the Company had a total of \$2.1 million in valuation allowances against deferred tax assets and a net deferred tax asset of \$21.9 million.

11. Debt

GE Credit Agreement

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

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest, based on the Company's election, at either LIBOR or GE Capital's base rate plus the respective applicable margins. All swing loans will, however, bear interest at the base loan rate. Commitment fees are paid based on the unused portion of the facility. If an event of default occurs, the applicable interest rate will increase by 2.0% per annum. As of September 30, 2015 and December 31, 2014 the aggregate interest rate was 4.75%. As of September 30, 2015 and December 31, 2014 the outstanding balance of the GE Credit Agreement was zero, and the remaining availability was \$20.0 million.

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio and (ii) maintain minimum earnings subject to defined adjustments as of specified dates. The agreement also (i) limits the payment of cash dividends, up to specified maximums and subject to satisfaction of specified conditions, (ii) requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as

defined within the agreement, of at least \$20.0 million, (iii) limits acquisitions or mergers except for certain permitted acquisitions, (iv) sets specified limits on the amount the Company can pay to purchase or redeem CryoLife common stock pursuant to a stock repurchase program and to fund estimated tax liabilities incurred by officers, directors, and employees as a result of awards of stock or stock equivalents, and (v) includes customary conditions on incurring new indebtedness. As of September 30, 2015 the Company was in compliance with the covenants of the GE Credit Agreement.

As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as long-term restricted cash as of September 30, 2015 and December 31, 2014 on the Company's Summary Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement.

Interest Expense

Interest expense was a favorable \$78,000 and \$18,000 for the three and nine months ended September 30, 2015, respectively, due to the reversal of interest on uncertain tax positions as discussed in Note 10 above. Interest expense was \$65,000 and \$110,000 for the three and nine months ended September 30, 2014, respectively. Interest expense in all periods included interest on debt and uncertain tax positions.

12. Commitments and Contingencies

Liability Claims

The Company's estimated unreported loss liability was \$1.5 million as of September 30, 2015 and \$1.4 million as of December 31, 2014. As of September 30, 2015 and December 31, 2014, the related recoverable insurance amounts were \$645,000 and \$600,000, respectively. The Company accrues its estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and records the related recoverable insurance amount as a component of other long-term assets, as appropriate. Further analysis indicated that the liability as of September 30, 2015 could have been estimated to be as high as \$2.8 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreements

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

The employment agreement of the Company's former President, CEO, and Executive Chairman, Mr. Steven G. Anderson, conferred certain benefits on Mr. Anderson upon his retirement or termination of employment in conjunction with certain change in control events. As of December 31, 2014 the Company had \$2.2 million included in its accrued expenses and other current liabilities on the Summary Consolidated Balance Sheet, primarily related to severance payable upon Mr. Anderson's voluntary retirement. Mr. Anderson's employment agreement took effect on January 1, 2013 and would have terminated on December 31, 2016.

On April 9, 2015 Mr. Anderson retired from service as an employee of the Company and Chair of its Board of Directors, and entered into a Separation Agreement (the Agreement) with the Company. In accordance with the Agreement, in addition to the severance benefit discussed above, Mr. Anderson will receive an additional \$400,000 in cash; 25% of the annual bonus he would have been entitled to under his employment agreement, estimated at target payout rates to be approximately \$100,000; reimbursement of a Medicare supplement policy for Mr. Anderson and his spouse for the duration of their lives; accelerated vesting of all outstanding and unvested stock options and awards; and reimbursement of attorneys' fees not to exceed \$20,000. The Company recorded expense of approximately \$1.4 million related to the Agreement in the second quarter of 2015. The acceleration of Mr. Anderson's stock options and awards was effective as of the date of his retirement. As of September 30, 2015 the Company had \$2.7 million, primarily in accrued compensation, on the Summary Consolidated Balance Sheet, representing severance and cash payments of which \$2.4 million was paid in October 2015, six months after Mr. Anderson's retirement. The annual bonus payment is expected to be made in February 2016 at the same time as annual bonus payments, if any, are made

to the Company's officers.

PerClot Technology

On September 28, 2010 the Company entered into a worldwide distribution agreement (the "Distribution Agreement") and a license and manufacturing agreement (the "License Agreement") with Starch Medical, Inc. ("SMI"), for PerClot, a polysaccharide hemostatic agent used in surgery. The Distribution Agreement contains certain minimum purchase requirements and has a term of 15 years. Following U.S. regulatory approval and the start of U.S. manufacturing, CryoLife may terminate the Distribution Agreement and the related requirements to purchase minimum amounts of PerClot manufactured by SMI. Upon termination of the Distribution Agreement, CryoLife would manufacture and sell PerClot pursuant to the License Agreement. The Company would pay royalties to SMI at stated rates on net revenues of products manufactured under the License Agreement.

In April 2014 CryoLife received 510(k) clearance from the FDA to market PerClot Topical in the U.S. PerClot Topical is a version of the Company's PerClot product, which was manufactured by the Company at its headquarters and labeled for use in certain topical indications. CryoLife launched PerClot Topical in August 2014. In March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot, including PerClot Topical, in the U.S. in accordance with the District Court's order discussed in Note 7.

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Management believes that the costs of this clinical trial will be significant in 2015 and 2016. The Company began enrollment in the second quarter of 2015 and currently expects to receive PMA from the FDA in 2018. However, if the Company does not prevail or reach a settlement with respect to the patent litigation discussed in Note 7, the timing of the launch of PerClot in the U.S. may be delayed until early 2019, when the 461 Patent expires.

CryoLife paid \$500,000 to SMI in January 2015 related to the achievement of a contingent milestone. The Company expects to make additional contingent payments to SMI of up to \$1.0 million if certain FDA regulatory and other commercial milestones are achieved.

13. Shareholders' Equity

Common Stock Repurchase

In February 2013 the Company's Board of Directors authorized the purchase of up to \$15.0 million of its common stock through October 31, 2014. During the year ended December 31, 2014 the Company purchased approximately 585,000 shares for an aggregate purchase price of \$5.6 million. These shares were recorded, at cost, as treasury stock on the Company's Summary Consolidated Balance Sheets. In the nine months ended September 30, 2015 the Company did not repurchase any common stock under a repurchase program, and no formal repurchase program was in effect during that period.

Cash Dividends

The Company initiated a quarterly cash dividend of \$0.025 per share of common stock outstanding in the third quarter of 2012 and increased this dividend to \$0.0275 per share in the second quarter of 2013 and \$0.03 per share in the second quarter 2014. The Company paid dividend payments of \$853,000 and \$2.6 million from cash on hand for the three and nine months ended September 30, 2015, respectively, and \$842,000 and \$2.5 million for the three and nine months ended September 30, 2014, respectively. The dividend payments were recorded as a reduction to retained earnings on the Company's Summary Consolidated Balance Sheets.

14. Stock Compensation

Overview

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

Equity Grants

During the nine months ended September 30, 2015 the Compensation Committee of the Company's Board of Directors (the Committee) authorized awards from approved stock incentive plans of RSUs to certain employees and RSAs and PSUs to certain Company officers, which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 405,000 shares and had an aggregate grant date market value of \$4.3 million. The PSUs granted in 2015 represent the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2015 was based on attaining specified levels of adjusted EBITDA, adjusted inventory levels, and trade accounts receivable days sales outstanding, each as defined in the PSU grant documents, for the 2015 calendar year. The Company currently believes that achievement of the performance component is probable, and it will reevaluate this likelihood on a quarterly basis.

During the nine months ended September 30, 2014 the Committee authorized awards from approved stock incentive plans of RSUs to certain employees and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 655,000 shares of common stock and had an aggregate grant date market value of \$6.6 million. The PSUs granted in 2014 represented the right to receive from 50% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2014 was based on attaining specified levels of adjusted EBITDA, as defined in the PSU grant documents, for the 2014 calendar year. The PSUs granted in 2014 earned 50% of the target number of shares.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 328,000 and 562,000 shares to certain Company officers during the nine months ended September 30, 2015 and 2014, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 78,000 and 111,000 shares in the nine months ended September 30, 2015 and 2014, respectively, through the ESPP.

Stock Compensation Expense

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

	Three Months Ended		Nine Months Ended	
	September 30, 2015		September 30, 2015	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	4.75 Years	.50 Years	4.50 Years	.50 Years
Expected stock price volatility	0.45	0.30	0.44	0.34
Dividends	1.24%	1.06%	1.12%	1.06%
Risk-free interest rate	1.49%	0.11%	1.41%	0.12%

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

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,		September 30,	
	2015	2014	2015	2014

RSA, PSA, RSU, and PSU expense	\$ 343	\$ 944	\$ 2,833	\$ 2,357
Stock option and ESPP option expense	289	219	1,084	590
Total stock compensation expense	\$ 632	\$ 1,163	\$ 3,917	\$ 2,947

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, PSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the ESPP. These amounts were recorded as stock compensation expense and were subject to the Company's normal allocation of expenses to inventory costs and deferred preservation costs. The Company capitalized \$79,000 and \$71,000 in the three months ended September 30, 2015 and 2014, respectively, and \$190,000 and \$211,000 in the nine months ended September 30, 2015 and 2014, respectively, of the stock compensation expense into its inventory costs and deferred preservation costs.

As of September 30, 2015 the Company had total unrecognized compensation costs of \$5.2 million related to RSAs, PSAs, RSUs, and PSUs and \$2.1 million related to unvested stock options, before considering the effect of expected forfeitures. As of September 30, 2015 this expense is expected to be recognized over a weighted-average period of 2.1 years for stock options, 1.9 years for PSAs, 1.9 years for RSUs, 1.4 years for RSAs, and 1.0 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):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
Basic income per common share	2015	2014	2015	2014
Net income	\$ 2,145	\$ 2,326	\$ 1,369	\$ 5,546
Net income allocated to participating securities	(44)	(53)	(31)	(112)
Net income allocated to common shareholders	\$ 2,101	\$ 2,273	\$ 1,338	\$ 5,434
Basic weighted-average common shares outstanding	27,823	27,367	27,687	27,414
Basic income per common share	\$ 0.08	\$ 0.08	\$ 0.05	\$ 0.20
Diluted income per common share	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net income	\$ 2,145	\$ 2,326	\$ 1,369	\$ 5,546
Net income allocated to participating securities	(44)	(52)	(32)	(110)
Net income allocated to common shareholders	\$ 2,101	\$ 2,274	\$ 1,337	\$ 5,436
Basic weighted-average common shares outstanding	27,823	27,367	27,687	27,414
Effect of dilutive stock options and awards ^a	773	901	800	931
Diluted weighted-average common shares outstanding	28,596	28,268	28,487	28,345
Diluted income per common share	\$ 0.07	\$ 0.08	\$ 0.05	\$ 0.19

^a The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to income (loss) per common share. Accordingly, stock options to purchase a weighted-average 714,000 and 787,000 shares for the three and nine months ended September 30, 2015, respectively, and 352,000 and 239,000 shares for the three and nine months ended September 30, 2014, respectively, were excluded from the calculation of diluted weighted-average common shares

outstanding.

16. Segment Information

The Company has two reportable segments organized according to its products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue[®] Surgical Adhesive, BioFoam[®] Surgical Matrix, PerClot, CardioGenesis cardiac laser therapy, HeRO Graft, ProCol, and PhotoFix. 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, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Revenues:				
Medical devices	\$ 19,859	\$ 20,405	\$ 59,168	\$ 60,210
Preservation services	16,844	16,664	46,892	47,280
Total revenues	36,703	37,069	106,060	107,490
Cost of products and preservation services:				
Medical devices	4,278	4,167	13,555	12,099
Preservation services	9,443	9,103	28,302	26,735
Total cost of products and preservation services	13,721	13,270	41,857	38,834
Gross margin:				
Medical devices	15,581	16,238	45,613	48,111
Preservation services	7,401	7,561	18,590	20,545
Total gross margin	\$ 22,982	\$ 23,799	\$ 64,203	\$ 68,656

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

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Products:				
BioGlue and BioFoam	\$ 14,283	\$ 15,116	\$ 42,844	\$ 45,745
PerClot	975	998	2,987	3,057
CardioGenesis cardiac laser therapy	1,852	2,306	5,932	6,074
HeRO Graft	1,934	1,984	5,538	5,304
ProCol	371	1	908	30
PhotoFix	444	--	959	--
Total products	19,859	20,405	59,168	60,210
Preservation services:				
Cardiac tissue	7,537	8,337	21,089	21,981
Vascular tissue	9,307	8,327	25,803	25,299

Total preservation services	16,844	16,664	46,892	47,280
Total revenues	\$ 36,703	\$ 37,069	\$ 106,060	\$ 107,490

17. Direct Sales in France

In June 2015 CryoLife signed a Business Transfer Agreement with its French distribution partner to facilitate an orderly transition of the Company to a direct sales model in France. In October 2015 the Company completed the acquisition of a portion of the business of its French distribution partner. The Company acquired in the transaction certain intangible assets, including commercial and business information, assignment of contracts, and a non-compete agreement with its former French distribution partner for a purchase price of 1.2 million Euros. During the third quarter of 2015 the Company established a wholly owned subsidiary in France, CryoLife France SAS, and certain members of the distributor's sales team who were responsible for selling the Company's products in France became employees of the Company's newly created subsidiary.

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, is a leader in medical device manufacturing and distribution and in the processing and distribution of implantable human tissues for use in cardiac and vascular surgeries. CryoLife's surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and PerCutan absorbable powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI). CryoLife's CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used for the treatment of coronary artery disease in patients with severe angina. CryoLife markets the Hemodialysis Reliable Outflow Graft (HeRO® Graft) and is the exclusive distributor of ProCol® Vascular Bioprosthesis (ProCol) for Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). Both HeRO Graft and ProCol are solutions for end-stage renal disease (ESRD) in certain hemodialysis patients. CryoLife is the exclusive distributor of PhotoFix™ for Genesee Biomedical, Inc. (GBI). PhotoFix is a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both of which are processed using CryoLife's proprietary SynerGraft® technology.

The Company reported third quarter revenues of \$36.7 million, a 1% decrease from the quarter ended September 30, 2014. This decrease was primarily due to a decrease in BioGlue revenues and cardiac tissue preservation services revenues, which was largely offset by revenue increases in vascular tissue preservation services and in the Company's newly distributed products, ProCol and PhotoFix. The Company's vascular preservation services reported an all-time quarterly record, reaching \$9.3 million in revenues. The Company's revenues were also affected by the unfavorable impact of foreign currency exchange rates during the first nine months of 2015. See the Results of Operations section below for additional analysis of the three and nine months ended September 30, 2015.

Recent Events

Direct Sales in France

In June 2015 CryoLife signed a Business Transfer Agreement with its French distribution partner to facilitate an orderly transition of the Company to a direct sales model in France. In October 2015 the Company completed the acquisition of a portion of the business of its French distribution partner. The Company acquired in the transaction certain intangible assets, including commercial and business information, assignment of contracts, and a non-compete agreement with its former French distribution partner for a purchase price of 1.2 million Euros. During the third quarter of 2015, the Company established a wholly owned subsidiary in France, CryoLife France SAS, and certain members of the distributor's sales team who were responsible for selling the Company's products in France became employees of the Company's newly created subsidiary.

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, 2014. 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, 2015 in any of its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2014.

New Accounting Pronouncements

In May 2014 the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. On July 9, 2015, the FASB approved the deferral of the effective date of ASU 2014-09 by one year. The new standard is effective for annual and interim reporting periods beginning after December 15, 2017, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2014-09 to have a material impact on its financial position, results of operations, or cash flows.

In July 2015 FASB issued ASU No. 2015-11, *Inventory - Simplifying the Measurement of Inventory*, which requires that inventory be measured at the lower of cost and net realizable value. Prior to the issuance of the new guidance, inventory was measured at the lower of cost or market. Replacing the concept of market with the single measurement of net realizable value is intended to create efficiencies for preparers. Inventory measured using the last-in, first-out (LIFO) method and the retail inventory method are not impacted by the new guidance. The ASU becomes effective for fiscal years beginning after December 15, 2016, including interim periods with those fiscal years and early application is permitted. The Company is evaluating the effect that ASU 2015-11 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2015-11 to have a material impact on its financial position, results of operations, or cash flows.

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

	Revenues for the				Revenues as a Percentage of	
	Three Months Ended				Total Revenues for the	
	September 30,				Three Months Ended	
	2015		2014		September 30,	2014
Products:						
BioGlue and BioFoam	\$	14,283	\$	15,116	39%	41%
PerClot		975		998	3%	3%
CardioGenesis cardiac laser therapy		1,852		2,306	5%	6%
HeRO Graft		1,934		1,984	5%	5%
ProCol		371		1	1%	--%
PhotoFix		444		--	1%	--%
Total products		19,859		20,405	54%	55%
Preservation services:						
Cardiac tissue		7,537		8,337	21%	23%
Vascular tissue		9,307		8,327	25%	22%
Total preservation services		16,844		16,664	46%	45%
Total	\$	36,703	\$	37,069	100%	100%

	Revenues for the				Revenues as a	
	Nine Months Ended				Percentage of	
	September 30,				Total Revenues for the	
	2015		2014		Nine Months Ended	September 30,
Products:						
BioGlue and BioFoam	\$	42,844	\$	45,745	40%	42%
PerClot		2,987		3,057	3%	3%

Edgar Filing: CRYOLIFE INC - Form 10-Q

CardioGenesis cardiac laser therapy	5,932	6,074	6%	6%
HeRO Graft	5,538	5,304	5%	5%
ProCol	908	30	1%	--%
PhotoFix	959	--	1%	--%
Total products	59,168	60,210	56%	56%
Preservation services:				
Cardiac tissue	21,089	21,981	20%	20%
Vascular tissue	25,803	25,299	24%	24%
Total preservation services	46,892	47,280	44%	44%
Total	\$ 106,060	\$ 107,490	100%	100%

Revenues decreased 1% for both the three and nine months ended September 30, 2015, as compared to the three and nine months ended September 30, 2014, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and nine months ended September 30, 2015 is presented below.

Products

Revenues from products decreased 3% and 2% for the three and nine months ended September 30, 2015, respectively, as compared to the three and nine months ended September 30, 2014, respectively. The decrease in BioGlue revenues during these periods was partially offset by increases in the Company's newest products ProCol and PhotoFix. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot; CardioGenesis cardiac laser therapy; HeRO Graft; and ProCol and PhotoFix 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. During the first nine months of 2015, the U.S. Dollar strengthened materially, as compared to the British Pound and Euro and, as a result, the Company's revenues denominated in these currencies decreased when translated into U.S. Dollars. Any further change in these exchange rates could have a material, adverse effect on the Company's revenues denominated in these currencies. Additionally, the Company's sales to many distributors around the world are denominated in U.S. Dollars, and, although these sales are not directly impacted by the strong U.S. Dollar, the Company believes that its distributors may be delaying or reducing purchases of products in U.S. Dollars due to the relative price of these goods in their local currencies. The Company expects that the effects of the strong U.S. Dollar will continue to unfavorably impact product revenues for the remainder of 2015 and into 2016.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, decreased 6% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. This decrease was primarily due to a 6% decrease in the volume of milliliters sold, which decreased revenues by 5%, and the unfavorable effect of foreign currency exchange, which decreased revenues by 2%, partially offset by an increase in average sales prices, which increased revenues by 1%.

Revenues from the sale of surgical sealants decreased 6% for the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014. This decrease was primarily due to a 6% decrease in the volume of milliliters sold, which decreased revenues by 6%, and the unfavorable effect of foreign currency exchange, which decreased revenues by 1%, partially offset by an increase in average sales prices, which increased revenues by 1%.

The decrease in sales volume of surgical sealants for the three and nine months ended September 30, 2015 was primarily due to a lack of shipments of BioGlue to the Company's French distributor in 2015, as the Company was in the process of transitioning this market from a distributor to a direct sales model effective October 1, 2015 and due to a reduction in shipments to the Company's distributor in Brazil, as a result of factors such as economic instability and local currency devaluation in Brazil. To a lesser extent the decrease in volume is due to a decrease in sales in domestic markets primarily due to declining procedure volume, as doctors are performing more minimally invasive procedures, and hospitals seeking to control costs by reducing spending on consumable items such as BioGlue.

The Company believes that the expanded BioGlue indication approved in July 2015 in Japan could begin to have a favorable impact on BioGlue revenues by the end of 2015. Management is currently seeking regulatory approval for BioGlue in China and, if successful, believes this will provide additional international growth opportunity for BioGlue in future years.

Domestic revenues accounted for 59% and 60% of total BioGlue revenues for the three and nine months ended September 30, 2015, respectively, and 56% of total BioGlue revenues for both the three and nine months ended September 30, 2014. BioFoam sales accounted for less than 1% of surgical sealant sales for each of the three and nine months ended September 30, 2015 and 2014. BioFoam is approved for sale in certain international markets.

PerClot

Revenues from the sale of PerClot decreased 2% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. This decrease was primarily due to a decrease in average selling prices, which decreased revenues by 8%, and the unfavorable effect of foreign currency exchange, which decreased revenues by 7%, largely offset by a 13% increase in revenues due to an increase in volume.

Revenues from the sale of PerClot decreased 2% for the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014. This decrease was primarily due to the unfavorable effect of foreign currency exchange, which decreased revenues 8%, and a decrease in average selling prices, which decreased revenues by 4%, largely offset by a 10% increase in revenues due to an increase in volume.

Revenues during these periods were largely for sales in certain international markets, as PerClot was only distributed domestically from August 2014 to March 2015 as discussed in Note 7 of the Notes to Summary Consolidated Financial Statements. The decrease in average selling prices for the three and nine months ended September 30, 2015 was primarily due to price reductions to certain distributors in Europe, as a result of pricing pressures from competitive products and to offset the relatively higher price of PerClot due to the strengthening of the U.S. Dollar. The effect of foreign exchange rate changes

discussed above had a larger impact on the Company's PerClot revenues, as a larger percentage of these revenues are denominated in foreign currencies than revenues from the Company's other products. The volume increase for the three and nine months ended September 30, 2015 was primarily due to sales increases in the Company's direct markets in Europe, largely for use in gynecology procedures. The revenue increase for the nine months ended September 30, 2015 was also due to increases in the first quarter of 2015 in sales in the U.S. and Latin America.

The Company expects that overall PerClot revenues in 2015 will be comparable to 2014; however, revenues may show some variability from quarter to quarter.

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Management believes that the costs of this clinical trial will be significant in 2015 and 2016. The Company began enrollment in the second quarter of 2015 and currently expects to receive Premarket Approval (PMA) from the FDA in 2018. However, if the Company does not prevail or reach a settlement with respect to the patent litigation as discussed in Note 7 of the Notes to Summary Consolidated Financial Statements , the timing of the launch of PerClot in the U.S. may be delayed until early 2019, when C.R. Bard, Inc.'s (Bard) related patent expires.

CardioGenesis Cardiac Laser Therapy

Revenues from the Company's CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from cardiac laser therapy decreased 20% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. Revenues from the sale of laser consoles were zero and \$87,000 for the three months ended September 30, 2015 and 2014, respectively. Revenues from the sale of handpieces decreased 17% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. This decrease was primarily due to a 20% decrease in unit shipments of handpieces, which decreased revenues by 20%, partially offset by an increase in average sales prices, which increased revenues by 3%.

Revenues from cardiac laser therapy decreased 2% for the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014. Revenues from the sale of laser consoles were \$69,000 and \$144,000 for the nine months ended September 30, 2015 and 2014, respectively. Revenues from the sale of handpieces decreased 1% for the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014. This decrease was primarily due to a 2% decrease in unit shipments of handpieces, which decreased revenues by 2%, partially offset by an increase in average sales prices, which increased revenues by 1%.

The decrease in handpiece revenues for the three and nine months ended September 30, 2015 was primarily due to a reduction in procedure volume, which can vary from quarter to quarter due to physician case volume and patient-specific factors, which can determine whether cardiac laser therapy can be used adjunctively with cardiac bypass surgery. For the nine months ended September 30, 2015 this decrease was largely offset by an increase in handpiece revenues in the first quarter of 2015, primarily due to the unusually low handpiece revenues in the first quarter of 2014, as a result of the slower than anticipated adoption of a new handpiece design, which was rolled out in the second half of 2013 and early 2014.

The Company expects that overall cardiac laser therapy revenues will decrease slightly in the fourth quarter of 2015 as compared to the fourth quarter of 2014, due to decreasing handpiece usage. Revenues from laser console sales are difficult to predict as laser sales can vary significantly from quarter to quarter due to the long lead time required to generate sales of capital equipment.

HeRO Graft

Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. HeRO Grafts are distributed in domestic and certain international markets as a solution for ESRD in hemodialysis patients. HeRO Graft revenues decreased 3% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. This decrease was primarily due to a 4% decrease in number of kits sold, which decreased revenues by 5%, and by the unfavorable effect of foreign currency exchange, which decreased revenues by 1%, partially offset by an increase in average sales prices, which increased revenues by 3%.

HeRO Graft revenues increased 4% for the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014. This increase was primarily due to a 4% increase in number of kits sold, which increased revenues by 3% and an increase in average sales prices, which increased revenues by 2%, partially offset by the unfavorable effect of foreign currency exchange, which decreased revenues by 1%.

The decrease in HeRO Graft volume for the three months ended September 30, 2015 was primarily due to a decrease in the volume of kits sold in domestic markets due to the timing of surgical cases. The increase in HeRO Graft volume for the nine

months ended September 30, 2015 was primarily due to an increase in the volume of kits sold in international markets as a result of an increase in procedure volume and an increase in the number of implanting physicians, partially offset by a decrease in domestic sales volume for the three months ended September 30, 2015.

Management currently expects that overall HeRO Graft revenues will increase slightly in 2015, as compared to 2014. Although HeRO Graft revenues are subject to variability quarter to quarter due to the timing of surgical cases, the Company believes that this variability will continue to decrease as the Company broadens its base of implanting physicians.

ProCol and PhotoFix

In 2014 CryoLife acquired the exclusive worldwide distribution rights from Hancock Jaffe for ProCol, a biological graft derived from a bovine mesenteric vein. ProCol is distributed in the U.S. to provide vascular access for ESRD hemodialysis patients. The Company began limited distribution of ProCol in the second quarter of 2014 and began its full U.S. launch in the fourth quarter of 2014.

In 2014 CryoLife acquired the distribution rights from GBI for PhotoFix, a bovine pericardial patch. PhotoFix is distributed in the U.S. and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure. The Company launched its distribution of PhotoFix in the first quarter of 2015.

Preservation Services

Revenues from preservation services increased 1% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. Revenues from preservation services decreased 1% for the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014. A detailed discussion of the changes in cardiac and vascular preservation services revenues is presented below.

During 2014 the Company made significant changes to various tissue processing and quality procedures, which resulted in a decrease in tissue processing throughput and an increase in the Company's cost of processing tissues. Preservation services revenues and costs were negatively impacted during 2014 due to these factors. These factors continued to impact revenues and costs in the first nine months of 2015 as the Company continued to ship tissues that were processed in 2014. The Company continues to review and modify its procedures as part of its ongoing compliance efforts and in an effort to improve tissue processing throughput and reduce costs. These efforts have begun to increase tissue availability, particularly vascular tissue availability as discussed further below, and have begun to reduce costs.

Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and nine months ended September 30, 2015.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, decreased 10% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. This decrease was primarily due to a 16% decrease in unit shipments of cardiac tissues, which decreased revenues by 14%, partially offset by an increase in average service fees, which increased revenues by 4%.

Revenues from cardiac preservation services decreased 4% for the nine months ended September 30, 2015, as compared to the nine months ended September 30, 2014. This decrease was primarily due to an 11% decrease in unit shipments of cardiac tissues, which decreased revenues by 8%, partially offset by an increase in average service fees, which increased revenues by 4%.

The decrease in cardiac volume for the three and nine months ended September 30, 2015 was primarily due to a decrease in the volume of pulmonary valve and patch shipments. This decrease in cardiac tissue shipments was due to the timing of tissue releases as compared to the prior year periods, which were unfavorably impacted by reduced tissue availability as discussed above.

The increase in average service fees for the three and nine months ended September 30, 2015 was primarily due to list fee increases in domestic markets that took effect in July 2015 and 2014 and the routine renegotiation of pricing contracts with certain customers.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 61% and 64% of total cardiac preservation services revenues for the three and nine months ended September 30, 2015, respectively, and 69% and 64% of total cardiac preservation services revenues for the three and nine months ended September 30, 2014, respectively.

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

The Company expects that cardiac preservation services revenues for the full year 2015 will decrease slightly as compared to revenues in 2014.

Vascular Preservation Services

Revenues from vascular preservation services increased 12% for the three months ended September 30, 2015, as compared to the three months ended September 30, 2014. This increase was primarily due to a 5% increase in unit shipments of vascular tissues, which increased revenues by 10% and an increase in average service fees, which increased revenues by 2%.

Revenues from vascular preservation services increased 2% for the nine months ended September 30, 2015, as compared to revenues for the nine months ended September 30, 2014. This increase was primarily due to an increase in average service fees, which increased revenues by 5%, 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, 2015 was primarily due to list fee increases in domestic markets that took effect in July 2015 and 2014, fee differences due to physical characteristics of vascular tissues, and the routine renegotiation of pricing contracts with certain customers.

The increase in volume for the three months ended September 30, 2015 was primarily due to increases in shipments of saphenous veins as a result of increased tissue availability, as discussed above. The decrease in volume for the nine months ended September 30, 2015 was primarily due to decreases in shipments of saphenous veins in the first quarter of 2015. The decrease in unit shipments of veins was primarily due to the timing of tissue releases as compared to the prior year periods, which were unfavorably impacted by reduced tissue availability as discussed above, and due to increasing competition in the vascular tissue market.

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

The Company expects that vascular preservation services revenues will increase for the full year 2015, as compared to 2014.

Cost of Products and Preservation Services

Cost of Products

Three Months Ended

Nine Months Ended

	September 30,		September 30,	
	2015	2014	2015	2014
Cost of products	\$ 4,278	\$ 4,167	\$ 13,555	\$ 12,099

Cost of products increased 3% and 12% for the three and nine months ended September 30, 2015, respectively, as compared to the three and nine months ended September 30, 2014, respectively. Cost of products in 2015 and 2014 includes costs related to BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Grafts, and ProCol. Cost of products in 2015 also includes costs related to PhotoFix.

The increase in cost of products in the three and nine months ended September 30, 2015 was primarily due to sales of the Company's new distributed products, PhotoFix and ProCol, partially offset by a decrease in unit sales of BioGlue and the per unit cost to manufacture BioGlue. The increase in cost of products in the nine months ended September 30, 2015 was also affected by the write-down of PerClot inventory manufactured for the U.S. market following the Company's cessation of marketing, sales, and distribution of PerClot in the U.S.

Cost of Preservation Services

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Cost of preservation services	\$ 9,443	\$ 9,103	\$ 28,302	\$ 26,735

Cost of preservation services increased 4% and 6% for the three and nine months ended September 30, 2015, respectively, as compared to the three and nine months ended September 30, 2014, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services increased in the three and nine months ended September 30, 2015 primarily due to an increase in the per unit cost of processing tissues, as a result of lower processing throughput of tissues, increased compliance and personnel costs, and an increase in the cost of materials, as discussed in *Preservation Services* above. This was partially offset by a decrease in the unit shipments of cardiac tissue for the three months ended September 30, 2015 and cardiac and vascular tissue for the nine months ended September 30, 2015. The Company expects that the per unit cost of processing tissues will decrease slightly in the fourth quarter of 2015 when compared to the fourth quarter of 2014, as the Company begins to realize the benefit of its 2015 processing improvements and increased tissue throughput.

Gross Margin

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Gross margin	\$ 22,982	\$ 23,799	\$ 64,203	\$ 68,656
Gross margin as a percentage of total revenues	63%	64%	61%	64%

Gross margin decreased 3% and 6% for the three and nine months ended September 30, 2015, respectively, as compared to the three and nine months ended September 30, 2014, respectively. Gross margin as a percentage of total revenues in the three and nine months ended September 30, 2015 decreased, as compared to the three and nine months ended September 30, 2014, respectively. These decreases were primarily due to an increase in the per unit cost of processing tissues, as discussed above, and a change in the tissue and product mix, as revenues decreased for the Company's higher margin BioGlue product and increased for some of the Company's lower margin products. The gross margin and gross margin as a percentage of total revenues for the nine months ended September 30, 2015 also decreased due to the write-down of PerClot inventory, as discussed above.

Operating Expenses**General, Administrative, and Marketing Expenses**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
General, administrative, and marketing expenses	\$ 17,494	\$ 18,882	\$ 55,790	\$ 55,116
General, administrative, and marketing expenses as a percentage of total revenues	48%	51%	53%	51%

General, administrative, and marketing expenses decreased 7% and increased 1% for the three and nine months ended September 30, 2015, respectively, as compared to the three and nine months ended September 30, 2014, respectively.

General, administrative, and marketing expenses for the three and nine months ended September 30, 2015 included severance and termination benefits of approximately \$1.1 million and \$2.9 million, respectively, related to one-time expenses associated with certain employee departures, including the retirement of Mr. Anderson, the Company's former President, Chief Executive Officer (CEO), and Executive Chairman, in April 2015. The decrease in expenses for the three months ended September 30, 2015 was due to a reduction in salary, commissions, and related expenses due to open positions, and the reduction in stock compensation expense related to forfeited stock options and awards, partially offset by an increase in severance and termination benefits, as discussed above, and increased costs related to business development activities. The increase in expenses for the nine months ended September 30, 2015 was due to the increased expenses noted above as well as the impairment of a PerClot Topical intangible asset and higher legal fees related to the litigation with Medafor, Inc. (Medafor). See Part II, Item 1, Legal Proceedings for discussion of the Company's litigation with Medafor.

Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Research and development expenses	\$ 2,960	\$ 1,902	\$ 7,896	\$ 6,607
Research and development expenses as a percentage of total revenues	8%	5%	7%	6%

Research and development expenses increased 56% and 20% for the three and nine months ended September 30, 2015, respectively, as compared to the three and nine months ended September 30, 2014, respectively. Research and development spending in these periods was primarily focused on clinical work with respect to PerClot, the Company's tissue processing, and BioGlue and BioFoam. The Company expects that research and development spending will increase materially for the full year of 2015, as compared to the full year of 2014, due to spending on the PerClot clinical study.

Gain on Sale of Medafor Investment

On October 1, 2013 Bard completed its acquisition of all outstanding shares of Medafor common stock. The gain on sale of Medafor investment was zero and \$891,000 for the three and nine months ended September 30, 2015, respectively, and zero for both the three and nine months ended September 30, 2014. The gain on the sale of Medafor investment in 2015 represents additional consideration received by the Company in April 2015 related to the release of transaction consideration from escrow. Based on a September 2015 letter from the representative of Medafor's former shareholders, the Company does not anticipate recording any additional gain on sale of Medafor Investment in the fourth quarter of 2015 or in 2016. The final release of funds from escrow is expected to be received in October 2017 and is expected to be nominal.

Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Income before income taxes	\$ 2,858	\$ 2,947	\$ 1,251	\$ 7,078
Income tax expense (benefit)	713	621	(118)	1,532
Net income	\$ 2,145	\$ 2,326	\$ 1,369	\$ 5,546
Diluted income per common share	\$ 0.07	\$ 0.08	\$ 0.05	\$ 0.19
Diluted weighted-average common shares outstanding	28,596	28,268	28,487	28,345

Income before income taxes decreased 3% and 82% for the three and nine months ended September 30, 2015, respectively, as compared to the three and nine months ended September 30, 2014, respectively. The decrease in

income before income taxes for the three and nine months ended September 30, 2015 was due to a decrease in gross margins, and for the nine months ended September 30, 2015 an increase in operating expenses, as discussed above.

The Company's effective income tax rate was approximately 25% and -9% for the three and nine months ended September 30, 2015, respectively, as compared to 21% and 22% for the three and nine months ended September 30, 2014, respectively.

The Company's income tax rate for both the three and nine months ended September 30, 2015 was favorably affected by the reversal of \$794,000 in uncertain tax positions, primarily related to research and development tax credits for which the statute of limitations has expired. This was partially offset by the unfavorable effect of the absence of the domestic production activities deduction, as the Company does not anticipate being eligible for this deduction in 2015. The Company expects that its effective income tax rate in the fourth quarter of 2015 will be higher than that of the third quarter of 2015, as the anticipated reversal of uncertain tax positions in the fourth quarter is expected to be significantly smaller than in the third quarter.

In June 2014 the Internal Revenue Service completed a limited scope examination of certain of the Company's federal income tax returns. At the resolution of this examination, the Company reevaluated its liabilities for uncertain tax positions, primarily related to its research and development tax credits and credit carryforwards, and, based on revised estimates and the settlement of the examination, reversed \$748,000 in uncertain tax liabilities and tax expense. The Company's income tax rate for the three and nine months ended September 30, 2014 was favorably affected by the reduction of uncertain tax positions and by favorable deductions taken on the Company's 2013 federal tax return, which was filed in the third quarter of 2014.

The Company's income tax rates for the nine months ended September 30, 2015 and 2014 did not include an anticipated benefit from the research and development tax credit, which had not yet been enacted within the respective time periods.

Net income and diluted income per common share decreased for the three and nine months ended September 30, 2015, as compared to the three and nine months ended September 30, 2014, respectively, primarily due to the decrease in income before income taxes, as discussed above.

Diluted income per common share could be affected in future periods by changes in the Company's common stock outstanding.

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 seasons in Europe and the U.S. The Company believes that demand for BioGlue in Japan may continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by the slower summer holiday season in Japan.

The Company does not believe the demand for CardioGenesis cardiac laser therapy or HeRO Grafts is seasonal, as the Company's data does not indicate a significant trend.

The Company is uncertain whether the demand for PerClot, ProCol, or PhotoFix will be seasonal, as these products have not fully penetrated many markets and, therefore, the nature of any seasonal trends may be obscured.

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

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

Liquidity and Capital Resources

Net Working Capital

At September 30, 2015 net working capital (current assets of \$112.8 million less current liabilities of \$22.2 million) was \$90.6 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of \$85.4 million and a current ratio of 5 to 1 at December 31, 2014.

Overall Liquidity and Capital Resources

The Company's largest cash requirements for the nine months ended September 30, 2015 were capital expenditures for facilities and equipment 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.

The Company believes that its cash from operations and existing cash and cash equivalents will enable the Company to meet its current operational liquidity needs for at least the next twelve months. The Company's future cash requirements are expected to include cash to fund business development activities, to fund the PerClot clinical trial, to fund the litigation against Medafor, to fund cash dividends to common shareholders, to fund additional research and development expenditures, for general working capital needs, for capital expenditures, to pay severance and post-employment benefits, and for other corporate purposes. These items individually or collectively may have a significant effect on the Company's cash flows during 2015. The Company may seek additional borrowing capacity or financing, pursuant to future shelf registration statements or privately, for general corporate purposes or to fund other future cash requirements. If the Company undertakes significant business development activity in 2015, this would likely require the Company to draw down monies under its credit agreement, discussed below, obtain additional debt financing, and/or issue or sell additional equities, either privately or in registered offerings.

Significant Sources and Uses of Liquidity

On September 26, 2014 CryoLife amended and restated its credit agreement with General Electric Capital Corporation (GE Capital), extending the expiration date and amending other terms, which are discussed further below. CryoLife s amended and restated credit agreement with GE Capital (the GE Credit Agreement) provides revolving credit for working capital, acquisitions, and general corporate purposes. The GE Credit Agreement provides borrowing capacity of \$20.0 million (including a letter of credit subfacility and a swingline subfacility) and expires on September 26, 2019. The commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. The GE Credit Agreement also permits CryoLife to request a term loan in an aggregate amount of up to \$25.0 million to finance or refinance the purchase price of a permitted acquisition. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company s liquidity needs during the term of the GE Credit Agreement and, as such, have been recorded as long-term restricted cash on the Company s Summary Consolidated Balance Sheets. Also, the GE Credit Agreement requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined in the agreement, of at least \$20.0 million. As of September 30, 2015 the outstanding balance under the GE Credit Agreement was zero and \$20.0 million was available for borrowing.

On October 1, 2013 Bard completed its previously announced acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately \$15.4 million in the fourth quarter of 2013 for its 2.4 million shares of Medafor common stock and received additional payments of \$530,000 in the fourth quarter of 2014 and \$891,000 in April 2015 related to the release of funds in escrow. In September 2015 the Company received a letter from Medafor s shareholder representative, indicating that net sales for the period were insufficient to trigger payment of additional contingent consideration by Bard. The final release of funds from escrow is expected to be received in October 2017 and is expected to be nominal. This subsequent payment will be recorded as an additional gain if, and when, received by the Company.

The Company is conducting its pivotal clinical trial to gain approval in the U.S. to commercialize PerClot for surgical indications. Management believes that the costs of this clinical trial will be significant in 2015 and 2016. The Company began enrollment in the second quarter of 2015 and currently expects to receive PMA from the FDA during 2018. However, even if the Company secures PMA by 2018, if the Company does not prevail or reach a settlement with respect to the Medafor patent litigation, as discussed in Note 7 of the Notes to Summary Consolidated Financial Statements , the timing of the launch of PerClot in the U.S. may be delayed until early 2019, when C.R. Bard, Inc. s (Bard) related patent expires.

On April 9, 2015 Mr. Anderson retired from service as an employee of the Company and Chair of its Board of Directors. The Company made a payment of approximately \$2.4 million in cash severance and compensation payments to Mr. Anderson in October 2015, six months after his retirement. Additionally, a bonus payment, estimated at target payout rates to be approximately \$100,000, is expected to be made in February 2016 at the same time as annual bonus payments, if any, are made to the Company s officers.

In October 2015 the Company completed the acquisition of a portion of the business of its French distribution partner. The Company acquired in the transaction certain intangible assets, including commercial and business information, assignment of contracts, and a non-compete agreement with its former French distribution partner for a purchase price of 1.2 million Euros.

The Company acquired net operating loss carryforwards from its acquisitions of Hemosphere, Inc. (Hemosphere) and Cardiogenesis Corporation that the Company believes will reduce required cash payments for federal income taxes by approximately \$1.5 million for the 2015 tax year.

As of September 30, 2015 approximately 9% of the Company's cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was \$10.0 million for the nine months ended September 30, 2015, as compared \$3.3 million for the nine months ended September 30, 2014. The increase in net cash provided is primarily due to a large cash requirement for working capital needs in the nine months ended September 30, 2014 that was not experienced in the nine months ended September 30, 2015.

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, items classified as investing and financing cash flows, and for changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2015 these non-cash items included a favorable \$4.5 million in depreciation and amortization expenses, \$3.7 million in non-cash compensation and \$2.0 million in deferred income taxes.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2015 these changes included unfavorable adjustments of \$1.6 million due to the timing difference between recording receivables and the receipt of cash and \$1.3 million in prepaid expenses and other assets, for which payments have already been made and a favorable adjustment of \$1.5 million due to timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the actual payment of cash.

Net Cash Flows from Investing Activities

Net cash used in investing activities was \$2.8 million for the nine months ended September 30, 2015, as compared to \$4.8 million for the nine months ended September 30, 2014. The current year cash used was primarily due to \$3.2 million in capital expenditures.

Net Cash Flows from Financing Activities

Net cash used in financing activities was \$2.0 million for the nine months ended September 30, 2015, as compared to \$6.3 million for the nine months ended September 30, 2014. The current year cash used was primarily due to \$2.6 million in cash dividends paid.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of September 30, 2015 were as follows (in thousands):

	Total	Remainder of 2015	2016	2017	2018	2019	Thereafter
Operating leases	\$ 25,046	\$ 574	\$ 3,457	\$ 3,529	\$ 3,516	\$ 3,462	\$ 10,508
Purchase commitments	5,452	2,340	1,560	1,526	26	--	--
Compensation payments	2,385	2,385	--	--	--	--	--
Research obligations	1,233	682	385	166	--	--	--
Contingent payments	1,000	--	--	--	1,000	--	--
Total contractual obligations	\$ 35,116	\$ 5,981	\$ 5,402	\$ 5,221	\$ 4,542	\$ 3,462	\$ 10,508

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. These minimum purchases are included only through 2017, based on the assumption that the Company will receive FDA approval for PerClot during 2018. Upon FDA approval of PerClot, the Company may terminate its minimum purchase requirements, which the Company expects to do. However, if the Company does not terminate this provision, it would have minimum purchase obligations of up to \$1.75 million per year through 2025. The Company's purchase commitments also include obligations to purchase intangible assets from the Company's French distribution partner and obligations from agreements with suppliers.

The Company's compensation payment obligations represent estimated payments for post-employment benefits for Mr. Anderson, the Company's former President, CEO, and Executive Chairman, primarily consisting of cash severance. The timing of Mr. Anderson's post-employment benefits, for purposes of the schedule above, is based on the payment of this benefit, which occurred in October 2015.

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

The contingent payment obligation includes payments that the Company will make to SMI for PerClot, if certain FDA regulatory approvals and other commercial milestones are achieved.

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, as no assessments have been made for specific litigation, (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be \$873,000, as no specific assessments have been made by any taxing authorities, and (iii) contingent payment obligations of up to \$4.5 million related to the Company's acquisition of Hemosphere, as the Company does not currently anticipate these contingent payments will be triggered.

Capital Expenditures

Capital expenditures were \$3.2 million for both the nine months ended September 30, 2015 and 2014. Capital expenditures in the nine months ended September 30, 2015 were primarily related to the routine purchases of computer software; manufacturing and tissue processing equipment, including support for the Company's HeRO Graft and PerClot product lines; computer and office equipment; CardioGenesis cardiac laser therapy laser consoles; 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, assume, and other similar terms generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Risks and Uncertainties and elsewhere in this Form 10-Q.

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

The Company's expectations and beliefs regarding the HJ Agreement and the delivery and availability of ProCol inventory;

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

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

Revenue trend estimates for the Company's products and services for 2015;

Expectations regarding market and growth opportunities for BioGlue in Japan and China;

Expectations regarding the expected timing and impact of distribution of BioGlue for expanded indications in Japan;

Expectations regarding 2015 tissue processing revenues and costs, including the impact of the Company's efforts to improve tissue processing throughput and reduce costs;

Expectations regarding the benefits associated with the transition to a direct distribution model in France;

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

Anticipated payment of quarterly dividends;

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

Estimates of fair value of acquired assets, and the Company's belief that the estimates are reasonable;

Expectations regarding the impact of the Company's adoption of new accounting pronouncements;

The anticipated impact of changes in prevailing economic conditions, interest rates, and foreign currency exchange rates, including the effects of the relative strength of the U.S. dollar;

Expectations regarding the Company's eligibility for the domestic production activities tax deduction;

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

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

Expectations that research and development expenses will increase materially for the full year of 2015;

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

Expectations regarding timing, costs, and results in the Medafor patent litigation;

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

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

Estimates of contingent payments and royalties that may be paid by the Company and the timing of such payments, as well as expectations regarding whether contingent payments will be triggered;

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

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

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

Issues that may affect the Company's future growth, financial performance, and cash flows; and

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

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risk factors set forth under Part I, Item 1A of the Company's Form 10-K for the year ended December 31, 2014, and other factors, many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

Risks and Uncertainties

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

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

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

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

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

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

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

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

We may be subject to 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 such actions. In addition, such actions could impact the availability of our products and tissues and our cost structure, including our revenues, financial condition, profitability, and cash flows;

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

We may ultimately be unsuccessful in our PerClot clinical trials and/or may be unable to obtain FDA approval to market and distribute PerClot in the U.S. Even if we receive FDA approval, we may be unsuccessful in our efforts to sell PerClot in the U.S., as other competing products may have penetrated the market by that time;

Our litigation with Medafor will continue to be expensive, and if we lose, we may be prohibited from selling PerClot and its derivative products, such as PerClot Topical, or we may have to pay substantial royalties or damages related to such sales until Medafor's patent expires in early 2019;

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

Certain of our key production inputs are sourced from single suppliers. Should those suppliers experience production or other disruptions or temporarily suspend or discontinue their business operations or relevant product lines or configurations, or should we be unable to successfully negotiate agreements with them for continued supply, our production output could be reduced or halted, which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows;

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;

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;

Edgar Filing: CRYOLIFE INC - Form 10-Q

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

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

Our credit facility limits our ability to pursue significant acquisitions and also may limit our ability to borrow;

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

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

We are dependent on key personnel.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company's interest income and interest expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents of \$38.5 million and restricted cash of \$5.0 million and interest paid on the Company's variable rate line of credit as of September 30, 2015. A 10% adverse change in interest rates, as compared to the rates experienced by the Company in the nine months ended September 30, 2015, affecting the Company's cash and cash equivalents, restricted cash and securities, and line of credit would not have a material effect on the Company's financial position, profitability, or cash flows.

Foreign Currency Exchange Rate Risk

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

The Company has revenues and expenses that are denominated in foreign currencies. Specifically, a significant portion of the Company's international BioGlue and PerClot revenues are denominated in British Pounds and Euros, and a portion of the Company's general, administrative, and marketing expenses are denominated in British Pounds, Euros, Swiss Francs, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates. During the first nine months of 2015, the U.S. Dollar has strengthened materially as compared to the British Pound and Euro, and as a result, the Company's revenues denominated in these currencies have decreased when translated into U.S. Dollars. Further changes in these exchange rates could have a material, adverse effect on the Company's revenues denominated in these currencies.

An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2015 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, 2015, affecting the Company's revenue and expense transactions denominated in foreign currencies, would not have had a material effect on the Company's financial position, profitability, or cash flows.

Item 4. Controls and Procedures.

The Company maintains disclosure controls and procedures ("Disclosure Controls") as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934. These Disclosure Controls are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms, and that such information is accumulated and communicated to management, including the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosures.

The Company's management, including the Company's Chairman, 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, 2015 the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in

its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

The Company's management utilizes the criteria set forth in Internal Control-Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its internal controls over financial reporting. During the quarter ended September 30, 2015 there were no changes in the Company's internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

Except as noted below, there are no material legal proceedings pending, or known by the Company to be contemplated, to which the Company is a party or to which any of its property is subject.

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

The lawsuit against the Defendants followed the receipt by CryoLife of a letter from Medafor in September 2012 stating that PerClot, when introduced in the U.S., would infringe the 461 Patent when used in accordance with the method published in CryoLife's literature and with the instructions for use. CryoLife received FDA 510(k) clearance for the sale of PerClot Topical in April 2014, and began distributing PerClot Topical in August 2014. CryoLife also received IDE approval in March 2014 to begin clinical trials for PerClot in certain surgical indications.

In August 2014, Medafor filed a counterclaim against CryoLife for infringement of the 461 Patent. In September 2014 Medafor filed a motion for a preliminary injunction, asking the District Court to enjoin CryoLife's marketing and sale of PerClot in the U.S. In March 2015 the District Court ruled that CryoLife's declaratory judgment lawsuit against Medafor may proceed but dismissed Bard and Davol from the lawsuit. The District Court also granted Medafor's motion for a preliminary injunction, which prohibits CryoLife from marketing, selling, and distributing PerClot in the U.S. while the litigation proceeds. In March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot in the U.S., including PerClot Topical, in accordance with the District Court's order. In April 2015 CryoLife appealed the District Court's ruling to the U.S. Court of Appeals for the Federal Circuit. CryoLife dismissed this appeal in June 2015. The case is proceeding through the discovery phase in the District Court.

Item 1A. Risk Factors.

The following Risk Factors replace the Risk Factors previously disclosed in Part I, Item 1A, Risk Factors in our 10-K for the year ended December 31, 2014.

Not Having Alternative Or Multiple Vendors For Key Materials, Supplies, Or Services Or Alternative Facilities Could Materially, Adversely Affect Our Business.

Certain of the materials, supplies, and services that are crucial to our medical device manufacturing or our tissue processing are sourced from single vendors. As a result, our ability to negotiate favorable terms with those vendors is

limited, and if those vendors experience operational, financial, or regulatory difficulties, or those vendors and/or their facilities cease operations temporarily or permanently, we could be forced to cease production of devices or processing of tissue until the vendor resumes operations or an alternative vendor could be identified and qualified, or we could be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. We conduct substantially all of our operations at one location. As a result, if our facilities cease operations temporarily or permanently, our business would be disrupted. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

Intense Competition May Impact Our Ability To Operate Profitably.

We face competition from other companies engaged in the following lines of business:

The marketing of mechanical, synthetic, and animal-based tissue valves for implantation; The marketing of surgical adhesives, surgical sealants, and hemostatic agents;

The marketing of CardioGenesis cardiac laser therapy;

The marketing of products addressing dialysis therapies; and

The processing and preservation of human tissue.

In 2016, we expect new products competitive with our BioGlue product to become available in the market. Many of our competitors have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets.

We cannot give assurance that our products and tissues will be able to compete successfully. In addition, if we are unable to successfully market and sell innovative and in-demand products and services our competitors may gain competitive advantages that may be difficult to overcome. If we fail to compete effectively, this could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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.

Our international operations are subject to a number of risks which may vary from the risks we face in the U.S., including:

Difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships and developing direct sales operations in selected territories;

Expanded compliance obligations, including the Foreign Corrupt Practices Act, and unexpected changes in regulatory requirements;

Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;

More limited protection for intellectual property in some countries;

Changes in currency exchange rates, particularly fluctuations in the British Pound and Euro as compared to the U.S. Dollar;

Adverse economic or political changes;

Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs; and

Potentially adverse tax consequences of overlapping tax structures.

Our failure to adequately address these risks could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

The success of our tissue preservation services depends upon, among other factors, the availability of sufficient quantities of tissue from human donors. We rely primarily upon the efforts of third-party procurement organizations, tissue banks, most of which are not-for-profit, and others to educate the public and foster a willingness to donate tissue. If the supply of donated human tissue is materially reduced, or we are unable to procure tissue for any other reason, this would restrict our growth and could have a material, adverse impact on our customer relationships and our revenues, financial condition, profitability, and cash flows.

We Are Dependent On Our Key Personnel.

Our business and future operating results depend in significant part upon the continued contributions of our key personnel, including qualified personnel with medical device and tissue processing experience, and senior management, many of whom would be difficult to replace. Our business and future operating results, including production at our tissue processing facilities, also depend in significant part upon our ability to attract and retain qualified management, tissue processing, marketing, sales, and support personnel for our operations. Competition for such personnel is intense, and we cannot ensure that we will be successful in attracting and retaining such personnel. If we lose any key employees, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees as needed, this could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Rapid Technological Change Could Cause Our Products And Services To Become Obsolete.

The technologies underlying our products and services are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that we will be able to develop, license, or procure innovative products and services or that others will not develop services, products, or processes with significant advantages over the products, services, and processes that we offer or are seeking to develop, license, or procure. Any such occurrence could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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, 2015 of equity securities that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934:

Issuer Purchases of Equity Securities**Common Stock and Common Stock Units**

Period	Total Number of Common Shares and Common Stock Units Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
07/01/15 - 07/31/15	--	\$ --	--	\$ --
08/01/15 - 08/31/15	306	10.32	--	--
09/01/15 - 09/30/15	--	--	--	--
Total	306		--	

The common shares purchased during the quarter ended September 30, 2015 were tendered to the Company in payment taxes on stock compensation and were not part of a publicly announced plan or program.

Under the Company's amended and restated credit agreement with GE Capital, the Company is required, after giving effect to stock repurchases, to maintain liquidity, as defined within the agreement, of at least \$20.0 million. The Company is also entitled to repurchase up to approximately \$14.0 million of common stock under an authorized stock repurchase plan without obtaining its lender's consent.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Edgar Filing: CRYOLIFE INC - Form 10-Q

On September 15, 2015 the Company submitted a late Form 4 filing for William R. Matthews due to delayed receipt of filing numbers from the SEC. On September 17, 2015 the Company submitted a late Form 4 filing for John E. Davis due to delayed receipt of filing numbers from the SEC.

On September 24, 2015 David M. Fronk, the Company's Senior Director, Quality and Assurance, left the Company. No disclosure of the foregoing was made in a current report on Form 8-K at the time of the event. The Company disclosed Mr. Fronk's departure on a Form 8-K filed on October 13, 2015.

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 10-Q filed October 28, 2014.)
3.2	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed July 27, 2011.) (File No. 001-13165)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.) (File No. 001-13165)
4.2	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.) (File No. 001-13165)
10.1*	Separation and Release Agreement between CryoLife and Bruce G. Anderson dated October 8, 2015.
10.2*	Separation and Release Agreement - Amended between CryoLife and David M. Fronk dated October 8, 2015.
10.3*	Amendment dated September 28, 2015 to Second Amended and Restated Credit Agreement, dated as of September 26, 2014, by and among the Company, certain subsidiaries of the Company party thereto, the lenders party thereto, and General Electric Capital Corporation, as agent.
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document

Edgar Filing: CRYOLIFE INC - Form 10-Q

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF* XBRL Taxonomy Extension Definition Linkbase
101.LAB* XBRL Taxonomy Extension Label Linkbase Document
101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

/s/ J. PATRICK MACKIN

J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer

(Principal Executive
Officer)

October 27, 2015

DATE

CRYOLIFE, INC.
(Registrant)

/s/ D. ASHLEY LEE

D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer,
and
Chief Financial Officer

(Principal Financial and
Accounting Officer)