CRYOLIFE INC
Form 10-Q
July 26, 2016

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 **June 30, 2016**

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	**59-2417093**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1655 Roberts Boulevard, NW, Kennesaw, Georgia	**30144**
(Address of principal executive offices)	(Zip Code)

(770) 419-3355

(Registrant s telephone number, including area code)

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

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

Yes x No ¨

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

Large accelerated filer ¨ Accelerated filer x
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 x

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

Class	Outstanding at July 21, 2016
Common Stock	34,110,017 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Revenues:				
Products	$ 30,045	$ 19,918	$ 57,063	$ 39,309
Preservation services	17,038	15,608	33,036	30,048
Total revenues	**47,083**	**35,526**	**90,099**	**69,357**
Cost of products and preservation services:				
Products	7,698	4,244	14,701	9,277
Preservation services	9,084	9,728	17,476	18,859
Total cost of products and preservation services	**16,782**	**13,972**	**32,177**	**28,136**
Gross margin	**30,301**	**21,554**	**57,922**	**41,221**
Operating expenses:				
General, administrative, and marketing	22,436	19,327	48,710	38,296
Research and development	3,279	2,684	5,888	4,936
Total operating expenses	**25,715**	**22,011**	**54,598**	**43,232**
Gain from sale of business components			(7,915)	
Operating income (loss)	**4,586**	**(457)**	**11,239**	**(2,011)**
Interest expense	797	30	1,514	60
Interest income	(18)	(12)	(30)	(15)

Gain on sale of Medafor investment		(891)		(891)
Other (income) expense, net	(58)	250	(167)	442
Income (loss) before income taxes	**3,865**	**166**	**9,922**	**(1,607)**
Income tax expense (benefit)	1,518	668	5,034	(831)
Net income (loss)	**$ 2,347**	**$ (502)**	**$ 4,888**	**$ (776)**
Income (loss) per common share:				
Basic	**$ 0.07**	**$ (0.02)**	**$ 0.15**	**$ (0.03)**
Diluted	**$ 0.07**	**$ (0.02)**	**$ 0.15**	**$ (0.03)**
Dividends declared per common share	**$**	**$ 0.03**	**$**	**$ 0.06**
Weighted-average common shares outstanding:				
Basic	32,010	27,713	31,519	27,619
Diluted	32,764	27,713	32,270	27,619
Net income (loss)	**$ 2,347**	**$ (502)**	**$ 4,888**	**$ (776)**
Other comprehensive (loss) income	(332)	342	(428)	225
Comprehensive income (loss)	**$ 2,015**	**$ (160)**	**$ 4,460**	**$ (551)**

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS)

	June 30, 2016	December 31, 2015
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,935	$ 37,588
Restricted securities	753	830
Receivables, net	31,731	26,672
Inventories	25,389	14,643
Deferred preservation costs	26,898	24,741
Prepaid expenses and other	4,075	5,189
Total current assets	**135,781**	**109,663**
Property and equipment, net	16,416	11,484
Restricted cash		5,000
Goodwill	76,760	11,365
Patents, net	1,061	1,417
Trademarks and other intangibles, net	67,867	18,480
Deferred income taxes		18,188
Other	5,151	5,582
Total assets	**$ 303,036**	**$ 181,179**
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,204	$ 4,648
Accrued compensation	6,687	6,335
Accrued procurement fees	4,611	4,445
Accrued expenses and other	6,434	4,177
Current portion of long-term debt	1,802	
Total current liabilities	**24,738**	**19,605**
Long-term debt	70,438	
Deferred income taxes	1,596	
Deferred rent obligations	2,368	1,735
Other	5,792	4,588

Total liabilities		**104,932**		**25,928**
Commitments and contingencies				
Shareholders equity:				
Preferred stock				
Common stock (issued shares of 34,055 in 2016 and 29,766 in 2015)		341		298
Additional paid-in capital		182,144		142,888
Retained earnings		28,253		23,365
Accumulated other comprehensive loss		(504)		(76)
Treasury stock at cost (shares of 1,356 in 2016 and 1,265 in 2015)		(12,130)		(11,224)
Total shareholders equity		**198,104**		**155,251**
Total liabilities and shareholders equity	**$**	**303,036**	**$**	**181,179**

See accompanying Notes to Summary Consolidated Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES

SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Six Months Ended June 30,	
	2016	**2015**
	(Unaudited)	
Net cash flows from operating activities:		
Net income (loss)	$ 4,888	$ (776)
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Gain from sale of business components	(7,915)	
Depreciation and amortization	4,089	3,111
Non-cash compensation	2,869	3,174
Gain on sale of Medafor investment		(891)
Other non-cash adjustments to income	4,696	2,380
Changes in operating assets and liabilities:		
Receivables	2,097	(326)
Inventories and deferred preservation costs	(4,373)	130
Prepaid expenses and other assets	(426)	(1,383)
Accounts payable, accrued expenses, and other liabilities	(87)	(225)
Net cash flows provided by operating activities	**5,838**	**5,194**
Net cash flows from investing activities:		
Acquisition of On-X, net of cash acquired	(91,152)	
Acquisition of PhotoFix technology	(1,226)	
Proceeds from sale of business components	19,795	
Decrease in restricted cash	5,000	
Capital expenditures	(1,608)	(2,192)
Proceeds from sale of Medafor investment		891
Other	30	(487)
Net cash flows used in investing activities	**(69,161)**	**(1,788)**
Net cash flows from financing activities:		
Proceeds from issuance of term loan	75,000	
Repayment of term loan	(469)	
Payment of debt issuance costs	(2,289)	

Cash dividends paid		(1,700)
Proceeds from exercise of stock options and issuance of common stock	1,027	707
Other	(216)	(884)
Net cash flows provided by (used in) financing activities	**73,053**	**(1,877)**
Effect of exchange rate changes on cash	(383)	171
Increase in cash and cash equivalents	**9,347**	**1,700**
Cash and cash equivalents, beginning of period	37,588	33,375
Cash and cash equivalents, end of period	**$ 46,935**	**$ 35,075**

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, 2015 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of, and for the three and six months ended, June 30, 2016 and 2015 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 six months ended June 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015 filed with the SEC on February 16, 2016.

2. Financial Instruments

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

June 30, 2016	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 715	$	$	$ 715
Restricted securities:				
Money market funds	753			753
Total assets	$ 1,468	$	$	$ 1,468

December 31, 2015	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 549	$	$	$ 549
Restricted securities:				
Money market funds	830			830
Total assets	$ 1,379	$	$	$ 1,379

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):

June 30, 2016	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 715	$	$ 715
Restricted cash and securities:			
Money market funds	753		753

December 31, 2015	Cost Basis	Unrealized Holding Gains	Estimated Market Value
Cash equivalents:			
Money market funds	$ 549	$	$ 549
Restricted cash and securities:			
Cash	5,000		5,000
Money market funds	830		830

As of June 30, 2016 and December 31, 2015 $753,000 and $830,000, 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 December 31, 2015 $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 debt agreement. As of June 30, 2016 the Company no longer had a financial covenant requirement for restricted cash under the Company s amended debt agreement. See further discussion of the Company s debt agreements in Note 11.

There were no gross realized gains or losses on cash equivalents in the three and six months ended June 30, 2016 and 2015. As of June 30, 2016 $753,000 of the Company s restricted securities had a maturity date between three months and one year. As of December 31, 2015 $595,000 of the Company s restricted securities had a maturity date within three months and $235,000 had a maturity date between three months and one year. As of December 31, 2015 $5.0 million of the Company s long-term restricted cash had no maturity date.

4. Acquisition of On-X Life Technologies

Overview

On December 22, 2015 the Company entered into an Agreement and Plan of Merger (On-X Agreement) to acquire On-X Life Technologies Holdings, Inc. (On-X), an Austin, Texas-based, privately held mechanical heart valve company, for approximately $130.0 million, subject to certain adjustments. The transaction closed on January 20, 2016, and On-X is being operated as a wholly owned subsidiary of CryoLife.

The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis (AAP). On-X also distributes CarbonAid CO_2 diffusion catheters, manufactures Chord-X ePTFE sutures for mitral chordal replacement, and offers pyrolytic carbon coating services to other medical device manufacturers. CryoLife believes that the On-X products will fit well into its product portfolio of medical devices for cardiac surgery and believes there is a significant opportunity for CryoLife s sales team to leverage their strong relationships with cardiac surgeons to introduce and to expand utilization of the On-X valves in the U.S. and internationally.

Accounting for the Transaction

The purchase price of the On-X transaction totaled approximately $128.2 million, consisting of cash of $93.6 million and 3,703,699 shares of CryoLife common stock, with a value of $34.6 million as determined on the date of the closing. This purchase price is subject to several potential adjustments, which have not yet been finalized. The Company s preliminary allocation of the $128.2 million purchase price to On-X s tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of January 20, 2016, is included in the table below. Goodwill is recorded based on the amount by which the purchase price exceeds the fair value of the net assets acquired and is not deductible for tax purposes.

The preliminary purchase price allocation as of January 20, 2016 is as follows (in thousands):

		Opening Balance Sheet
Cash and cash equivalents	$	2,472
Receivables		6,416
Inventories		12,924
Intangible assets		53,950
Goodwill		66,695
Other assets		6,200
Liabilities assumed		(20,440)
Total purchase price	$	128,217

The preliminary allocation of the purchase price is based on preliminary valuations performed to determine the fair value of such assets as of the acquisition date. As the Company s acquisition accounting is incomplete, the Company may adjust the amounts recorded as of June 30, 2016 to reflect any revised evaluations of the assets acquired or liabilities assumed. Goodwill from this transaction will be allocated to the Company s medical devices segment.

CryoLife incurred transaction and integration costs of $6.5 million for the six months ended June 30, 2016 related to the acquisition, which include, among other costs, expenses related to the termination of international and domestic distribution agreements. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on the Company s Summary Consolidated Statements of Operations and Comprehensive Income.

Pro Forma Results

The Company s unaudited pro forma results of operations for the six months ended June 30, 2016 and 2015, assuming the On-X acquisition had occurred as of January 1, 2015, are presented for comparative purposes below. These amounts are based on available information of the results of operations of On-X prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the acquisition been completed on January 1, 2015. The pro forma adjustments related to the acquisition of On-X are based on a preliminary purchase price allocation. Differences between the preliminary and final purchase price allocation could have an impact on the pro forma financial information presented below and that impact could be material. This unaudited pro forma information does not project operating results post acquisition.

This preliminary pro forma information is as follows (in thousands, except per share amounts):

		Six Months Ended June 30, 2016		2015
Total revenues	$	91,726	$	86,056
Net income (loss)		8,861		(6,634)
Pro forma income (loss) per common share - basic	$	0.27	$	(0.21)
Pro forma income (loss) per common share - diluted	$	0.27	$	(0.21)

Pro forma net income was calculated using a normalized tax rate of approximately 38%.

5. Sales of Business Components

Divestiture of the HeRO Graft Product Line

On February 3, 2016 the Company sold its Hemodialysis Reliable Outflow Graft (HeRO® Graft) product line to Merit Medical Systems, Inc. (Merit) for $18.5 million in cash (HeRO Sale), of which $17.8 million was received on the transaction date. Under terms of the agreement, Merit acquired the HeRO Graft product line, including worldwide marketing rights, customer relationships, intellectual property, inventory, and certain property and equipment. The Company agreed to continue to manufacture the HeRO Graft under a transition supply agreement. The sales transfer to Merit was completed in the second quarter of 2016. Sales prices under the transition supply agreement are at lower average prices than the Company s previous sales to hospitals at end-user prices. The disposal of the HeRO Graft is part of a strategic shift of the Company s focus to selling its

expanded portfolio of cardiac surgery products, including the On-X heart valve. The HeRO Graft product line was included as part of the Company s Medical Devices segment. The Company recorded a pre-tax gain of approximately $8.8 million on the HeRO Sale.

Divestiture of the ProCol Product Line

On March 18, 2016 the Company sold its ProCol® Vascular Bioprosthesis (ProCol) distribution rights and purchase option to LeMaitre Vascular, Inc. (LeMaitre) for $2.0 million in cash (ProCol Sale), all of which was received by March 31, 2016. Under terms of the agreement, LeMaitre acquired the ProCol related assets, including inventory, customer lists, related marketing assets, and the Company s purchase option to acquire ProCol. LeMaitre exercised the option to acquire ProCol from Hancock Jaffe Laboratories. The disposal of ProCol is part of a strategic shift of the Company s focus to selling its expanded portfolio of cardiac surgery products, including the On-X heart valve. The ProCol product was included as part of the Company s Medical Devices segment. The Company recorded a pre-tax loss of approximately $845,000 on the ProCol Sale.

In 2014 CryoLife acquired the exclusive worldwide distribution rights to ProCol from Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). In accordance with the terms of the agreement with Hancock Jaffe, 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, portions of which the Company received in 2014, 2015, and 2016. CryoLife made additional payments of $1.2 million in the aggregate during 2015 and the first quarter of 2016. As of June 30, 2016 CryoLife had made a total of $3.4 million in payments to Hancock Jaffe and had received $1.7 million in inventory. The remaining $1.7 million in prepayments were settled as part of the ProCol Sale.

Disclosure of the HeRO Sale and the ProCol Sale

Financial Accounting Standards Board (FASB) ASU 2014-08, *Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity,* defines the criteria for reporting discontinued operations and requires additional disclosures about discontinued operations. The standard requires that an entity report as a discontinued operation only a disposal that represents a strategic shift in operations that has a major effect on the Company s operations and financial results.

In the first quarter of 2016 the Company completed the HeRO Sale and the ProCol Sale. The Company received cash for these transactions and recorded the results of these sales in March 2016. Therefore, as of March 31, 2016 both transactions meet the disposed of by sale criteria under discontinued operations.

The Company then evaluated the HeRO Sale and the ProCol Sale to determine whether these disposals represent a strategic shift that has, or will have, a major effect on the Company s financial position, results of operations, or cash flows. The Company evaluated the impact of the HeRO Sale and the ProCol Sale on the Company s business. As the HeRO Graft and ProCol product lines combined represented less than 10% of total Company revenues for the year ended December 31, 2015 and the Company s total assets as of December 31, 2015, the Company believes that these transactions did not have a major effect on the Company s operations and financial condition, either individually or in the aggregate, and therefore the Company did not disclose these transactions as discontinued operations. The combined net gain from the HeRO Sale and ProCol Sale was therefore reported as gain from sale of business components on the Company s Summary Consolidated Statements of Operations and Comprehensive Income.

6. PhotoFix Distribution Agreement and Acquisition

Overview

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 U.S. Food and Drug Administration (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. In January 2015 the Company received its initial shipments and launched its distribution of PhotoFix.

The agreement between CryoLife and GBI (the GBI Agreement) had an initial five-year term and was renewable for two one-year periods at CryoLife s option. Under the terms of the GBI Agreement, CryoLife purchased PhotoFix inventory for resale at an agreed upon transfer price and had the option, which became effective in March 2015, to acquire the PhotoFix product line from GBI.

Accounting for the Transaction

On April 13, 2016 the Company exercised its right to acquire the PhotoFix technology from GBI for approximately $2.3 million, of which $1.2 million was paid in cash at closing, approximately $600,000 was previously provided to GBI as an advance under the distribution agreement, and approximately $400,000 is payable to GBI within 18 months of signing or earlier, subject to certain conditions. The Company s preliminary allocation of the purchase price to the tangible and identifiable intangible assets acquired, based on their estimated fair values resulted in the allocation of the majority of the purchase price to amortizable intangible assets. GBI will continue to manufacture PhotoFix until the Company is able to establish manufacturing operations.

7. Medafor Matters

Investment in Medafor Common Stock

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

On October 1, 2013 C.R. Bard, Inc. (Bard), and its subsidiaries completed its acquisition of all outstanding shares of Medafor common stock. The Company received payments of approximately $15.4 million in 2013, $530,000 in 2014, and $891,000 in April 2015 for its 2.4 million shares of Medafor common stock. 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.

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 District Court for the District of Delaware (the Court). CryoLife requested that the Court declare that CryoLife s manufacture, use, offer for sale, and sale of PerClot in the U.S. does not, and would not, infringe Bard s U.S. Patent No. 6,060,461 (the 461 Patent). In addition, CryoLife requested that the Court declare that the claims of the 461 Patent are invalid. 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 this product in August 2014. 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 also received investigational device exemption 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 Court to enjoin CryoLife s marketing and sale of PerClot in the U.S. In March 2015 the Court ruled that CryoLife s declaratory judgment lawsuit against Medafor may proceed but dismissed Bard and Davol from the lawsuit. The Court also granted Medafor s motion for a preliminary injunction, which prohibited CryoLife from marketing, selling, and distributing PerClot in the U.S. while the litigation proceeded. In March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot in the U.S., including PerClot Topical, in accordance with the Court s order. In April 2015 CryoLife appealed the 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. On November 18, 2015, the lawsuit was resolved by entry by the Court of the Parties Joint Stipulation for

Dismissal, which resulted in the dismissal with prejudice of all parties claims and counterclaims in the lawsuit, the continuation of the preliminary injunction prohibiting CryoLife from marketing, selling and distributing PerClot in the U.S. until expiration of the 461 Patent on February 8, 2019, each party bearing its own attorneys fees and costs associated with the lawsuit, and the continuation of the Court s jurisdiction over the parties to enforce the resolution.

8. Inventories and Deferred Preservation Costs

Inventories at June 30, 2016 and December 31, 2015 are comprised of the following (in thousands):

	June 30, 2016	December 31, 2015
Raw materials and supplies	$ 8,683	$ 8,590
Work-in-process	2,169	633
Finished goods	14,537	5,420
Total inventories	$ 25,389	$ 14,643

Deferred preservation costs at June 30, 2016 and December 31, 2015 are comprised of the following (in thousands):

	June 30, 2016	December 31, 2015
Cardiac tissues	$ 13,980	$ 11,722
Vascular tissues	12,918	13,019
Total deferred preservation costs	$ 26,898	$ 24,741

The Company maintains consignment inventory of its On-X heart valves at domestic and international hospital locations to facilitate usage. The Company retains title to this consignment inventory until the valve is implanted, at which time the Company invoices the hospital. As of June 30, 2016 the Company had $4.3 million in consignment inventory, with approximately 80% in domestic locations and 20% in foreign locations.

9. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of June 30, 2016 and December 31, 2015 the carrying values of the Company s indefinite lived intangible assets are as follows (in thousands):

	June 30, 2016	December 31, 2015
Goodwill	$ 76,760	$ 11,365
Procurement contracts and agreements	2,013	2,013
Trademarks	840	860

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 June 30, 2016 and December 31, 2015 the value of the Company s goodwill, all of which is related to its Medical Devices segment, is as follows (in thousands):

	Medical Devices Segment
Balance as of December 31, 2015	$ 11,365
Goodwill from On-X acquisition	66,695
Goodwill allocated to sale of HeRO Graft product line	(1,200)
Goodwill allocated to sale of ProCol distribution rights and purchase option	(100)
Balance as of June 30, 2016	$ 76,760

Definite Lived Intangible Assets

As of June 30, 2016 and December 31, 2015 the gross carrying values, accumulated amortization, and approximate amortization period of the Company s definite lived intangible assets are as follows (in thousands):

June 30, 2016	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 38,478	$ 4,850	11 22 Years
Customer lists and relationships	29,140	1,441	13 22 Years
Distribution and manufacturing rights and know-how	4,059	1,388	11 15 Years
Patents	3,709	2,648	17 Years
Non-compete agreement	381	362	10 Years
Other	1,336	339	3 Years

December 31, 2015	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 14,020	$ 4,954	11 16 Years
Patents	4,081	2,664	17 Years
Distribution and manufacturing rights and know-how	4,059	1,245	11 15 Years
Customer lists and relationships	3,370	1,054	13 17 Years
Non-compete agreement	381	343	10 Years
Other	1,583	210	3 5 Years

The increase in gross carrying value of the Company s intangible assets as of June 30, 2016 when compared to December 31, 2015 is primarily due to the Company s acquisitions of On-X and PhotoFix, partially offset by reductions due to the HeRO Sale. See Note 4 for further discussion of the acquisition of On-X, Note 6 for further discussion of the acquisition of PhotoFix, and Note 5 for further discussion of the HeRO Sale.

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Amortization expense	$ 1,156	$ 502	$ 2,118	$ 1,017

As of June 30, 2016 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

Remainder of 2016	2017	2018	2019	2020	2021
$ 2,309	$ 4,575	$ 4,457	$ 4,114	$ 3,950	$ 3,927

Amortization expense	

10. Income Taxes

Income Tax Expense

The Company s effective income tax rate was approximately 39% and 51% for the three and six months ended June 30, 2016, respectively, as compared to 402% and 52% for the three and six months ended June 30, 2015, respectively. The Company s income tax rate for the three and six months ended June 30, 2016 was unfavorably impacted by the tax treatment of certain expenses related to the On-X acquisition, which had a larger impact on the tax rate in the first quarter of 2016. The Company s income tax rate for the six months ended June 30, 2016 was also unfavorably impacted by book/tax basis differences related to the HeRO Sale.

The Company s income tax rate for the three months ended June 30, 2015 was unfavorably affected by changes in the Company s estimated full year effective tax rate, which had a large impact when compared to the Company s small pretax book income for the quarter. The Company s income tax rate for the three and six months ended June 30, 2015 was unfavorably impacted by the absence of the domestic production activities deduction, and by other permanent book/tax differences, which had a proportionally large impact in 2015 due to the Company s anticipated full year pretax book income for 2015. The Company s income tax rate for the six months ended June 30, 2015 did not include an anticipated benefit from the research and development tax credit, as this credit had not yet been enacted at that time.

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 deferred tax assets, primarily net operating loss carryforwards, from its acquisitions of On-X, Hemosphere, and Cardiogenesis Corporation. 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 June 30, 2016 the Company maintained a total of $2.3 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and had a net deferred tax liability of $1.6 million. As of December 31, 2015 the Company had a total of $2.1 million in valuation allowances against deferred tax assets and a net deferred tax asset of $18.2 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 second amended and restated credit agreement with GE Capital (the GE Credit Agreement) provided revolving credit for working capital, permitted acquisitions, and general corporate purposes. The GE Credit Agreement had aggregate commitments of $20.0 million for revolving loans, including swing loans, subject to a sublimit, and letters of credit, and was due to mature on September 26, 2019.

Amounts borrowed under the GE Credit Agreement were secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries. Commitment fees were paid based on the unused portion of the facility. As of December 31, 2015 the aggregate interest rate was 4.75%. As of December 31, 2015 the outstanding balance of the GE Credit Agreement was zero, and the remaining availability was $20.0 million.

The GE Credit Agreement placed limitations on the amount that the Company may borrow and included 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) limited the payment of cash dividends, up to specified maximums and subject to satisfaction of specified conditions, (ii) required that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined within the agreement, of at least $20.0 million, (iii) limited acquisitions or mergers except for certain permitted acquisitions, (iv) set 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) included customary conditions on incurring new indebtedness.

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

Amended Debt Agreement

In connection with the closing of the On-X acquisition, discussed above in Note 4, on January 20, 2016 the Company and certain of its subsidiaries entered into the Third Amended and Restated Credit Agreement (Amended Debt Agreement) with Capital One, National Association, who acquired GE Capital s Healthcare Financial Services lending business in late 2015. The designated credit parties are Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association, collectively the (Lending Parties). The Amended Debt Agreement amended and restated the GE Credit Agreement discussed above and provides the Company with a senior secured credit facility in an aggregate principal amount of $95 million, which

includes a $75 million term loan and a $20 million revolving credit facility (including a $4 million letter of credit sub-facility and a $3 million swing-line sub-facility). The $75 million term loan was used to finance, in part, the acquisition of On-X and will mature on January 20, 2021.

The Company and its domestic subsidiaries, subject to certain exceptions and exclusions, have guaranteed the obligations of the Amended Debt Agreement. Borrowings under the Amended Debt Agreement are secured by substantially all of the Company s real and personal property.

The loans under the Amended Debt Agreement (other than the swing-line loans) bear interest, at the Company s option, at either a floating rate equal to the base rate, as defined in the Amended Debt Agreement, plus a margin of between 1.75% and 2.75%, depending on the Company s consolidated leverage ratio, or a per annum rate equal to LIBOR plus a margin of between 2.75% and 3.75%, depending on the Company s consolidated leverage ratio. As of June 30, 2016 the aggregate interest rate was approximately 3.5%. Swing-line loans shall bear interest at a floating rate equal to the base rate plus a margin of between 1.75% and 2.75%, depending on the Company s consolidated leverage ratio. The Company is obligated to pay an unused commitment fee equal to 0.50% of the un-utilized portion of the revolving loans. In addition, the Company is also obligated to pay other customary fees for a credit facility of this size and type. If and while a payment event of default exists, the Company is obligated to pay a per annum default rate of interest of 2.00% above the applicable interest rate on the past due principal amount of the loans outstanding. If and while a bankruptcy or insolvency event of default exists, the Company is obligated to pay a per annum default rate of interest of 2.00% above the applicable interest rate on all loans outstanding.

Interest is due and payable, with respect to base rate loans, on a quarterly basis. Interest is due and payable, with respect to LIBOR loans, on the last day of the applicable interest period, if the interest period is shorter than six months, or on the last day of each three month interval, if the interest period is six months or greater.

The Amended Debt Agreement prohibits the Company from exceeding a maximum consolidated leverage ratio during the term of the Amended Debt Agreement and requires the Company to maintain a minimum interest coverage ratio. In addition, the Amended Debt Agreement contains certain customary affirmative and negative covenants, including covenants that limit the ability of the Company and its subsidiaries which are parties to the loan agreement to, among other things, grant liens, incur debt, dispose of assets, make loans and investments, make acquisitions, make certain restricted payments, merge or consolidate, change their business and accounting or reporting practices, in each case subject to customary exceptions for a credit facility of this size and type. As of June 30, 2016 the Company was in compliance with the covenants of the Amended Debt Agreement.

The Amended Debt Agreement includes certain customary events of default that include, among other things, non-payment of principal, interest or fees; inaccuracy of representations and warranties; violation of covenants; cross-default on certain other indebtedness; bankruptcy and insolvency; and change of control. Upon the occurrence and during the continuance of an event of default, the lenders may declare all outstanding principal and accrued but unpaid interest under the Amended Debt Agreement immediately due and payable, and may exercise the other rights and remedies provided for under the Amended Debt Agreement and related loan documents.

The short-term and long-term balances of the Company s term loan are as follows (in thousands):

	As of June 30,	
	2016	**2015**
Term loan balance	$ 74,532	$

Less unamortized loan origination costs		(2,292)		
Total borrowed		72,240		
Less short-term loan balance		(1,802)		
Long-term loan balance	$	70,438	$	

Interest Expense

Interest expense was $797,000 and $1.5 million for the three and six months ended June 30, 2016, respectively, and $30,000 and $60,000 for the three and six months ended June 30, 2015, respectively. Interest expense in the 2016 and 2015 periods included interest on debt and uncertain tax positions.

12. Commitments and Contingencies

Liability Claims

The Company s estimated unreported loss liability was $1.4 million as of both June 30, 2016 and December 31, 2015. As of June 30, 2016 and December 31, 2015, the related recoverable insurance amounts were $628,000 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 June 30, 2016 could have been estimated to be as high as $3.1 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreements

The employment agreement of the Company s Chairman, President, and Chief Executive Officer (CEO), Mr. J. Patrick Mackin, 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. 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 with the Company. The Company recorded expense of approximately $1.4 million related to Mr. Anderson s separation agreement in the second quarter of 2015. The Company had remaining obligations due under Mr. Anderson s separation agreement of $93,000 and $195,000 as of June 30, 2016 and December 31, 2015, respectively.

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 has a term of 15 years, but can be terminated for any reason before the expiration date by CryoLife by providing 180 days notice. The Distribution Agreement also contains minimum purchase requirements that expire upon the termination of the Distribution Agreement or following U.S. regulatory approval for PerClot. Separate and apart from the terms of the Distribution Agreement, pursuant to the License Agreement, as amended by a September 2, 2011 technology transfer agreement, CryoLife can manufacture and sell PerClot, assuming appropriate regulatory approvals, in the U.S. and certain other jurisdictions and may be required to pay royalties to SMI at certain rates on net revenues of products.

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

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company began enrollment in the trial in the second quarter of 2015 but later suspended enrollment pending consultation with the FDA regarding the trial protocol. These discussions with the FDA resulted in two amendments to the trial protocol, the last of which was approved in July 2016. The Company anticipates resuming enrollment in the trial in the second half of 2016 and receiving Premarket Approval (PMA) from the FDA in 2019.

As of June 30, 2016 the Company had $1.5 million in prepaid royalties and $3.1 million in net intangible assets on the Company s Summary Consolidated Balance Sheets related to the PerClot product line. If the Company does not

ultimately pursue or receive FDA approval to commercialize PerClot in the U.S., these assets could be materially impaired in future periods.

13. Shareholders Equity

Cash Dividends

The Company initiated a cash dividend in the third quarter of 2012 and paid the dividend quarterly until the Company s Board of Directors discontinued dividend payments for the foreseeable future in December 2015. The Company paid dividend payments of $850,000 and $1.7 million for the three and six months ended June 30, 2015, respectively, from cash on hand. The dividend payments were recorded as a reduction to retained earnings on the Company s Summary Consolidated Balance Sheets.

Common Shares Issued

In January 2016 the Company issued 3,703,699 shares of CryoLife common stock, as part of the consideration for the acquisition of On-X. The stock had a value of $34.6 million as determined on the date of the closing. See Note 4 for further discussion of the On-X acquisition.

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 six months ended June 30, 2016 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 463,000 shares and had an aggregate grant date market value of $5.1 million. The PSUs granted in 2016 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 2016 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 2016 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 six months ended June 30, 2015 the Committee authorized awards from approved stock incentive plans of RSUs to certain employees and RSAs and PSUs to certain Company officers, which, including PSUs at target levels, together totaled 283,000 shares of common stock and had an aggregate grant date market value of $3.1 million. The PSUs granted in 2015 represented 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, as defined in the PSU grant documents, for the 2015 calendar year. The PSUs granted in 2015 earned 127% of the target number of shares.

The Committee authorized, from approved stock incentive plans, grants of stock options to purchase a total of 384,000 and 290,000 shares to certain Company officers during the six months ended June 30, 2016 and 2015, respectively. The exercise prices of the options were equal to the closing stock prices on their respective grant dates.

Employees purchased common stock totaling 38,000 shares in both the three and six months ended June 30, 2016 and 36,000 shares in both the three and six months ended June 30, 2015 through the ESPP.

Stock Compensation Expense

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

	Three Months Ended June 30, 2016		Six Months Ended June 30, 2016	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	0.5 Years	4.75 Years	0.5 Years
Expected stock price volatility	N/A	0.30	0.40	0.30
Dividends	N/A	%	%	%
Risk-free interest rate	N/A	0.49%	1.20%	0.49%

	Three Months Ended June 30, 2015		Six Months Ended June 30, 2015	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	2.82 Years	0.5 Years	4.47 Years	0.5 Years
Expected stock price volatility	0.37	0.34	0.44	0.34
Dividends	1.17%	1.06%	1.10%	1.06%
Risk-free interest rate	0.78%	0.12%	1.40%	0.12%

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
RSA, PSA, RSU, and PSU expense	$ 1,131	$ 1,625	$ 2,219	$ 2,490
Stock option and ESPP option expense	400	487	782	795
Total stock compensation expense	$ 1,531	$ 2,112	$ 3,001	$ 3,285

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 $75,000 and $132,000 in the three and six months ended June 30, 2016, respectively, and $75,000 and $111,000 in the three and six months ended June 30, 2015, respectively, of the stock compensation expense into its inventory costs and deferred preservation costs.

As of June 30, 2016 the Company had total unrecognized compensation costs of $7.0 million related to RSAs, PSAs, RSUs, and PSUs and $2.5 million related to unvested stock options, before considering the effect of expected forfeitures. As of June 30, 2016 this expense is expected to be recognized over a weighted-average period of 2.3 years for RSUs, 2.0 years for stock options, 1.8 years for RSAs, 1.3 years for PSUs, and 1.2 years for PSAs.

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):

Basic income (loss) per common share	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net income (loss)	$ 2,347	$ (502)	$ 4,888	$ (776)

Net (income) loss allocated to participating securities	(46)	11	(92)	19
Net income (loss) allocated to common shareholders	$ 2,301	$ (491)	$ 4,796	$ (757)
Basic weighted-average common shares outstanding	32,010	27,713	31,519	27,619
Basic income (loss) per common share	$ 0.07	$ (0.02)	$ 0.15	$ (0.03)

Diluted income (loss) per common share	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Net income (loss)	$ 2,347	$ (502)	$ 4,888	$ (776)
Net (income) loss allocated to participating securities	(45)	11	(90)	19
Net income (loss) allocated to common shareholders	$ 2,302	$ (491)	$ 4,798	$ (757)
Basic weighted-average common shares outstanding	32,010	27,713	31,519	27,619
Effect of dilutive stock options and awards[a]	754		751	
Diluted weighted-average common shares outstanding	32,764	27,713	32,270	27,619
Diluted income (loss) per common share	$ 0.07	$ (0.02)	$ 0.15	$ (0.03)

[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. The Company also excluded common stock equivalents from stock awards from the calculation of diluted weighted-average common shares outstanding during periods of net losses because the inclusion of these common stock equivalents would be antidilutive to income (loss) per common share. Accordingly, stock options to purchase a weighted-average 631,000 and 572,000 shares for the three and six months ended June 30, 2016, respectively, and 795,000 and 716,000 shares for the three and six months ended June 30, 2015, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding. Additionally, the Company excluded a weighted-average of 274,000 and 309,000 shares of common stock equivalents for outstanding stock awards for the three and six months ended June 30, 2015, respectively.

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; On-X products, since the acquisition of On-X; CardioGenesis cardiac laser therapy; PerClot; PhotoFix; HeRO Graft; and ProCol, through the date of the ProCol Sale. 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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
Medical devices	$ 30,045	$ 19,918	$ 57,063	$ 39,309
Preservation services	17,038	15,608	33,036	30,048
Total revenues	47,083	35,526	90,099	69,357
Cost of products and preservation services:				
Medical devices	7,698	4,244	14,701	9,277
Preservation services	9,084	9,728	17,476	18,859
Total cost of products and preservation services	16,782	13,972	32,177	28,136
Gross margin:				
Medical devices	22,347	15,674	42,362	30,032
Preservation services	7,954	5,880	15,560	11,189
Total gross margin	$ 30,301	$ 21,554	$ 57,922	$ 41,221

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Products:				
BioGlue and BioFoam	$ 16,187	$ 14,519	$ 31,503	$ 28,561
On-X	9,554		16,269	
CardioGenesis cardiac laser therapy	1,860	1,943	3,844	4,080
PerClot	1,042	1,036	2,033	2,012
PhotoFix	490	343	871	515
HeRO Graft	912	1,744	2,325	3,604
ProCol	--	333	218	537
Total products	30,045	19,918	57,063	39,309
Preservation services:				
Cardiac tissue	7,548	6,889	13,976	13,552
Vascular tissue	9,490	8,719	19,060	16,496
Total preservation services	17,038	15,608	33,036	30,048
Total revenues	$ 47,083	$ 35,526	$ 90,099	$ 69,357

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 Securities Exchange Act of 1934 (the Exchange Act). Forward-looking statements give the Company s current expectations or forecasts of future events. The words could, may, might, wil would, shall, should, pro forma, potential, pending, intend, believe, expect, anticipate, estimate, and other similar expressions generally identify forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements, which are made as of the date of this Form 10-Q. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Risks and Uncertainties and elsewhere in this Form 10-Q.

All statements included herein, other than statements of historical facts, that address activities, events, or developments that the Company expects or anticipates will or may occur in the future or that reflect the Company s beliefs and/or expectations, are forward-looking statements, including statements about the following:

The market and growth opportunities for BioGlue in China;

The market and growth opportunities for the On-X mechanical heart valve, including the impact of disruptions to the sales channel during the initial integration period, the benefits of moving to a direct sales model in certain countries, and acceleration of growth after the initial integration period;

The significant opportunity for the Company s now larger re-aligned sales team to become fully trained and leverage their strong relationships with cardiac surgeons to introduce and to expand utilization of the On-X heart valve in the U.S. and internationally;

The expected decrease in cardiac laser therapy revenues in 2016 relative to 2015, due to a projected decrease in laser console sales;

The plans, costs, and expected timelines regarding clinical trials to obtain U.S. regulatory approval for PerClot, the distribution of PerClot manufactured by SMI and the Company in certain markets, including in the U.S., the termination, if any, of the Company s Distribution Agreement with SMI, and the payment, if any, of royalties to SMI under the License Agreement with SMI;

The anticipated sales for the remainder of 2016 of the HeRO Graft and ProCol Vascular Bioprosthesis after the disposal of the HeRO Graft product line and termination of the Transition Supply Agreement and after the sale of the Company s distribution rights and purchase option for the ProCol Vascular Bioprosthesis;

2016 tissue preservation services revenues, cost of preservation services, and gross margins, including the impact on revenues, costs, and gross margins, tissues processed in 2014 and 2015, and the Company s plans continuing

into the future to improve tissue processing throughput and reduce costs, as well as tissue availability, timing of tissue releases, and other factors;

The revenue trends and trend estimates for the Company s products and services for 2016, including the impact of foreign exchange on such trends and trend estimates and international distributor purchases;

The sales, costs of products, and gross margins of the Company s products, including the factors affecting such sales and costs of products;

The seasonal nature of the demand for BioGlue and tissue preservation services, as well as uncertainties regarding the seasonal demand for most of its other products;

The Company having sufficient cash to meet its expected operational liquidity needs for at least the next twelve months, its expectations regarding future cash requirements, and the impact that the Company s cash requirements for 2016 may have on its cash flows for 2016;

The potential impact of constraints imposed on the Company by its lenders under the existing credit facility;

The impact of certain adverse changes in interest rates or exchange rates on the Company s financial position, profitability, or cash flows;

The impact of certain new accounting pronouncements; and

The revenue impact associated with the transition to a direct distribution model in certain foreign countries, particularly in France related to BioGlue and PerClot.

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 under Part II, Item 1A, as well as in Part I, Item 1A of the Company s Form 10-K for the year ended December 31, 2015, 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.

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, processing, and distribution of medical devices and implantable human tissues used in cardiac surgical procedures. CryoLife s medical devices include: BioGlue® Surgical Adhesive (BioGlue); BioFoam® Surgical Matrix (BioFoam); On-X valves and surgical products; CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, that are used for the treatment of coronary artery disease in patients with severe angina; PerClot®, an absorbable powdered hemostat, which the Company distributes internationally for Starch Medical, Inc. (SMI); and PhotoFix™, 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 record revenues of $47.1 million in the three months ended June 30, 2016, a 33% increase from the quarter ended June 30, 2015. This increase was primarily due to the acquisition of On-X Life Technologies Holdings, Inc. (On-X) in January 2016, which the Company continued to integrate into its existing business and salesforce during the second quarter of 2016. In April 2016 the Company acquired the PhotoFix product line, as discussed further below. The acquisitions of On-X in January 2016 and PhotoFix in April 2016 are part of the Company s focus on its portfolio of cardiac surgery products, predominantly products related to aortic and mitral valve repair and replacement surgery. See the Results of Operations section below for additional analysis of the three and six months ended June 30, 2016.

Acquisition of the PhotoFix Product Line

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. Under the terms of the Company s agreement with GBI, CryoLife had the option, which became effective in March 2015, to acquire the PhotoFix product line from GBI. On April 13, 2016 the Company acquired the PhotoFix technology from GBI for approximately $2.3 million. GBI will continue to manufacture PhotoFix until the Company is able to establish its own manufacturing operations, which is currently anticipated to occur by mid 2017.

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, 2015. 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 June 30, 2016 in any of its Critical Accounting Policies from those contained in the Company s Form 10-K for the year ended December 31, 2015.

New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) amended its Accounting Standards Codification and created a new Topic 842, *Leases*. The final guidance requires lessees to recognize a right-of-use asset and a lease liability for all leases (with the exception of short-term leases) at the commencement date and recognize expenses on their income statements similar to the current Topic 840, *Leases*. It is effective for fiscal years and interim periods beginning after December 15, 2018, and early adoption is permitted. The Company is evaluating the impact the adoption of this standard will have on its financial position, results of operations, and cash flows.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* as part of its simplification initiative, which involves several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in this update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company is evaluating the impact the adoption of this standard will have on its financial position, results of operations, and cash flows.

In May 2014 the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers,* and issued a subsequent amendment to the standard in March 2016 with ASU 2016-08. The original standard provides guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. The standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The amendment to the standard clarifies implementation guidance on principal versus agent considerations. Adoption of the new standard is effective for reporting periods beginning after December 15, 2017. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2014-09 to have a material impact on its financial position, results of operations, or cash flows.

Results of Operations

(Tables in thousands)

Revenues

	Revenues for the Three Months Ended June 30,		Revenues as a Percentage of Total Revenues for the Three Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Products:				
BioGlue and BioFoam	$ 16,187	$ 14,519	35%	41%
On-X	9,554		20%	%
CardioGenesis cardiac laser therapy	1,860	1,943	4%	5%
PerClot	1,042	1,036	2%	3%
PhotoFix	490	343	1%	1%
HeRO Graft	912	1,744	2%	5%
ProCol		333	%	1%
Total products	30,045	19,918	64%	56%
Preservation services:				
Cardiac tissue	7,548	6,889	16%	19%
Vascular tissue	9,490	8,719	20%	25%
Total preservation services	17,038	15,608	36%	44%
Total	$ 47,083	$ 35,526	100%	100%

	Revenues for the Six Months Ended June 30,		Revenues as a Percentage of Total Revenues for the Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Products:				
BioGlue and BioFoam	$ 31,503	$ 28,561	35%	41%
On-X	16,269		18%	--%
CardioGenesis cardiac laser therapy	3,844	4,080	4%	6%

PerClot	2,033	2,012	2%	3%
PhotoFix	871	515	1%	1%
HeRO Graft	2,325	3,604	3%	5%
ProCol	218	537	%	1%
Total products	57,063	39,309	63%	57%
Preservation services:				
Cardiac tissue	13,976	13,552	16%	19%
Vascular tissue	19,060	16,496	21%	24%
Total preservation services	33,036	30,048	37%	43%
Total	$ 90,099	$ 69,357	100%	100%

Revenues increased 33% and 30% for the three and six months ended June 30, 2016, respectively, as compared to the three and six months ended June 30, 2015, respectively, primarily due to the acquisition of On-X in January 2016. A detailed discussion of the changes in product revenues and preservation services revenues for the three and six months ended June 30, 2016 is presented below.

Products

Revenues from products increased 51% and 45% for the three and six months ended June 30, 2016, respectively, as compared to the three and six months ended June 30, 2015, respectively, primarily due to the acquisition of On-X during the first quarter of 2016. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; On-X; CardioGenesis cardiac laser therapy; PerClot; PhotoFix; HeRO Graft; and ProCol is presented below.

The Company s sales of certain products through its direct sales force to U.K. hospitals are denominated in British Pounds, and its sales to German, Austrian, French, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. During 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. This trend continued during the six months ended June 30, 2016. 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.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 11% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. This increase was primarily due to an 8% increase in the volume of milliliters sold, which increased revenues by 11%. Revenues from the sale of BioGlue and BioFoam, increased 10% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. This increase was primarily due to an 8% increase in the volume of milliliters sold, which increased revenues by 10%.

The increase in sales volume of surgical sealants for the three and six months ended June 30, 2016 was primarily due to sales of BioGlue in France. In 2015 the Company was in the process of transitioning the French market from a distributor to a direct sales model, and as a result, there were no shipments of BioGlue into France in the comparable period in 2015. To a lesser extent BioGlue revenues in the three and six months ended June 30, 2016 were affected by an increase in sales volume in domestic markets, as a result of the Company s larger, realigned domestic salesforce, and a decrease in sales volume in Japan due to the timing of distributor ordering patterns based on stock levels and expected seasonal variations.

The Company received an expanded indication for BioGlue in Japan in mid-2015. The Company is currently seeking regulatory approval for BioGlue in China and, if this effort is successful, management believes this will provide an additional international growth opportunity for BioGlue in future years.

Domestic revenues accounted for 57% of total BioGlue revenues for both the three and six months ended June 30, 2016, and 58% and 60% of total BioGlue revenues for the three and six months ended June 30, 2015, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for each of the three and six months ended June 30, 2016 and 2015. BioFoam is approved for sale in certain international markets.

On-X

On January 20, 2016 CryoLife acquired On-X, an Austin, Texas-based, privately held mechanical heart valve company. The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valves and the On-X ascending aortic prosthesis (AAP). On-X product revenues also include revenues from the distribution of CarbonAid CO_2 diffusion catheters, the sale of Chord-X ePTFE sutures for mitral chordal replacement, and revenue from pyrolytic carbon coating services to other medical device manufacturers. On-X products are distributed in both

domestic and international markets.

On-X combined pre- and post-acquisition revenues for the three and six months ended June 30, 2016 each increased approximately 7%, when compared to On-X s pre-acquisition revenues for the three and six months ended June 30, 2015, respectively, despite disruptions in the sales channel caused by the transition to direct selling in various domestic and international markets that On-X previously served through distributors.

Management believes that the combined pre- and post-acquisition On-X revenues for the full year 2016 will increase over On-X s pre-acquisition revenues in 2015, although revenues could be adversely impacted in any individual quarter by sales channel disruptions during the initial integration period. Management believes that the growth rate for On-X products will accelerate after this initial integration period due to the selling efforts of the Company s larger, realigned salesforce as they become fully trained and experienced with selling On-X products. The Company expects this salesforce will drive an increase in implants and will open additional hospitals to using On-X products.

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 4% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. Revenues from the sale of laser consoles were zero for both the three months ended June 30, 2016 and 2015. Revenues from the sale of handpieces decreased 5% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. This decrease was primarily due to a 6% decrease in unit shipments of handpieces, which decreased revenues by 7%, partially offset by an increase in average sales prices, which increased revenues by 2%.

Revenues from cardiac laser therapy decreased 6% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. Revenues from the sale of laser consoles were zero and $69,000 for the six months ended June 30, 2016 and 2015, respectively. Revenues from the sale of handpieces decreased 6% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. This decrease was primarily due to a 9% decrease in unit shipments of handpieces, which decreased revenues by 9%, partially offset by an increase in average sales prices, which increased revenues by 3%.

The decrease in handpiece revenues for the three and six months ended June 30, 2016 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.

The Company expects that cardiac laser therapy revenues will decrease for the full year of 2016 as compared to the full year of 2015, due to a projected decrease in laser console sales. Revenues from laser console sales are difficult to predict as laser console sales can vary significantly from quarter to quarter due to the long lead time required to generate sales of capital equipment.

PerClot

Revenues from the sale of PerClot increased 1% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. This increase was primarily due to a 4% increase in revenues due to an increase in volume, partially offset by a decrease in average selling prices, which decreased revenues by 3%.

Revenues from the sale of PerClot increased 1% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. This increase was primarily due to a 6% increase in revenues due to an increase in volume, partially offset by a decrease in average selling prices, which decreased revenues by 4%, and the unfavorable effect of foreign currency exchange, which decreased revenues by 1%.

The volume increase for the three and six months ended June 30, 2016 was primarily due to sales increases in the Company s direct markets in Europe, largely due to sales in France and increasing usage in gynecology procedures.

The decrease in average selling prices for the three and six months ended June 30, 2016 was primarily due to price reductions to certain customers in Europe as a result of pricing pressures from competitive products.

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company began enrollment in the trial in the second quarter of 2015 but later suspended enrollment pending consultation with the FDA regarding the trial protocol. These discussions with the FDA resulted in two amendments to the trial protocol, the last of which was approved in July 2016. The Company anticipates resuming enrollment in the trial in the second half of 2016 and receiving Premarket Approval (PMA) from the FDA in the first half of 2019.

PhotoFix

PhotoFix revenues increased 43% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. This increase was primarily due to an increase in units sold, which increased revenues by 47%, partially offset by a decrease in average sales prices, which decreased revenues by 4%. PhotoFix revenues increased 69% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. This increase was primarily due to an increase in units sold, which increased revenues by 75%, partially offset by a decrease in average sales prices, which decreased revenues by 6%. The increase in volume for both the three and six months ended June 30, 2016 is primarily due to an increase in the number of implanting physicians when compared to the prior year period, as the Company launched its distribution of PhotoFix in the first quarter of 2015.

PhotoFix is distributed in the U.S. for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure.

HeRO Graft

On February 3, 2016 the Company sold its HeRO Graft product line to Merit Medical Systems, Inc. (Merit), and the Company agreed to continue to manufacture the HeRO Graft for Merit for up to six months under a transition supply agreement.

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. Revenues include sales to hospitals through February 3, 2016 and to Merit after that date. HeRO Graft revenues decreased 48% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. This decrease was primarily due to a decrease in average sales prices, which decreased revenues by 81%, partially offset by a 41% increase in number of kits sold, which increased revenues by 33%. HeRO Graft revenues decreased 35% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. This decrease was primarily due to a decrease in average sales prices, which decreased revenues by 64%, partially offset by a 25% increase in number of kits sold, which increased revenues by 29%.

The decrease in HeRO Graft average selling prices and the increase in volume for the three and six months ended June 30, 2016 were primarily due to sales of HeRO Graft to Merit under the transition supply agreement. These sales are at lower average prices than the Company s previous sales to hospitals at end-user prices. The volume of sales also increased as the Company produced HeRO Grafts at the request of Merit. The sales transfer to Merit was completed in the second quarter of 2016; therefore, no further HeRO Graft sales are anticipated in future periods.

ProCol

On March 18, 2016 the Company sold its ProCol product line to LeMaitre Vascular, Inc. (LeMaitre), at which time the Company ceased sales of these products.

Preservation Services

Revenues from preservation services increased 9% and 10% for the three and six months ended June 30, 2016, respectively, as compared to the three and six months ended June 30, 2015, respectively. 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. These factors adversely impacted revenues and costs during 2015 as the Company continued to ship tissues that were processed in 2014. In 2015 the Company reviewed and modified its procedures as part of its ongoing compliance efforts and in an effort to improve tissue processing throughput and reduce costs. The Company expects to continue these efforts as part of its ongoing commitments to quality and efficiency. As a result of these efforts, tissue availability began to increase in the second half of 2015, particularly vascular tissue availability as discussed further below, and the cost of tissue processing decreased.

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 six months ended June 30, 2016.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, increased 10% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. This increase was primarily due to a 9% increase in unit shipments of cardiac tissues, which increased revenues by 6%, and an increase in average service fees, which increased revenues by 4%.

Revenues from cardiac preservation services increased 3% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. This increase was primarily due to an increase in average service fees, which increased revenues by 3%.

The increase in cardiac volume for the three months ended June 30, 2016 was primarily due to an increase in the volume of cardiac patch shipments. The increase in average service fees for the three and six months ended June 30, 2016 was primarily due to list fee increases in domestic markets and the routine negotiation of pricing contracts with certain customers.

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.

Vascular Preservation Services

Revenues from vascular preservation services increased 9% for the three months ended June 30, 2016, as compared to the three months ended June 30, 2015. This increase was primarily due to the effect of favorable tissue mix despite a 5% decrease in unit shipments of vascular tissues, which in the aggregate increased revenues by 5%, and an increase in average service fees, which increased revenues by 4%.

Revenues from vascular preservation services increased 16% for the six months ended June 30, 2016, as compared to the six months ended June 30, 2015. This increase was primarily due to the total effect of favorable tissue mix and a 1% increase in unit shipments of vascular tissues, which increased revenues by 10%, and an increase in average service fees, which increased revenues by 6%.

The favorable tissue mix for the three and six months ended June 30, 2016 was primarily due to a shift to long saphenous veins, at higher average fees, from shorter saphenous veins, as a result of improvements in tissue availability as discussed above.

The increase in average service fees for the three and six months ended June 30, 2016 was primarily due to fee differences due to physical characteristics of vascular tissues, list fee increases in domestic markets, and the routine negotiation of pricing contracts with certain customers.

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

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Cost of products	$ 7,698	$ 4,244	$ 14,701	$ 9,277

Cost of products increased 81% and 58% for the three and six months ended June 30, 2016, respectively, as compared to the three and six months ended June 30, 2015, respectively. Cost of products in 2016 and 2015 includes costs related to BioGlue, BioFoam, CardioGenesis cardiac laser therapy, PerClot, PhotoFix, HeRO Grafts, and ProCol. Cost of products in 2016 also includes costs related to On-X.

The increase in cost of products in the three and six months ended June 30, 2016 was primarily due to sales of On-X products following the Company s acquisition of On-X in January 2016. Cost of products in the three and six months ended June 30, 2016 includes $902,000 and $1.5 million, respectively, in acquisition inventory basis step-up expense, related to the On-X inventory fair value adjustment recorded in purchase accounting. Cost of products in the six

months ended June 30, 2015 included 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. during that quarter.

Cost of Preservation Services

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Cost of preservation services	$ 9,084	$ 9,728	$ 17,476	$ 18,859

Cost of preservation services decreased 7% for both the three and six months ended June 30, 2016, as compared to the three and six months ended June 30, 2015, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services decreased in the three and six months ended June 30, 2016 primarily due to a decrease in the per unit cost of processing tissues, as a result of processing changes implemented in 2015, as discussed in Preservation Services above. This was partially offset by an increase in the unit shipments of tissues in 2016. The Company expects that the per unit cost of processing tissues will decrease for the full year of 2016 when compared to 2015, as a result of these processing improvements.

Gross Margin

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Gross margin	$ 30,301	$ 21,554	$ 57,922	$ 41,221
Gross margin as a percentage of total revenues	64%	61%	64%	59%

Gross margin increased 41% for both the three and six months ended June 30, 2016, as compared to the three and six months ended June 30, 2015, respectively. These increases were primarily due to the addition of margins related to the On-X product line; increases in tissue margins due to higher revenues and a decrease in the per unit cost of processing tissues; and an increase in BioGlue margins due to increased revenues, predominately in countries in which we typically achieve higher margins.

Gross margin as a percentage of total revenues increased in the three and six months ended June 30, 2016, as compared to the three and six months ended June 30, 2015, respectively. These increases were primarily due to increases in tissue margins, due to a decrease in the per unit cost of processing tissues, partially offset by the unfavorable impact of the On-X acquisition inventory basis step-up expense discussed above. The gross margin and gross margin as a percentage of total revenues for the six months ended June 30, 2015 were impacted by the write-down of PerClot inventory, as discussed above.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
General, administrative, and marketing expenses	$ 22,436	$ 19,327	$ 48,710	$ 38,296
General, administrative, and marketing expenses as a percentage of total revenues	48%	54%	54%	55%

General, administrative, and marketing expenses increased 16% and 27% for the three and six months ended June 30, 2016, respectively, as compared to the three and six months ended June 30, 2015, respectively.

General, administrative, and marketing expenses for the three and six months ended June 30, 2016 included $1.1 million and $6.6 million, respectively, in transaction and integration costs primarily related to the acquisition of On-X in January 2016, which include, among other costs, expenses related to the termination of international and domestic distribution agreements. The Company also incurred additional general, administrative, and marketing expenses during the first half of 2016 related to the expanded sales staff and the ongoing operations of On-X, and the effect of this increase will continue throughout 2016.

Research and Development Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Research and development expenses	$ 3,279	$ 2,684	$ 5,888	$ 4,936
Research and development expenses as a percentage of total revenues	7%	8%	7%	7%

Research and development expenses increased 22% and 19% for the three and six months ended June 30, 2016, respectively, as compared to the three and six months ended June 30, 2015, respectively. Research and development spending in these periods was primarily focused on clinical work with respect to PerClot, the Company s tissue processing, On-X products, and BioGlue.

Interest Expense

Interest expense was $797,000 and $1.5 million for the three and six months ended June 30, 2016, respectively, and $30,000 and $60,000 for the three and six months ended June 30, 2015, respectively. Interest expense in the 2016 and 2015 periods included interest on debt and uncertain tax positions. The increase in interest expense in 2016 was due to borrowings under the $75 million term loan the Company entered into in January 2016 to finance, in part, the acquisition of On-X.

Gain from Sale of Business Components

Gain on sale of business components for the six months ended June 30, 2016 consisted of the net of an $8.8 million gain on the HeRO Sale and an $845,000 loss on the ProCol Sale. The Company sold its HeRO Graft and ProCol product lines during the first quarter of 2016 as part of its strategic shift to have a greater focus on selling the Company s expanded portfolio of cardiac surgery products.

Earnings

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Income (loss) before income taxes	$ 3,865	$ 166	$ 9,922	$ (1,607)
Income tax expense (benefit)	1,518	668	5,034	(831)
Net income (loss)	$ 2,347	$ (502)	$ 4,888	$ (776)
Diluted income (loss) per common share	$ 0.07	$ (0.02)	$ 0.15	$ (0.03)
Diluted weighted-average common shares outstanding	32,764	27,713	32,270	27,619

Income before income taxes increased in the three and six months ended June 30, 2016, as compared to the loss before income taxes in the three and six months ended June 30, 2015, respectively. The increase in income before income taxes for the three months ended June 30, 2016 was primarily due to an increase in revenues and gross margins as a result of the acquisition of On-X, partially offset by an increase in general, administrative, and marketing expenses and interest expense, as discussed above. The increase in income before income taxes for the six months ended June 30, 2016 was also due to the gain on disposal of business components, particularly the HeRO Sale, as discussed above.

The Company s effective income tax rate was approximately 39% and 51% for the three and six months ended June 30, 2016, respectively, as compared to 402% and 52% for the three and six months ended June 30, 2015, respectively.

The Company s income tax rate for the three and six months ended June 30, 2016 was unfavorably impacted by the tax treatment of certain expenses related to the On-X acquisition, which had a larger impact on the tax rate in first quarter of 2016. The Company s income tax rate for the six months ended June 30, 2016 was also unfavorably impacted by

book/tax basis differences related to the HeRO Sale.

The Company s income tax rate for the three months ended June 30, 2015 was unfavorably affected by changes in the Company s estimated full year effective tax rate, which had a large impact when compared to the Company s small pretax book income for the quarter. The Company s income tax rate for the three and six months ended June 30, 2015 was unfavorably affected by the absence of the domestic production activities deduction, and by other permanent book/tax differences, which had a proportionally large impact in 2015 due to the Company s anticipated full year pretax book income for 2015. The Company s income tax rate for the six months ended June 30, 2015 did not include an anticipated benefit from the research and development tax credit, as this credit had not yet been enacted at that time.

Net income and diluted income per common share increased for the three and six months ended June 30, 2016, as compared to the three and six months ended June 30, 2015, respectively, primarily due to the increase in income before income taxes, partially offset by an increase in income tax expense as discussed above.

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 is uncertain whether the demand for On-X products, PerClot, 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 does not believe the demand for CardioGenesis cardiac laser therapy is seasonal, as the Company s data does not indicate a significant trend.

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

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

Liquidity and Capital Resources

Net Working Capital

At June 30, 2016 net working capital (current assets of $135.8 million less current liabilities of $24.7 million) was $111.1 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $90.1 million and a current ratio of 6 to 1 at December 31, 2015.

Overall Liquidity and Capital Resources

The Company s largest cash requirement for the six months ended June 30, 2016 was cash used to fund the acquisition of On-X. To a lesser extent, the Company s cash requirements included capital expenditures for facilities and equipment and to fund the purchase of the PhotoFix technology. The Company funded its cash requirements by issuing debt in the form of a new $75 million term loan, discussed further below, through the sale of certain components of the Company s business, the Company s 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 interest and principle payments under our debt agreement, the PerClot clinical trial, additional research and development expenditures, general working capital needs, capital expenditures, and other corporate purposes and may include cash to fund business development activities. These items may have a significant effect on the Company s cash flows during the next twelve months. Subject to the terms of its credit facility and other obligations of the Company, the Company may seek additional borrowing capacity or financing, pursuant to its current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If the Company undertakes any further significant business development activity in 2016, it may need to finance such activities by drawing down monies under its credit agreement, discussed below, obtaining additional debt financing, or using a registration statement to sell equity securities. There can be no assurance that we will be able to obtain any additional debt or equity financing at the time we need it or that such financing will be available on terms that are favorable or acceptable to us.

Significant Sources and Uses of Liquidity

On January 20, 2016 the Company completed its acquisition of On-X, an Austin, Texas-based, privately held mechanical heart valve company, which is being operated as a wholly-owned subsidiary of CryoLife. The purchase price of the transaction totaled approximately $128.2 million, consisting of cash of $93.6 million and 3,703,699 shares of CryoLife common stock, with a value of $34.6 million as determined on the date of the closing. This purchase price is subject to several potential adjustments, which have not yet been finalized.

In January 2016 in connection with the closing of the On-X acquisition, the Company entered into the Third Amended and Restated Credit Agreement (Amended Debt Agreement) with Capital One, National Association; Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association, collectively the (Lending Parties). The Amended Debt Agreement provides the Company with a senior secured credit facility in an aggregate principal amount of $95 million, which includes a $75 million term loan and a $20 million revolving credit facility. The $75 million term loan was used to finance, in part, the acquisition of On-X discussed above. The Company and its domestic subsidiaries, subject to certain exceptions and exclusions, have guaranteed the obligations under the Amended Debt Agreement. Borrowings under the Amended Debt Agreement are secured by substantially all of the Company s real and personal property.

On February 3, 2016 the Company sold its HeRO Graft product line to Merit for $18.5 million in cash, of which $17.8 million had been received by June 30, 2016. On March 18, 2016 the Company sold its ProCol Vascular Bioprosthesis distribution rights and purchase option to LeMaitre for $2.0 million in cash, all of which was received by June 30, 2016. The Company recorded a pre-tax gain of approximately $8.8 million on the HeRO Sale and a pre-tax loss of approximately $845,000 on the ProCol Sale.

On April 13, 2016 the Company exercised its right to acquire the PhotoFix technology from GBI for approximately $2.3 million, of which $1.2 million was paid in cash. GBI will continue to manufacture PhotoFix until the Company is able to establish manufacturing operations, which is expected to occur by mid 2017.

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company began enrollment in the trial in the second quarter of 2015 but later suspended enrollment pending consultation with the FDA regarding the trial protocol. These discussions with the FDA resulted in two amendments to the trial protocol, the last of which was approved in July 2016. The Company anticipates resuming enrollment in the trial in the second half of 2016 and receiving Premarket Approval (PMA) from the FDA in the first half of 2019.

The Company acquired net operating loss carryforwards from its acquisitions of On-X, Hemosphere, Inc. (Hemosphere), and Cardiogenesis Corporation that the Company believes will reduce required cash payments for federal income taxes by approximately $6.0 million for the 2016 tax year.

As of June 30, 2016 approximately 7% 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 $5.8 million for the six months ended June 30, 2016, as compared to $5.2 million for the six months ended June 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 six months ended June 30, 2016 these non-cash items included $7.9 million in gain from sale of business components, partially offset by $4.1 million in depreciation and amortization expenses and $2.9 million in non-cash compensation. The gain from sale of business components is the gain on the HeRO Sale, partially offset by the loss on the ProCol Sale.

The Company s working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the six months ended June 30, 2016 these changes included favorable effects of $2.1 million due to the timing difference between recording receivables and the receipt of cash, largely offset by the unfavorable adjustment of $4.4 million due to increases in inventory balances and deferred preservation costs.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $69.1 million for the six months ended June 30, 2016, as compared to $1.8 million for the six months ended June 30, 2015. The current year cash used was primarily due to $91.2 million for the acquisition of On-X, net of cash acquired, $1.6 million in capital expenditures, and $1.2 million for the acquisition of the PhotoFix technology, partially offset by $19.8 million in proceeds from the sale of business components related to the HeRO Sale and the ProCol Sale and $5.0 million for the decrease in restricted cash.

Net Cash Flows from Financing Activities

Net cash provided by financing activities was $73.0 million for the six months ended June 30, 2016, as compared to cash used of $1.9 million for the six months ended June 30, 2015. The current year cash provided was primarily due to $75.0 million in proceeds from the issuance of a term loan, which was used to finance, in part, the acquisition of On-X, partially offset by $2.3 million in debt issuance costs.

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 June 30, 2016 were as follows (in thousands):

	Total	Remainder of 2016	2017	2018	2019	2020	Thereafter
Long-term debt obligations	$ 74,531	$ 938	$ 3,281	$ 3,750	$ 3,750	$ 5,156	$ 57,656
Operating leases	25,766	1,850	4,462	4,421	4,269	3,790	6,974
Interest payments	10,506	1,271	2,469	2,340	2,210	2,056	160
Purchase commitments	4,226	1,190	1,525	1,511			
Contingent payments	1,000				1,000		
Research obligations	1,229	798	285	55	66	25	
Other long-term liabilities	980	446	534				
Total contractual obligations	$ 118,238	$ 6,493	$ 12,556	$ 12,077	$ 11,295	$ 11,027	$ 64,790

The Company s long-term debt obligations result from scheduled principal payments and anticipated interest payments related to the Company s Amended Debt Agreement.

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 obligations from agreements with suppliers, one of which is the minimum purchase requirements for PerClot under the Distribution Agreement. Pursuant to the terms of the Distribution Agreement, the Company may terminate that agreement, including the minimum purchase requirements set forth in the agreement for various reasons, one of which is if the Company obtains FDA approval for PerClot. These minimum purchases are included in the table above through 2018, based on the assumption that CryoLife will not terminate the Distribution Agreement before it receives FDA approval for PerClot in 2019. However, if the Company does not obtain FDA approval for PerClot and chooses not to terminate the Distribution Agreement, CryoLife may have minimum purchase obligations of up to $1.75 million per year through the end of the contract term in 2025.

The contingent payments obligation includes payments that the Company may make if certain U.S. regulatory approvals and certain commercial milestones are achieved related to the Company s transaction with SMI for PerClot.

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

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, as no assessments have been made for specific litigation, and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently

estimated to be $2.0 million, as no specific assessments have been made by any taxing authorities.

Capital Expenditures

Capital expenditures were $1.6 million and $2.2 million for the six months ended June 30, 2016 and 2015, respectively. Capital expenditures in the six months ended June 30, 2016 were primarily related to the routine purchases of computer software; manufacturing and tissue processing equipment; computer and office equipment; CardioGenesis cardiac laser therapy laser consoles; and leasehold improvements needed to support the Company s business.

Risks and Uncertainties

See the risks identified in Part II, Item 1A of this Form 10-Q.

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 $46.9 million as of June 30, 2016 and interest paid on the outstanding balances, if any, of the Company s variable rate line of credit and $75 million term loan. A 10% adverse change in interest rates, as compared to the rates experienced by the Company in the six months ended June 30, 2016, affecting the Company s cash and cash equivalents, restricted cash and securities, $75 million term loan, 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 portion of the Company s international BioGlue, On-X, and PerClot revenues are denominated in British Pounds and Euros, and a portion of the Company s general, administrative, and marketing expenses are denominated in British Pounds, Euros, Swiss Francs, and Singapore Dollars. These foreign currency transactions are sensitive to changes in exchange rates. In this regard, changes in exchange rates could cause a change in the U.S. Dollar equivalent of net income from transactions conducted in other currencies. As a result, the Company could recognize a reduction in revenues or an increase in expenses related to a change in exchange rates.

An additional 10% adverse change in exchange rates from the exchange rates in effect on June 30, 2016, affecting the Company s balances denominated in foreign currencies, would not have had a material effect on the Company s financial position, profitability, or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by the Company for the six months ended June 30, 2016, 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 Exchange Act. These Disclosure Controls are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the Commission s rules and forms, and that such information is accumulated and communicated to management, including the Chief Executive Officer (CEO) and Chief Financial Officer (CFO), as appropriate, to allow timely decisions regarding required disclosures.

The Company s management, including the Company s President and CEO and the Company s Executive Vice President of Finance, Chief Operating Officer, and CFO, does not expect that its Disclosure Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must

reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. The Company s Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

The Company s management utilizes the criteria set forth in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of June 30, 2016, the CEO and CFO have concluded that the Company s Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by

the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission s rules and forms. During the quarter ended June 30, 2016 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.

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, that is required to be disclosed.

Item 1A. Risk Factors.

Risks Relating To Our Business

We are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting them.

BioGlue® Surgical Adhesive (BioGlue) is a significant source of our revenues, representing 34% and 41% of revenues in the three months ended June 30, 2016 and 2015, respectively. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

BioGlue is a mature product, our U.S. Patent for BioGlue expired in mid-2012, and our patents in most of the rest of the world for BioGlue expired in mid-2013. Other companies may use the inventions disclosed in the expired patents to develop and make competing products;

Other companies have obtained regulatory approval or expanded indications for competitive products from the FDA; one of which has already been launched, and another competitive product is expected to launch later in 2016. These companies have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets. Companies other than these may also pursue regulatory approval for competitive products;

Competitors have obtained FDA approval for indications in which BioGlue has been used off-label and for which we cannot market BioGlue, which in the past has reduced addressable procedures for BioGlue, and such approvals may again reduce addressable procedures;

We may be unable to obtain regulatory approvals to commercialize BioGlue in certain countries other than the U.S. at the same rate as our competitors or at all. We also may not be able to capitalize on new regulatory approvals we obtain for BioGlue in countries other than the U.S., including approvals for new indications; and

BioGlue is subject to potential adverse developments with regard to its safety, efficacy, or reimbursement practices.

We are significantly dependent on our revenues from tissue preservation services and are subject to a variety of risks affecting them.

Tissue preservation services are a significant source of our revenues, representing 36% and 44% of revenues in the three months ended June 30, 2016 and 2015, respectively. The following could materially adversely affect our revenues, financial condition, profitability, and cash flows, if we are unable to:

Source 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. Factors beyond our control such as supply, regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue;

Process donated tissue cost effectively or at all due to factors such as employee turnover, ineffective or inefficient operations, or an insufficiently skilled workforce;

Compete effectively with a major non-profit competitor in tissue preservation services, as it may have advantages over us in terms of cost structure, pricing, and sourcing tissue; or

Mitigate sufficiently the risk that processed tissue cannot be sterilized and hence carries an inherent risk of infection or disease transmission; there is no assurance that our quality controls will be adequate to mitigate such risk.

In addition, U.S. and foreign governments and regulatory agencies have adopted restrictive laws, regulations, and rules that apply to our tissue preservation services. These include:

The National Organ Transplant Act of 1984 or NOTA , which prohibits the acquisition or transfer of human organs for valuable consideration for use in human transplantation, but allows for the payment of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human organs;

U.S. Department of Labor, Occupational Safety and Health Administration and U.S. Environmental Protection Agency requirements for prevention of occupational exposure to infectious agents and hazardous chemicals and protection of the environment; and

European Union directives, called the EUCTD, which require that countries in the European Economic Area take responsibility for regulating tissues and cells through a Competent Authority.

Any of these laws, regulations, and rules could change, or the U.S. or foreign governments and regulatory agencies could adopt more restrictive laws or regulations in the future regarding tissue preservation services that could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

We may not realize all of the anticipated benefits of the On-X acquisition.

On January 20, 2016, we acquired On-X, at a price of $128.2 million, subject to certain adjustments, which is the largest acquisition we have ever made, and pursuant to which we borrowed $75.0 million through a senior secured credit facility, subject to certain restrictions on our business, and we issued shares of common stock worth at the time approximately $34.6 million.

Our ability to realize the anticipated business opportunities, growth prospects, cost savings, synergies, and other benefits of the On-X acquisition will depend on a number of factors including:

The success of our integration of the direct sales forces of On-X and CryoLife into a single salesforce to sell, with limited exception, the entire suite of products of the combined businesses;

Our ability to successfully manage independent sales representative and distributor relationships, particularly internationally;

The success of moving to a direct sales model with the On-X products in markets in which CryoLife currently operates through a direct sales model;

Our ability to attract and retain key personnel;

Our ability to resolve unanticipated or undisclosed pre-existing On-X liabilities including any regulatory or quality issues;

Our ability to execute on existing On-X clinical trials in a timely and cost effective manner;

Our ability to retain existing customers and obtain new customers for On-X products; and

Unforeseen negative economic or market conditions impacting the On-X business.

Many of these factors are outside of our control and any one of them could result in increased costs, decreased revenues and diversion of management s time and energy, which could materially, adversely impact our business, financial condition, and profitability. As a result of these or other factors, we may not realize the full benefits of the acquisition, including achieving anticipated sales, capitalizing on the FDA s approved reduced INR indication and other growth opportunities, capturing market share from major competitors, all of whom are substantially larger and better resourced than CryoLife, or realizing expected synergies and costs savings. These benefits may not be achieved within the anticipated time frame or at all. Any of these factors could negatively impact our earnings per share, decrease or delay the expected accretive effect of the acquisition, and negatively impact the price of our common stock. In addition, if we fail to realize the anticipated benefits of the acquisition, we could experience an interruption or loss of momentum in our existing business activities which could adversely affect our revenues, financial condition, profitability, and cash flows.

We are significantly dependent on our revenues from On-X and are subject to a variety of risks affecting them.

On-X is a significant source of our revenues, representing 20% of revenues in the three months ended June 30, 2016. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

Our ability to achieve anticipated sales of On-X products;

Our ability to capitalize on the FDA s approved reduced INR indication;

Our ability to overcome high levels of inventory in certain markets;

Our ability to compete effectively with our major competitors, as they may have advantages over us in terms of cost

structure, pricing, sales-force footprint, and brand recognition; and

Changes in technology that may impact the market for mechanical heart valve and TAVR devices.

Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S.

In 2010 and 2011, we entered into various agreements with SMI pursuant to which, among other things, we (a) may distribute PerClot in certain international markets and are licensed to manufacture PerClot in the U.S.; (b) acquired the technology to produce the key component in the manufacture of PerClot; and (c) obtained the exclusive right to pursue, obtain, and maintain FDA Premarket Approval for PerClot. The initial consideration under those SMI agreements was approximately $8.0 million paid in cash and stock. We made additional payments of $1.75 million through 2015 and may pay contingent amounts of up to an additional $1.0 million if certain U.S. regulatory and other commercial milestones are achieved. We may also pay SMI, subject to certain off-sets, royalties on our future sales of PerClot that we manufacture after December 31, 2015.

In March 2014, we received approval of our investigational device exemption (IDE) for PerClot from the FDA, pursuant to which we began, in the first half of 2015, our pivotal clinical trial for surgical indications. We spent approximately $2.0 million in 2015 to pursue U.S. regulatory approval and anticipate that we will spend another $7.0 to $8.0 million over the next several years to obtain such approval, most of which we expect to incur in the remainder of 2016, 2017, and 2018. Our costs to obtain FDA approval for PerClot are estimates only and may ultimately be greater than anticipated.

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company began enrollment in the trial in the second quarter of 2015 but later suspended enrollment pending consultation with the FDA regarding the trial protocol. These discussions with the FDA resulted in two amendments to the trial protocol, the last of which was approved in July 2016. The Company anticipates resuming enrollment in the trial in the second half of 2016 and receiving Premarket Approval (PMA) from the FDA in the first half of 2019. Under our agreements with SMI, we could lose our exclusive license to pursue, obtain, and maintain the Premarket Approval, if we do not secure such approval for PerClot by October of 2017. Even though the FDA has approved the revised protocol, we may not be able to continue or may elect to discontinue the PerClot IDE. Finally, under the terms of our resolution with Medafor, we are precluded from marketing, selling or distributing PerClot in the U.S. until February 8, 2019, even if we obtain FDA Premarket Approval for PerClot before that date.

We will not be able to sell the surgical version of PerClot in the U.S. in future years unless, and until, we obtain FDA approval and only after the Medafor injunction has expired on February 8, 2019. Failure to obtain FDA approval could materially, adversely affect our financial condition, anticipated future revenues, and profitability. There is no guarantee that we will obtain FDA approval when anticipated, or at all. The estimated timing of regulatory approval for PerClot is based on factors beyond our control, including but not limited to, the pace of enrollment in the IDE after enrollment is resumed and the approval process may be delayed because of unforeseen scheduling difficulties and unfavorable results at various stages in the IDE or the process. Management may also decide to delay or terminate our pursuit of U.S. regulatory approval for PerClot at any time due to changing conditions in our Company, in the marketplace, or in the economy in general.

Finally, even if we receive FDA Premarket Approval for PerClot, we may be unsuccessful in selling PerClot in the U.S. as competing products may have penetrated the market by the time we receive FDA approval and have substantial market share or significant market protections due to contracts, among other things. We may also be unsuccessful in selling in countries other than the U.S. due, in part, to a proliferation in other countries of multiple generic competitors, SMI s breach of its contractual obligations, or the lack of adequate intellectual property protection or enforcement. Any of these occurrences could materially, adversely affect our future revenues, financial condition,

profitability, and cash flows.

Reclassification by the FDA of CryoValve® SGPV may make it commercially infeasible to continue processing the CryoValve SGPV.

In October 2014 the FDA convened an advisory committee meeting to consider the FDA s recommendation to re-classify more than minimally manipulated (MMM) allograft heart valves from an unclassified medical device to a Class III medical device. The class of MMM allograft heart valves includes our CryoValve SG pulmonary heart valve (CryoValve SGPV). At the meeting, a majority of the advisory committee panel recommended to the FDA that MMM allograft heart valves be re-classified as a Class III product. We expect that the FDA will issue a proposal for reclassification of MMM allograft heart valves, which will be subject to a public comment period before finalization. After publication of the reclassification rule, we expect to have thirty months to submit for an FDA Premarket Approval, after which the FDA will determine if, and for how long, we may continue to provide these tissues to customers. To date, the FDA has not issued a proposed reclassification for MMM allograft heart valves.

We have continued to process and ship our CryoValve SGPV tissues. However, if the FDA ultimately classifies our CryoValve SGPV as a Class III medical device, we anticipate requesting a meeting with the FDA to determine the specific requirements to file for and obtain a Premarket Approval, and we will determine an appropriate course of action in light of those requirements. If there are delays in obtaining the Premarket Approval, if we are unsuccessful in obtaining the Premarket Approval, or if the costs associated with these activities are significant, this could materially, adversely affect our revenues, financial condition, profitability, and/or cash flows in future periods. In addition, we could decide that the requirements for obtaining a Premarket Approval make continued processing of the CryoValve SGPV infeasible, necessitating that we discontinue distribution of these tissues.

Our investment in PhotoFix is subject to a variety of risks.

In April 2016 we exercised our option and acquired the PhotoFix product line from GBI. We began distribution of PhotoFix in the first quarter of 2015 and have continued to sell PhotoFix after the acquisition.

Simultaneously with our acquisition of the PhotoFix product line, we entered into a Transition Supply Agreement with GBI, pursuant to which GBI will continue to manufacture product for us until we have completed the transfer of manufacturing operations to us (the Transition Period). During the Transition Period, we are reliant on GBI to produce quality products in the quantities we and our customers require. If GBI experiences quality, supply, or production challenges, its products could be subject to recall or other quality action; its business operations and/or its facilities that make the products could be shut down temporarily or permanently, whether by government order, natural disaster, or otherwise; and there may not be sufficient product to enable us to meet demand. Even though we have acquired PhotoFix, we may be unable to continue the manufacturing, marketing, or distribution of the product consistent with our current projections or within the time frame anticipated. Further, we may be unable to secure anticipated approvals from the FDA or international regulatory bodies to remove certain labelling restrictions or to be able to commercialize PhotoFix in key international markets, such as Europe. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

Our products and tissues are highly regulated and subject to significant quality and regulatory risks.

The manufacture and sale of medical devices and processing, preservation, and distribution of human tissues are highly complex and subject to significant quality and regulatory risks. Any of the following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

Our products and tissues may be recalled or placed on hold by us, the FDA, or other regulatory bodies. For example, in 2002 the FDA issued an order related to our cardiac patch, vascular, and orthopaedic tissues processed from October of 2001 until August of 2002 and, pursuant to that order, we recalled these tissues or placed them on quarantine hold. We no longer process orthopaedic tissues due, in part, to this recall;

Our products and tissues allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose, us to product and tissue processing liability claims, and such claims could lead to additional regulatory scrutiny and inspections;

Our manufacturing and tissue processing operations are subject to regulatory scrutiny and inspections, including by the FDA and foreign regulatory agencies, and these agencies could require us to change or modify our manufacturing operations, processes, and procedures;

Regulatory agencies could reclassify or reevaluate our clearances and approvals to sell our products and distribute tissues; and

Adverse publicity associated with our products or processed tissues or our industry could lead to a decreased use of our products or tissues, additional regulatory scrutiny, and/or product or tissue processing liability lawsuits.

As an example of these risks, in January 2013 we received a warning letter from the FDA, related to the manufacture of our products and our processing, preservation, and distribution of human tissue, as well as a subsequent 2014 Form 483, after a re-inspection by the FDA related to the warning letter, that included observations concerning design and process validations, environmental monitoring, product controls and handling, corrective and preventive actions, and employee training. Despite an FDA re-inspection in the first quarter of 2015, after which the FDA closed out the warning letter issued in 2013, we remain subject to further inspections and oversight by the FDA and, if the FDA is not satisfied with our quality and regulatory compliance, it could institute a wide variety of enforcement actions, ranging from issuing additional Form 483s or warning letters, to more severe sanctions such as fines; injunctions; civil penalties; recalls of our products and/or tissues; operating restrictions; suspension of production; non-approval or withdrawal of approvals or clearances for new products or existing products; and criminal prosecution. Any further Form 483s, warning letters, recalls, holds, or other adverse action from the FDA may decrease demand for our products or tissues or cause us to write down our inventories or deferred preservation costs and could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

We are heavily dependent on our suppliers to provide quality materials and supplies.

The materials and supplies used in our product manufacturing and our tissue processing are subject to stringent quality standards and requirements, and many of these materials and supplies are subject to significant regulatory oversight and action. If materials or supplies used in our processes fail to meet these standards and requirements or are subject to recall or other quality action, an outcome could be the rejection or recall of our products or tissues and/or the immediate expense of the costs of the manufacturing or preservation. In addition, if these materials and supplies are recalled or the suppliers and/or their facilities that make them are shut down temporarily or permanently, whether by government order, natural disaster, or otherwise, there may not be sufficient materials or supplies available for purchase to allow us to manufacture our products or process tissues. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

We are dependent on sole source suppliers and single facilities.

Certain of the materials, supplies, and services that are key components of our product 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, quality, or regulatory difficulties, or those vendors and/or their facilities cease operations temporarily or permanently, we could be forced to cease product manufacturing or tissue processing until the vendors resume operations or alternative vendors could be identified and qualified. We could also be forced to purchase alternative materials, supplies, or services with unfavorable terms due to diminished bargaining power. We also conduct substantially all of our operations at two facilities Austin, Texas for our On-X heart valve products, and Kennesaw, Georgia for all of our other products. If one of these facilities ceases operations temporarily or permanently, due to natural disaster or other reason, our business could be substantially disrupted.

Our existing insurance coverage may be insufficient, and we may be unable to obtain insurance in the future.

Although we have insurance for product and tissue processing liabilities, securities, property, and general liabilities, it is possible that:

- We could be exposed to product and tissue processing liability claims, and security claims greater than the amount that we have insured;
- 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; or
- Because we are not insured against all potential losses, natural disasters, or other catastrophes could adversely impact our business.

Our products and tissues allegedly have caused, and may in the future cause, injury to patients using our products or tissues, and we have been, and may be, exposed to product and tissue processing liability claims. We maintain claims-made insurance policies to mitigate our financial exposure to product and tissue processing liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. In addition, our product and tissue processing liability insurance policies do not include coverage for any punitive damages.

If we are unsuccessful in arranging acceptable settlements of future product or tissue processing liability claims or future securities class action or derivative claims, we may not have sufficient insurance coverage and liquid assets to

meet these obligations. If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from product or tissue processing liability or securities claims. Additionally, if one or more claims with respect to which we may become, in the future, a defendant should result in a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are unable to meet required future cash payments to resolve any outstanding or any future claims, this will materially, adversely affect our financial condition, profitability, and cash flows. Further, although we have an estimated reserve for our unreported product and tissue processing liability claims for which we do expect that we will obtain recovery under our insurance policies, these costs could exceed our current estimates. In addition, insurance rates could be significantly higher than in the past, and insurers may provide less coverage than we have estimated or expected. Finally, our facilities could be materially damaged by tornadoes, flooding, other natural disasters, or catastrophic circumstances, for which we are not fully covered by business interruption and disaster insurance, and, even with such coverage, we could suffer substantial losses in our operational capacity, along with a potential adverse impact on our customers and opportunity costs for which our insurance would not compensate us.

Any of these events could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

We operate in highly competitive market segments, face competition from large, well-established medical device companies with significant resources and may not be able to compete effectively.

The market for our products and services is intensely competitive, and significantly affected by new product introductions and activities of other industry participants. We face intense competition from other companies engaged in the following lines of business:

- The sale of mechanical, synthetic, and animal-based tissue valves for implantation;
- The sale of synthetic and animal-based patches for implantation;
- The sale of surgical adhesives, surgical sealants, and hemostatic agents; and
- The processing and preservation of human tissue.

A significant percentage of market revenues from these products was generated by Baxter International Inc., Ethicon (a Johnson & Johnson Company), Medtronic, Inc., St. Jude Medical, Inc., LivaNova PLC, Edwards Life Sciences Corp., C.R., Bard, Inc., Integra Life Sciences Holdings, or LifeNet. Several of our competitors enjoy competitive advantages over us, including:

- Greater financial and other resources for product research and development, sales and marketing, acquisitions, and patent litigation;
- Enhanced experience in, and resources for, launching, marketing, distributing, and selling products;
- Greater name recognition as well as more recognizable trademarks for products similar to the products that we sell;
- More established record of obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements;
- More established relationships with healthcare providers and payors;
- Lower cost of goods sold or preservation costs; and
- Larger direct sales forces and more established distribution networks.

Our competitors may develop services, products or processes with significant advantages over the products, services and processes that we offer or are seeking to develop, and our products and tissues may not 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.

Certain of our products and technologies are subject to significant intellectual property risks and uncertainty.

We own patents, patent applications, and licenses relating to our technologies, which we believe provide us with important competitive advantages. In addition, we have certain proprietary technologies and methods that we believe provide us with important competitive advantages. We cannot be certain that our pending patent applications will issue as patents or that no one will challenge the validity or enforceability of any patent that we own or license. Furthermore, competitors may independently develop similar technologies or duplicate our technologies or design around the patented aspects of such technologies. In addition, our technologies or products or services could infringe patents or other rights owned by others, or others could infringe our patents. If we become involved in a patent dispute, the costs of the dispute could be expensive, and if we were to lose or decide to settle the dispute, the amounts or effects of the settlement or award by a tribunal could be costly. For example, in 2015 we resolved a patent infringement case with Medafor related to technology we licensed from SMI. The settlement of that patent infringement case resulted in the continuation of an injunction prohibiting us from marketing, selling, or distributing PerClot in the U.S. until February 8, 2019. We incurred substantial attorneys fees and costs in pursuing and defending that case, and only a portion of those fees and costs are subject to recovery through indemnification. Should we be forced to sue a potential infringer, if we are unsuccessful in prohibiting infringements of our patents, should the validity of our patents be successfully challenged by others, or if we are sued by another party for alleged infringement (whether we ultimately prevail or not), our revenues, financial condition, profitability, and cash flows could be materially, adversely affected.

Our key growth vectors may not generate anticipated benefits.

Our strategic plan is focused on four growth vectors, primarily in the cardiac surgery segment, which are expected to drive our business in the near term. These growth vectors and their key elements are described below:

New Products Drive growth through the rollout of the Company s new products including the On-X heart valve and PhotoFix;

New Indications Broaden the reach of certain of the Company s products, including the On-X heart valve and BioGlue, with new or expanded approvals and indications in the U.S. or in international markets;

Global Expansion Expand the Company s current products and services into new markets, including emerging markets, and accelerate growth by developing new direct sales territories overseas; and

Business Development Selectively pursue potential acquisition, licensing, or distribution rights of companies or technologies that complement CryoLife s existing products, services, and infrastructure and expand our footprint in the cardiac surgery space, such as the recent acquisition of On-X and the PhotoFix product line, as well as divestitures of certain of our non-cardiac surgery product lines, such as the HeRO Graft and ProCol, to be able to focus better on expanding our cardiac surgery footprint.

Although management continues to implement these strategies, we cannot be certain that they will ultimately drive business expansion and enhance shareholder value.

We continue to evaluate expansion through acquisitions of, or licenses with, investments in, and other distribution arrangements with, other companies or technologies, which may carry significant risks.

One of our growth strategies is to selectively pursue potential acquisition, licensing, or distribution rights of companies or technologies that complement CryoLife s existing products, services, and infrastructure. In connection with one or more of the acquisition transactions, we may:

Issue additional equity securities that would dilute our stockholders ownership interest in us;

Use cash that we may need in the future to operate our business;

Incur debt, including on terms that could be unfavorable to us or debt that we might be unable to repay;

Structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;

Be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales;

Be unable to integrate, upgrade, or replace the purchasing, accounting, financial, sales, billing, employee benefits, payroll, and regulatory compliance functions of an acquisition target;

Be unable to secure or retain the services of key employees related to the acquisition;

Be unable to succeed in the marketplace with the acquisition; or

Assume material unknown liabilities associated with the acquired business.

As an example of these risks, we recently acquired On-X, which we financed by incurring further debt, using cash on hand, and issuing additional equity securities. This acquisition poses many of the same risks as set forth above.

Any of the above risks, should they occur, could materially, adversely affect our revenues, financial condition, profitability, and cash flows, including the inability to recover our investment or cause a write down or write off of such investment, associated goodwill, or assets.

Our indebtedness could adversely affect our ability to raise additional capital to fund our operations and limit our ability to react to changes in the economy or our industry.

Our current and future levels of indebtedness could:

- Limit our ability to borrow money for our working capital, capital expenditures, development projects, strategic initiatives, or other purposes;
- Require us to dedicate a substantial portion of our cash flow from operations to the repayment of our indebtedness, thereby reducing funds available to us for other purposes;
- Limit our flexibility in planning for, or reacting to, changes in our operations or business;
- Make us more vulnerable to downturns in our business, the economy, or the industry in which we operate;
- Restrict us from making strategic acquisitions, introducing new technologies, or exploiting business opportunities; or
- Expose us to the risk of increased interest rates as most of our borrowings are at a variable rate of interest.

The agreements governing our indebtedness contain restrictions that limit our flexibility in operating our business.

The agreements governing our indebtedness contain, and any instruments governing future indebtedness of ours may contain, covenants that impose significant operating and financial restrictions on us, including restrictions or prohibitions on our ability to, among other things:

Incur or guarantee additional debt;

Pay dividends on or make distributions in respect of our share capital or make other restricted payments;

Repurchase or redeem capital stock or subordinated indebtedness;

Transfer or sell certain assets;

Create liens on certain assets;

Consolidate or merge with, or sell or otherwise dispose of all, or substantially all, of our assets to, other companies;

Enter into certain transactions with our affiliates;

Pledge the capital stock of any of our subsidiaries;

Enter into agreements which restrict our ability to pay dividends or incur liens;

Make material changes in our equity capital structure;

Engage in any line of business substantially different than that in which we are currently engaged; or

Make certain investments, including strategic acquisitions.

As a result of these covenants, we are limited in the manner in which we conduct our business, and we may be unable to engage in favorable business activities or finance future operations or capital needs.

We have pledged substantially all of our assets as collateral under our existing debt agreements. If we default on the terms of such debt agreements and the holders of our indebtedness accelerate the repayment of such indebtedness, there can be no assurance that we will have sufficient assets to repay our indebtedness.

Under our existing credit agreement, we are required to satisfy and maintain specified financial ratios including a maximum consolidated leverage ratio and a minimum interest coverage ratio. Our ability to meet those financial ratios can be affected by events beyond our control, and there can be no assurance that we will meet those ratios. A failure to comply with the covenants contained in our existing debt agreements could result in an event of default under such agreements, which, if not cured or waived, could have a material, adverse effect on our business, financial condition, and profitability. In the event of any default under our existing debt agreements, the holders of our indebtedness thereunder:

- Will not be required to lend any additional amounts to us;
- Could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable; or
- Could require us to apply all of our available cash to repay such indebtedness.

If we are unable to repay those amounts, the holders of our secured indebtedness could proceed against the collateral granted to them to secure that indebtedness. If the indebtedness under our existing debt agreements were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full.

We are subject to a variety of risks as we seek to expand our business globally.

The expansion of our international operations is subject to a number of risks which may vary significantly from the risks we face in our U.S. operations, including:

- Difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships and developing direct sales operations in key foreign countries;
- Expanded compliance obligations, including with the Foreign Corrupt Practices Act, the U.K. Bribery Law, and local anti-corruption laws;
- Broader exposure to corruption;
- Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement, policies and programs;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;
- Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;

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Changes in currency exchange rates, particularly fluctuations in the British Pound and Euro as compared to the U.S. Dollar, including any fluctuations in exchange rates due to the exit of the U.K. from the European Union;

Differing local product preferences and product requirements;

Adverse economic or political changes or political instability;

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

Potential 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.

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 with experience in the medical device or tissue processing space, many of whom would be difficult to replace. Our business and future operating results, including production at our manufacturing and tissue processing facilities, also depend in significant part upon our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel for our operations. Our main facilities are in the Atlanta, Georgia area and Austin, Texas, where the local supply of qualified personnel in the medical device and tissue processing industries is limited. 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.

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

The majority of our foreign product and tissue processing revenues are denominated in British Pounds and Euros and, as such, are sensitive to changes in exchange rates. In addition, a portion of our dollar-denominated product sales are made to customers in other countries who must convert local currencies into U.S. Dollars in order to purchase these products. We also have balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Fluctuations in exchange rates of British Pounds and Euros or other local currencies in relation to the U.S. Dollar could materially reduce our future revenues as compared to the comparable prior periods. Should this occur, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Significant disruptions of information technology systems or breaches of information security could adversely affect our business.

We rely upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including, but not limited to,

personal information, intellectual property and, in some instances, patient data). We have also outsourced elements of our operations to third parties, including elements of our information technology infrastructure and, as a result, we manage a number of independent vendor relationships with third parties who may or could have access to our confidential information. The complexity of our information technology and information security systems make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. We have only limited cyber-insurance coverage for our On-X subsidiary that will not cover a number of the events described above and this insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. We thus have no insurance for most of the claims that could be raised and, for those where we have coverage, those claims could exceed the limits of our coverage. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they may use to trade in our securities.

Health care policy changes, including U.S. health care reform legislation signed in 2010, may have a material, adverse effect on us.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third-party payers to control these costs and, more generally, to reform the U.S. health care system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material, adverse effect on our financial condition and profitability.

The Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 imposed significant new taxes on medical device makers in the form of a 2.3 percent excise tax on all U.S. medical device sales that commenced in January 2013. While this tax has been suspended for 2016 and 2017, there is no guarantee that it will not be reinstated.

Our sales are affected by challenging domestic and international economic conditions and their constraining effect on hospital budgets, and demand for our products and tissue preservation services could decrease in the future, which could materially, adversely affect our business.

The demand for our products and tissue preservation services can fluctuate from time to time. In challenging economic environments, hospitals attempt to control costs by reducing spending on consumable and capital items, which can result in reduced demand for some of our products and services. If demand for our products or tissue preservation services decreases significantly in the future, our revenues, profitability, and cash flows would likely decrease, possibly materially. In addition, the manufacturing throughput of our products and the processing throughput of our preservation services would necessarily decrease, which would likely adversely impact our margins and, therefore, our profitability, possibly materially. Further, if demand for our products and/or tissue preservation services materially decreases in the future, we may not be able to ship our products and/or tissues before they expire, which would cause us to write down our inventories and/or deferred preservation costs.

Our sales may also be affected by challenging economic conditions in countries around the world, in addition to the U.S., particularly in countries where we have significant BioGlue or On-X heart valve sales or where BioGlue or the On-X heart valve is still in a growth phase. These factors could materially, adversely affect our revenues, financial condition, and profitability.

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.

Our growth and profitability will depend, in part, upon our ability to complete development of, and successfully introduce, new products and services, or expand upon existing indications, which requires that we invest significant time and resources to obtain required regulatory approvals, including significant investment of time and resources into clinical trials. Although we have conducted clinical studies on certain products and services under development, which indicate that such products and services may be effective in a particular application, we cannot be certain that we will be able to successfully execute on these clinical trials or that the results we obtain from clinical studies will be sufficient for us to obtain any required regulatory approvals or clearances. As noted above, we are currently engaged in a Premarket Approval clinical trial for PerClot, as well as clinical trials in China for BioGlue and in the United States for the On-X valve. Each of these trials is subject to the risks outlined herein.

We cannot give assurance that the relevant regulatory agencies will clear or approve these or any new products and services, or new indications, on a timely basis, if ever, or that the new products and services, or new indications, will adequately meet the requirements of the applicable market or achieve market acceptance. We may encounter delays or

rejections during any stage of the regulatory approval process if clinical or other data fails to satisfactorily demonstrate compliance with, or if the service or product fails to meet, the regulatory agency s requirements for safety, efficacy, and quality, or the regulatory agency otherwise has concerns about our quality or regulatory compliance. Regulatory requirements for safety, efficacy, and quality may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials may also be delayed or halted due to the following, among other factors:

Unanticipated side effects;

Lack of funding;

Inability to locate or recruit clinical investigators;

Inability to locate, recruit, and qualify sufficient numbers of patients;

Redesign of clinical trial programs;

Inability to manufacture or acquire sufficient quantities of the product, tissues, or any other components required for clinical trials;

Changes in development focus; or

Disclosure of trial results by competitors.

Our ability to complete the development of any of our products and services is subject to all of the risks associated with the commercialization of new products and services based on innovative technologies. Such risks include unanticipated technical or other problems, manufacturing or processing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Consequently, we may not be able to successfully introduce and market our products or services, or we may not be able to do so on a timely basis. These products and services may not meet price or performance objectives and may not prove to be as effective as competing products and services.

If we are unable to successfully complete the development of a product, service, or application, or if we determine for financial, technical, competitive, or other reasons not to complete development or obtain regulatory approval or clearance of any product, service, or application, particularly in instances when we have expended significant capital, this could materially, adversely affect our revenues, financial condition, profitability, and cash flows. Research and development efforts are time consuming and expensive, and we cannot be certain that these efforts will lead to commercially successful products or services. Even the successful commercialization of a new product or service in the medical industry can be characterized by slow growth and high costs associated with marketing, under-utilized production capacity, and continuing research and development and education costs. The introduction of new products or services may require significant physician training and years of clinical evidence derived from follow-up studies on human patients in order to gain acceptance in the medical community.

All of these could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

The success of certain of our products and preservation services depends upon relationships with healthcare professionals.

If we fail to maintain our working relationships with healthcare professionals, many of our products and preservation services may not be developed and marketed to appropriately meet the needs and expectations of the professionals who use and support our products and preservation services. The research, development, marketing, and sales of many of our new and improved products and preservation services are dependent upon our maintaining working relationships with healthcare professionals. We rely on these professionals to provide us with considerable knowledge and experience regarding our products and preservation services. Healthcare professionals assist us as researchers, marketing and training consultants, product consultants, and speakers. If we are unable to maintain our relationships with these professionals and do not continue to receive their advice and input, the development and commercialization of our products and preservation services could suffer, which could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

If healthcare providers are not adequately reimbursed for procedures conducted with our products, or if reimbursement policies change adversely, we may not be successful in marketing and selling our products or preservation services.

Healthcare providers, facilities, and government agencies are unlikely to purchase our products or implant our tissues if they are not adequately reimbursed for these procedures. Unless a sufficient amount of peer-reviewed clinical data about our products and preservation services has been published, third-party payors, including insurance companies and government agencies, may refuse to provide reimbursement. Furthermore, even if reimbursement is provided, it may not be adequate to fully compensate the clinicians or hospitals. Some third-party payors may impose restrictions on the procedures for which they will provide reimbursement. If healthcare providers cannot obtain sufficient reimbursement from third-party payors for our products or preservation services or the screenings conducted with our

products, we may not achieve significant market acceptance. Acceptance of our products in international markets will depend upon the availability of adequate reimbursement or funding within prevailing healthcare payment systems. Reimbursement, funding, and healthcare payment systems vary significantly by country. We may not obtain approvals for reimbursement in a timely manner or at all.

We are subject to various federal and state anti-kickback, self-referral, false claims privacy, and transparency laws, and similar laws, any breach of which could cause a material, adverse effect on our business, financial condition, and profitability.

Our relationships with physicians, hospitals and other healthcare providers are subject to scrutiny under various federal anti-kickback, self-referral, false claims, privacy and transparency laws and similar laws, often referred to collectively as healthcare compliance laws. Healthcare compliance laws are broad, can be ambiguous and are complex, and even minor inadvertent violations can give rise to claims that the relevant law has been violated. Possible sanctions for violation of these healthcare compliance laws include monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers compensation programs, and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents), and forfeiture of amounts collected in violation of such

prohibitions. Any government investigation or a finding of a violation of these laws could result in a material, adverse effect on our business, financial condition, and profitability.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid, or other government-sponsored healthcare programs. We have entered into consulting agreements, speaker agreements, research agreements, and product development agreements with healthcare professionals, including some who may order our products or make decisions to use them. While these transactions were structured with the intention of complying with all applicable laws, including state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties. We have also adopted the AdvaMed Code of Conduct into our Code of Business Conduct, which governs our relationships with healthcare professionals, including our payment of travel and lodging expenses, research and educational grant procedures, and sponsorship of third-party conferences. In addition, we regularly conduct training sessions on these principles. However, there can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws or that one or more of our employees or agents will not disregard the rules we have established. Because our strategy relies on the involvement of healthcare professionals who consult with us on the design of our products, perform clinical research on our behalf, or educate the market about the efficacy and uses of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with healthcare professionals who refer, or order, our products to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the healthcare professionals we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally-funded healthcare programs, including Medicare and Medicaid, for non-compliance.

The Federal False Claims Act (FCA) imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. Government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice (DOJ) on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers, including the off-label promotion of products or the payment of prohibited kickbacks to doctors, violated the FCA, resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts, and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

The Physician Payments Sunshine Act and similar state laws require us to annually report in detail certain payments and transfer of value from us to healthcare professionals, such as reimbursement for travel and meal expenses or compensation for services provided such as training, consulting, and research and development. This information is then posted on the website of the Center of Medicare and Medicaid Services (CMS). Certain states also prohibit some forms of these payments, require adoption of marketing codes of conduct and regulate our relationships with physicians and other referral sources.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the scarcity of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material, adverse effect on our business, financial condition, and

profitability. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going-forward basis only.

Risks Related to Ownership of our Common Stock

We do not anticipate paying any dividends on our common stock for the foreseeable future.

In December 2015 our Board of Directors discontinued dividend payments on our common stock for the foreseeable future. If we do not pay cash dividends, our shareholders may receive a return on their investment in our common stock only if the market price of our common stock has increased when they sell shares of our common stock that they own.

Provisions of Florida law and anti-takeover provisions in our organizational documents may discourage or prevent a change of control, even if an acquisition would be beneficial to shareholders, which could affect our share price adversely and prevent attempts by shareholders to remove current management.

We are subject to the Florida affiliated transactions statute, which generally requires approval by the disinterested directors or supermajority approval by shareholders for affiliated transactions between a corporation and an interested stockholder. Additionally our organizational documents contain provisions restricting persons who may call shareholder meetings and allowing the Board of Directors to fill vacancies and fix the number of directors. These provisions of Florida law and our articles of incorporation and bylaws could prevent attempts by shareholders to remove current management, prohibit or delay mergers or other changes of control transactions, and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(c) The Company did not repurchase any of its equity securities during the three months ended June 30, 2016.

Under the Company s Amended Debt Agreement, the Company is prohibited from repurchasing its common stock, except for the repurchase of stock from employees or directors of the Company when tendered in payment of taxes or the exercise price of stock options, upon the satisfaction of certain requirements.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit

Number	**Description**
3.1	Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed November 23, 2015.)
3.2	Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K filed March 1, 2016.)
4.1	Form of Certificate for the Company s Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
4.2	Registration Rights Agreement, dated as of January 20, 2016, by and between CryoLife, Inc. and the Investors party thereto. (Incorporated herein by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 25, 2016.)
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
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

CRYOLIFE, INC.
(Registrant)

/s/ J. PATRICK MACKIN
J. PATRICK MACKIN
Chairman, President, and
Chief Executive Officer
(Principal Executive Officer)

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

July 26, 2016

DATE