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

FORM 10-Q

☑ QUARTERLY REPORT PURSUANT SECURITIES EXCHAN		HE	
For the quarterly period end	ded March 31, 2014		
OR			
☐ TRANSITION REPORT PURSUANT SECURITIES EXCHAN		НЕ	
For the transition period from	to		
Commission file nur	mber: 1-13165		
CRYOLIF	E, INC.		
(Exact name of registrant as s	specified in its charter)		
Florida		2417093	
(State or other jurisdiction of incorporation or organization)	•	Employer cation No.)	
1655 Roberts Boulevard, NW, Kennesaw, Georgia (Address of principal executive offices)		9 0144 p Code)	
(770) 419-3 (Registrant's telephone number			
Not Applie (Former name, former address and former fi		t)	
Indicate by check mark whether the registrant (1) has filed all reports require turing the preceding 12 months (or for such shorter period that the registrant was requirements for the past 90 days. Yes \boxtimes No \square			34
Indicate by check mark whether the registrant has submitted electronically are equired to be submitted and posted pursuant to Rule 405 of Regulation S-T during			vas
equired to submit and post such files).	Yes ⊠	No 🗆	
Indicate by check mark whether the registrant is a large accelerated filer, an are the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting			ee
Large accelerated filer □ Non-accelerated filer □ (Do not check if a smaller reporting company)	Accelerated filer Smaller reporting compa	ny □	
Indicate by check mark whether the registrant is a shell company (as defined	in Rule 12b-2 of the Exchange Act) Yes □	No ⊠	
Indicate the number of shares outstanding of each of the issuer's classes of co	ommon stock, as of the latest practic	cable date.	
Class		g at April 25, 2014	
Common Stock, \$.01 par value per share	28,08	34,041 Shares	

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements.

CRYOLIFE, INC. AND SUBSIDIARIES SUMMARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (IN THOUSANDS, EXCEPT PER SHARE DATA)

Three Months Ended

	March 31,			
	 2014		2013	
	(Una	udited)		
Revenues:				
Products	\$ 19,455	\$	19,796	
Preservation services	16,276		15,677	
Other	 		63	
Total revenues	35,731		35,536	
Cost of products and preservation services:				
Products	3,801		3,465	
Preservation services	 9,457		8,795	
Total cost of products and preservation services	 13,258		12,260	
Gross margin	 22,473		23,276	
Operating expenses:				
General, administrative, and marketing	18,275		17,977	
Research and development	 2,502		1,988	
Total operating expenses	 20,777		19,965	
Operating income	1,696		3,311	
Interest expense	61		50	
Interest income	(3)		(2)	
Other (income) expense, net	 (99)		219	
Income before income taxes	1,737		3,044	
Income tax expense	 678		852	
Net income	\$ 1,059	\$	2,192	
Income per common share:				
Basic	\$ 0.04	\$	0.08	
Diluted	\$ 0.04	\$	0.08	
Dividends declared per common share	\$ 0.0275	\$	0.0250	
•				
Weighted-average common shares outstanding:				
Basic	27,376		26,861	
Diluted	28,463		27,488	
Net income	\$ 1,059	\$	2,192	
Other comprehensive loss	 (35)		(33)	
Comprehensive income	\$ 1,024	\$	2,159	

See accompanying Notes to Summary Consolidated Financial Statements.

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

	<u> </u>	March 31, 2014	De	cember 31, 2013
	J)	Unaudited)		
ASSETS				
Current assets:				
Cash and cash equivalents	\$	32,763	\$	37,643
Restricted cash and securities		5,684		5,350
Receivables, net		21,000		18,307
Deferred preservation costs		26,215		27,297
Inventories		11,489		9,771
Deferred income taxes		5,713		5,162
Prepaid expenses and other		2,988		2,797
Total current assets		105,852		106,327
Property and equipment, net		11,994		12,171
Goodwill		11,365		11,365
Patents, net		1,852		1,934
Trademarks and other intangibles, net		19,829		19,985
Notes receivable		2,000		2,000
Deferred income taxes		16,370		16,885
Other		4,255		4,016
Total assets	\$	173,517	\$	174,683
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	5,000	\$	5,514
Accrued compensation	Ψ	3,087	Ψ	4,886
Accrued procurement fees		5,013		5,427
Accrued expenses and other		4,883		4,579
Deferred income		380		316
Total current liabilities		18,363		20,722
Contingent consideration liability		1,786		1,884
Other		7,798		7,330
Total liabilities		27,947		29,936
Commitments and contingencies				
Shareholders' equity:				
Preferred stock				
Common stock (issued shares of 28,567 in 2014 and 28,244 in 2013)		286		282
Additional paid-in capital		129,966		128,585
Retained earnings		19,028		18,741
Accumulated other comprehensive (loss) income		(28)		7
Treasury stock at cost (shares of 495 in 2014 and 413 in 2013)		(3,682)		(2,868)
Total shareholders' equity		145,570		144,747
Total liabilities and shareholders' equity	\$	173,517	\$	174,683

CRYOLIFE, INC. AND SUBSIDIARIES SUMMARY CONSOLIDATED STATEMENTS OF CASH FLOWS (IN THOUSANDS)

Three Months Ended

	March 31,		
	2014		
	(Unaudited))	
Net cash flows from operating activities:			
Net income	\$ 1,059 \$	2,192	
Adjustments to reconcile net income to net cash from operating activities:			
Depreciation and amortization	1,462	1,453	
Non-cash compensation	845	782	
Deferred income taxes	(36)	187	
Other non-cash adjustments to income	(323)	398	
Changes in operating assets and liabilities:			
Receivables	(2,693)	(3,321)	
Deferred preservation costs and inventories	(821)	1,153	
Prepaid expenses and other assets	(430)	373	
Accounts payable, accrued expenses, and other liabilities	(1,101)	(4,386)	
Net cash flows used in operating activities	(2,038)	(1,169)	
Net cash flows from investing activities:			
Capital expenditures	(1,037)	(988)	
Other	 (642)	(84)	
Net cash flows used in investing activities	(1,679)	(1,072)	
Net cash flows from financing activities:			
Cash dividends paid	(772)	(687)	
Proceeds from exercise of stock options and issuance of common stock	357	229	
Repurchases of common stock		(1,203)	
Other	(705)	(474)	
Net cash flows used in financing activities	(1,120)	(2,135)	
Effect of exchange rate changes on cash	 (43)	(1)	
	(4.000)	(4.255)	
Decrease in cash and cash equivalents	(4,880)	(4,377)	
Decrease in cash and cash equivalents Cash and cash equivalents, beginning of period	37,643	13,009	

CRYOLIFE, INC. AND SUBSIDIARIES NOTES TO SUMMARY CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. Basis of Presentation

The accompanying summary consolidated financial statements include the accounts of CryoLife, Inc. and its subsidiaries ("CryoLife," the "Company," "we," or "us"). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Summary Consolidated Balance Sheet as of December 31, 2013 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of and for the three months ended March 31, 2014 and 2013 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission ("SEC"). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. These summary consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2013.

2. Financial Instruments

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

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

<u>December 31, 2013</u>	 Level 1	Level 2	Level 3	Total
Cash equivalents:	 	 	 	
Money market funds	\$ 5,349	\$ 	\$ 	\$ 5,349
Certificates of deposit	749			749
Restricted securities:				
Money market funds	 350	 	 	 350
Total assets	\$ 6,448	\$ 	\$ 	\$ 6,448
Long-term liabilities:				
Contingent consideration	\$ 	\$ 	\$ (1,884)	\$ (1,884)
Total liabilities	\$ 	\$ 	\$ (1,884)	\$ (1,884)

The Company used prices quoted from its investment management companies to determine the Level 1 valuation of its investments in money market funds, certificates of deposit, and securities. The Company recorded a contingent consideration liability, classified as Level 3, as a result of its acquisition of Hemosphere, Inc. ("Hemosphere") in May 2012. Refer to Note 5 for further discussion of the Level 3 contingent consideration liability.

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

	C	Contingent
	Cor	nsideration
Balance as of December 31, 2013	\$	1,884
Gain on remeasurement of contingent consideration		(98)
Balance as of March 31, 2014	\$	1,786

3. Cash Equivalents and Restricted Cash and Securities

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

			Ţ	Unrealized Holding Gains		Estimated Market Value
March 31, 2014		Cost Basis	<u></u>			
Cash equivalents:	_					
Money market funds	\$	2,482	\$		\$	2,482
U.S. Treasury debt securities		20,000				20,000
Restricted cash and securities:						
Cash		5,000				5,000
Money market funds		684				684
<u>December 31, 2013</u>						
Cash equivalents:						
Money market funds	\$	5,349	\$		\$	5,349
Certificates of deposit		749				749
Restricted cash and securities:						
Cash		5,000				5,000
Money market funds		350				350

As of March 31, 2014 and December 31, 2013 \$684,000 and \$350,000, respectively, of the Company's money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations. As of March 31, 2014 and December 31, 2013 \$5.0 million of the Company's cash was designated as short-term restricted cash due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation ("GE Capital"), as discussed in Note 11. This restriction will lapse upon expiration of the credit agreement with GE Capital on October 28, 2014.

There were no gross realized gains or losses on cash equivalents in the three months ended March 31, 2014 and 2013. As of March 31, 2014 \$20,000 of the Company's restricted securities had a maturity date within three months and \$664,000 of the Company's restricted securities had a maturity date of between three months and one year. As of December 31, 2013 \$328,000 of the Company's restricted securities had a maturity date within three months and \$22,000 of the Company's restricted securities had a maturity date between three months and one year. As of March 31, 2014 and December 31, 2013 \$5.0 million of the Company's restricted cash had no maturity date.

4. ProCol Distribution Agreement

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

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

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

5. Hemosphere Acquisition

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

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

The fair value of the contingent consideration liability was based on unobservable inputs, including management estimates and assumptions about future revenues, and is, therefore, classified as Level 3 within the fair value hierarchy presented in Note 2. The Company will remeasure this liability at each reporting date and will record changes in the fair value of the contingent consideration liability in other (income) expense, net on the Company's Summary Consolidated Statement of Operations and Comprehensive Income. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the timing and amount of Company revenue estimates.

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

6. ValveXchange

Preferred Stock Investment

In July 2011 the Company purchased shares of series A preferred stock of ValveXchange, Inc. ("ValveXchange") for approximately \$3.5 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. As ValveXchange's stock is not actively traded on any public stock exchange, and as the Company's investment is in preferred stock, the Company initially accounted for this investment using the cost method. The Company initially recorded its investment as a long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

During the fourth quarter of 2013 the Company reevaluated its investment in ValveXchange preferred stock for impairment. Based on this analysis, the Company believed that its investment in ValveXchange was fully impaired as of December 31, 2013, and the impairment was other than temporary. Therefore, in the fourth quarter of 2013 the Company recorded an other non-operating expense of \$3.2 million to write-down the remaining value of its investment in ValveXchange preferred stock. As of March 31, 2014 and December 31, 2013 the carrying value of the Company's investment in ValveXchange preferred stock was zero.

Loan Agreement

The Company's agreement with ValveXchange, as amended, makes available up to \$2.0 million to ValveXchange in debt financing through a revolving credit facility (the "Loan"). The Loan includes various affirmative and negative covenants, including financial covenant requirements, and expires on July 30, 2018, unless terminated earlier. Amounts outstanding under the Loan earn interest at an 8% annual rate and are secured by substantially all of the tangible and intangible assets of ValveXchange. The Company incurred loan origination costs, net of fees charged to ValveXchange, of approximately \$117,000, which are being expensed on a straight-line basis over the life of the Loan. In 2012 the Company advanced \$2.0 million to ValveXchange under the Loan. The \$2.0 million advance is recorded as long-term notes receivable on the Company's Summary Consolidated Balance Sheets as of March 31, 2014 and December 31, 2013.

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

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

Option Agreement

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

7. Medafor Matters

Investment in Medafor Common Stock

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

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

Legal Action

CryoLife received a letter from Medafor in September 2012 stating that PerClot ®, when introduced in the U.S., will, when used in accordance with the method published in CryoLife's literature and with the instructions for use, infringe Medafor's (now Bard's) U.S. patent. CryoLife has received no further communications from Medafor or Bard related to the September letter.

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

8. Deferred Preservation Costs and Inventories

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

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

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

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

9. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

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

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

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

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

Definite Lived Intangible Assets

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

	Gross	s Carrying	Acci	umulated	Amortization		
March 31, 2014		Value		Value Amortiza		ortization	Period
Acquired technology	\$	14,020	\$	2,961	11-16 Years		
Patents		4,236		2,384	17 Years		
Distribution and manufacturing rights and know-how		3,559		776	15 Years		
Customer lists and relationships		3,370		632	13-17 Years		
Non-compete agreement		381		276	10 Years		
Other		470		185	1-5 Years		

D	Gross Carrying	Accumulated	Amortization
<u>December 31, 2013</u>	Value	Amortization	Period
Acquired technology	\$ 14,020	\$ 2,677	11-16 Years
Patents	4,348	2,414	17 Years
Distribution and manufacturing rights and know-how	3,559	714	15 Years
Customer lists and relationships	3,370	572	13-17 Years
Non-compete agreement	381	267	10 Years
Other	202	171	1-3 Years

Amortization Expense

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

		Three Mon	ths Ended	
	March 31,			
	2014 2013			
Amortization expense	\$	496	\$	514

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

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

10. Income Taxes

The Company's effective income tax rate was approximately 39% for the three months ended March 31, 2014, as compared to 28% for the three months ended March 31, 2013. The Company's income tax rate for the three months ended March 31, 2014 was unfavorably affected by the research and development tax credit, which has not yet been enacted for the 2014 tax year. The Company's income tax rate in 2013 was favorably affected by the full year 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company's tax expense during the first quarter of 2013

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

As of March 31, 2014 the Company maintained a total of \$1.5 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of \$22.1 million. As of December 31, 2013 the Company had a total of \$1.5 million in valuation allowances against deferred tax assets and a net deferred tax asset of \$22.0 million.

11. Debt

GE Credit Agreement

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

The GE Credit Agreement places limitations on the amount that the Company may borrow and includes various affirmative and negative covenants, including financial covenants such as a requirement that CryoLife (i) not exceed a defined leverage ratio, (ii) maintain a minimum adjusted earnings subject to defined adjustments as of specified dates, and (iii) not make or commit capital expenditures in excess of a defined limitation. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which GE Capital has a first priority perfected lien. These amounts are recorded as restricted cash as of March 31, 2014 and December 31, 2013 on the Company's Summary Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement. The GE Credit Agreement allows the payment of cash dividends up to a maximum of \$3.5 million per year, subject to satisfaction of specified conditions. Also, the GE Credit Agreement requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined within the agreement, of at least \$20.0 million. The GE Credit Agreement includes customary conditions on incurring new indebtedness.

Commitment fees are paid based on the unused portion of the facility. As of March 31, 2014 the Company was in compliance with the covenants of the GE Credit Agreement.

Amounts borrowed under the GE Credit Agreement are secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries and bear interest as determined by GE Capital at either LIBOR, with a minimum rate of 4.25%, or GE Capital's base rate, with a minimum rate of 3.25%, plus the applicable margin. As of March 31, 2014 and December 31, 2013 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate was 6.50%, and the remaining availability was \$20.0 million.

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

Interest Expense

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

12. Commitments and Contingencies

Liability Claims

At March 31, 2014 and December 31, 2013 the Company's estimated unreported loss liability was \$1.5 million. The related recoverable insurance amounts were \$595,000 and \$580,000 as of March 31, 2014 and December 31, 2013, respectively. The Company accrues its estimate of unreported product and tissue processing liability claims as a component of other long-term liabilities and records the related recoverable insurance amount as a component of other long-term assets, as appropriate. Further analysis indicated that the liability as of March 31, 2014 could have been estimated to be as high as \$2.7 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreement

The Company has an employment agreement with its Chief Executive Officer ("CEO") that confers benefits which become payable upon the occurrence of certain events, including his voluntary retirement or termination of his employment in conjunction with certain change in control events. As of both March 31, 2014 and December 31, 2013 the Company had \$2.1 million in accrued expenses and other current liabilities on the Summary Consolidated Balance Sheets representing benefits payable upon the CEO's voluntary retirement, for which he is currently eligible. The CEO's current employment agreement took effect on January 1, 2013 and terminates on December 31, 2015.

13. Shareholders' Equity

Common Stock Repurchase

In February 2013 the Company's Board of Directors authorized the purchase of up to \$15.0 million of its common stock through October 31, 2014.

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

Cash Dividends

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

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

14. Stock Compensation

Overview

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

Equity Grants

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

During the three months ended March 31, 2013 the Compensation Committee of the Company's Board of Directors authorized awards from approved stock incentive plans of RSAs and PSUs to certain Company officers which, assuming that performance under the PSUs were to be achieved at target levels, together totaled 324,000 shares of common stock and had an aggregate market value of \$1.9 million. Shares issued under the 2013 PSU awards were earned at approximately 115% of the target number of shares.

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

Employees purchased common stock totaling 59,000 and 49,000 shares in the three months ended March 31, 2014 and 2013, respectively, through the Company's ESPP.

Stock Compensation Expense

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

March 31, 2013

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

March 31, 2014

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

	1	March 31,			
	2	014		2013	
RSA, RSU, and PSU expense	\$	712	\$	635	
Stock option and ESPP option expense		207		211	
Total stock compensation expense	\$	919	\$	846	

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continued to vest during the period, and compensation related to the Company's ESPP. These amounts were recorded as stock compensation expense and were subject to the Company's normal allocation of expenses to deferred preservation costs and inventory costs. The Company capitalized \$74,000 and \$64,000 in the three months ended March 31, 2014 and 2013, respectively, of the stock compensation expense into its deferred preservation costs and inventory costs.

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

15. Income Per Common Share

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

Three Months Ended

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

Three Months Ended

	March 31,					
<u>Diluted income per common share</u>		2014		2013		
Net income	\$	1,059	\$	2,192		
Net income allocated to participating securities		(21)		(50)		
Net income allocated to common shareholders	\$	1,038	\$	2,142		
Basic weighted-average common shares outstanding		27,376		26,861		
Effect of dilutive stock options and awards a		1,087		627		
Diluted weighted-average common shares outstanding		28,463		27,488		
Diluted income per common share	\$	0.04	\$	0.08		

The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares because the inclusion of these stock options would be antidilutive to income per common share. Accordingly, stock options to purchase a weighted-average 131,000 shares and 1.2 million shares for the three months ended March 31, 2014 and 2013, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

16. Segment Information

The Company has two reportable segments organized according to its products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue ® Surgical Adhesive ("BioGlue"), BioFoam® Surgical Matrix ("BioFoam"), PerClot, revascularization technologies, and HeRO Graft. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

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

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

Three Months Ended

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

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

Three Months Ended

	March 31,	March 31,			
	2014		2013		
Products:					
BioGlue and BioFoam	\$ 15,240	\$	15,464		
PerClot	916		864		
Revascularization technologies	1,684		2,191		
HeRO Graft	1,615		1,277		
Total products	19,455		19,796		
Preservation services:					
Cardiac tissue	7,190		6,645		
Vascular tissue	9,086		9,032		
Total preservation services	16,276		15,677		
Other ^a			63		
Total revenues	\$ 35,731	\$	35,536		

a The "Other" designation includes grant revenue.

PART I - FINANCIAL INFORMATION

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

Overview

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

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

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

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

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

Recent Events

CryoLife Asia Pacific

In February 2014 CryoLife announced the establishment of CryoLife Asia Pacific, a wholly owned subsidiary of CryoLife, to expand the Company's presence in the rapidly growing Asia-Pacific medical device market. To support this new subsidiary, CryoLife relocated Mr. Rich Gridley, Vice President Sales, Canada, Asia-Pacific, and The Americas, to a new regional headquarters in Singapore. In addition to his previous responsibilities, Mr. Gridley assumed the position of general manager, CryoLife Asia Pacific. He will manage CryoLife's sales expansion, product registrations, and new product introductions in the Company's Asia-Pacific distribution network, including Japan and China.

ProCol Distribution Agreement

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

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

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

PerClot

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

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

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

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

Regulatory Activity

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

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

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

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

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

Critical Accounting Policies

A summary of the Company's significant accounting policies is included in Note 1 of the "Notes to Consolidated Financial Statements," contained in the Company's Form 10-K for the year ended December 31, 2013. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company's operating results and financial condition. The summary consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require the Company to make estimates and assumptions. The Company did not experience any significant changes during the quarter ended March 31, 2014 in any of its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2013.

New Accounting Pronouncements

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

Results of Operations (Tables in thousands)

Revenues

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

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

Products

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

The Company's sales of products through its direct sales force to U.K. hospitals are denominated in British Pounds, and its sales to German, Austrian, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. If the exchange rates between the U.S. Dollar and the British Pound and/or Euro decline materially in the future, this would have a material, adverse effect on the Company's revenues denominated in these currencies.

BioGlue and BioFoam

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

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

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

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

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

PerClot

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

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

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

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

Revascularization Technologies

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

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

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

HeRO Graft

Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. HeRO Grafts are primarily distributed in domestic markets as a solution for ESRD in certain hemodialysis patients. HeRO Graft revenues for the three months ended March 31, 2014 increased 26%, as compared to the three months ended March 31, 2013, primarily due to an increase in the volume of kits sold as a result of an increase in procedure volume and an increase in the number of implanting physicians.

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

Preservation Services

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

Preservation services revenues, particularly revenues for certain high demand tissues, can vary from quarter-to-quarter and year-to-year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services. See further discussion of any specific items affecting cardiac and vascular preservation services revenues for the three months ended March 31, 2014 below.

Cardiac Preservation Services

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

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

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

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

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

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

Vascular Preservation Services

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

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

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

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

Cost of Products and Preservation Services

Cost of Products

			Ionths Ended arch 31.		
	_	2014 2013			
Cost of products	\$	\$ 3,801 \$			

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

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

Cost of Preservation Services

Three Months Ended

		March 31,	
	2014		
t of preservation services	\$ 9,457	\$	8,795

Cost of preservation services increased 8% for the three months ended March 31, 2014, as compared to the three months ended March 31, 2013. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

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

Gross Margin

Three Months Ended

		March 31,	
	2014		2013
Gross margin	\$ 22,473	\$	23,276
Gross margin as a percentage of total revenues	63%		65%

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

Operating Expenses

General, Administrative, and Marketing Expenses

Three Months Ended

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

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

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

Research and Development Expenses

Three Months Ended

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

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

Earnings

Three Months Ended

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

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

The Company's effective income tax rate was approximately 39% for the three months ended March 31, 2014, as compared to 28% for the three months ended March 31, 2013. The Company's income tax rate for the three months ended March 31, 2014 was unfavorably affected by the research and development tax credit, which has not yet been enacted for the 2014 tax year. The Company's income tax rate in 2013 was favorably impacted by the full year 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company's tax expense during the first quarter of 2013.

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

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

Seasonality

The Company believes the demand for BioGlue is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to the summer

holiday season in Europe and in the U.S. The Company's market for BioGlue in Japan is still in a growth phase, however, the Company believes that demand for BioGlue in Japan may continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by the slower summer holiday season in Japan.

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

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

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

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

Liquidity and Capital Resources

Net Working Capital

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

Overall Liquidity and Capital Resources

The Company's largest cash requirement for the three months ended March 31, 2014 was cash for general working capital needs, as the Company's accounts receivable balance increased significantly and its accrual and payable balances decreased significantly from December 31, 2013. The accounts receivable increase was due to the Company's recent sales, which have not yet been converted to cash. The accrual and payable decrease was due to a large number of scheduled annual payments which were made in the first quarter that are not normally paid in the rest of the year. In addition, the Company's other cash requirements included capital expenditures and cash dividend payments. The Company funded its cash requirements through its existing cash reserves.

CryoLife's credit agreement with General Electric Capital Corporation, as amended (the "GE Credit Agreement"), provides revolving credit for working capital, acquisitions, and other corporate purposes. The borrowing capacity under the GE Credit Agreement, which expires October 28, 2014, is \$20.0 million (including a letter of credit subfacility). The borrowing capacity may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least \$5.0 million in accounts in which General Electric Capital Corporation has a first priority perfected lien. As a result, these funds will not be available to meet the Company's liquidity needs during the term of the GE Credit Agreement and, as such, have been recorded as restricted cash and securities on the Company's Consolidated Balance Sheets. Also, the GE Credit Agreement requires that, after giving effect to a stock repurchase, the Company maintain liquidity, as defined in the agreement, of at least \$20.0 million. As of March 31, 2014 the outstanding balance under the GE Credit Agreement was zero, and \$20.0 million was available for borrowing.

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

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

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

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

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

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

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

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

The Company believes that its anticipated cash from operations and existing cash and cash equivalents will enable the Company to meet its current operational liquidity needs for at least the next twelve months. The Company's future cash requirements are expected to include cash to fund the PerClot clinical trials, to fund the PerClot declaratory judgment action, to make payments to Hancock Jaffe related to the ProCol distribution agreement, to fund business development activities, to repurchase the Company's common stock, to fund the cash dividend to common shareholders, to fund additional research and development expenditures, for general working capital needs, for capital expenditures, and for other corporate purposes. These items may have a significant effect on the Company's cash flows during the remainder of 2014. The Company may seek additional borrowing capacity or financing, pursuant to its shelf registration statement, for general corporate purposes or to fund other future cash requirements. If the Company undertakes further significant business development activity in 2014, it may need to finance such activities by drawing down monies under the GE Credit Agreement, obtaining additional debt financing, or using its shelf registration statement to sell equities.

The Company acquired net operating loss carryforwards from its acquisitions of Hemosphere and Cardiogenesis that the Company believes will reduce required cash payments for federal income taxes by approximately \$1.5 million for the 2014 tax year.

Net Cash Flows from Operating Activities

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

The Company uses the indirect method to prepare its cash flow statement and, accordingly, the operating cash flows are based on the Company's net income, which is then adjusted to remove non-cash items and for changes in operating assets and liabilities

from the prior year end. For the three months ended March 31, 2014 these non-cash items included a favorable \$1.5 million in depreciation and amortization expenses and \$845,000 in non-cash compensation.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the three months ended March 31, 2014 these changes included unfavorable adjustments of \$2.7 million due to the timing differences between the recording of receivables and the receipt of cash, \$1.1 million due to timing differences between the recording of accounts payable, accrued expenses, and other liabilities and the actual payment of cash, and \$821,000 in increased balances of inventory and deferred preservation costs for which payments have already been made.

Net Cash Flows from Investing Activities

Net cash used in investing activities was \$1.7 million for the three months ended March 31, 2014, as compared to \$1.1 million for the three months ended March 31, 2013. The current year cash used was primarily due to \$1.0 million in capital expenditures.

Net Cash Flows from Financing Activities

Net cash used in financing activities was \$1.1 million for the three months ended March 31, 2014, as compared to \$2.1 million for the three months ended March 31, 2013. The current year cash used was primarily due to \$772,000 in cash dividends paid.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of March 31, 2014 are as follows (in thousands):

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

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

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

The contingent payment obligations include obligations related to the Company's acquisition of Hemosphere and transaction with SMI. The contingent payment obligation for Hemosphere represents the payments that the Company will make if certain revenue milestones are achieved. The schedule includes one contingent milestone payment for \$2.5 million that the Company believes it is likely to pay in 2016, although the timing of this payment may change. The schedule excludes one Hemosphere contingent milestone payment of up to \$2.0 million, as the Company cannot make a reasonably reliable estimate of when this future payment may be made, if at all. The contingent payment obligation for PerClot represents the payments that the Company will make if certain FDA regulatory approvals and other commercial milestones are achieved. The schedule excludes one PerClot contingent milestone payment of \$500,000, as the Company cannot make a reasonably reliable estimate of timing of this future payment.

The Company's compensation payment obligations represent estimated payments for post-employment benefits for the Company's Chief Executive Officer ("CEO"). The timing of the CEO's post-employment benefits is based on the December 2015 expiration date of the CEO's current employment agreement; however, payment of this benefit may be accelerated upon the

occurrence of certain events, including the voluntary retirement of the CEO or termination of the CEO's employment in conjunction with certain change in control events, and payment could be extended in the event the term of the CEO's employment contract is extended. The Company's Compensation Committee has entered into negotiations with our CEO regarding a one-year extension of his employment contract.

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

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

Capital Expenditures

Capital expenditures were \$1.0 million for both of the three month periods ended March 31, 2014 and 2013. Capital expenditures in the three months ended March 31, 2014 were primarily related to the routine purchases of manufacturing and tissue processing equipment, including support for the Company's HeRO Graft and PerClot product lines; revascularization technologies lasers; computer and office equipment; computer software; and leasehold improvements needed to support the Company's business.

Forward-Looking Statements

This Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. Forward-looking statements give the Company's current expectations or forecasts of future events. The words "could," "may," "might," "will," "would," "should," "pro forma," "potential," "pending," "intend," "believe," "expect," "anticipate," "estimate," "plan," "future," 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, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding:

- Plans, costs, and expected timelines regarding clinical trials to obtain PMA to distribute PerClot in the U.S., regulatory approval for PerClot, the distribution of PerClot in certain markets after the requisite regulatory approvals are obtained, and the Company's expectation that it will terminate its minimum purchase requirements after regulatory approval of PerClot;
- Plans regarding the timing, scope, and targeted indications for the launch of PerClot Topical;
- Potential benefits and additional applications of the Company's surgical adhesives, sealants, hemostats, and TMR treatment;
- Revenue trend estimates for the Company's products and services for 2014;
- Plans related to regulatory approval in certain markets for BioFoam, and the subsequent distribution of BioFoam in those markets;
- Expectations regarding growth opportunities for BioGlue in Japan and China;
- Expectations regarding 2014 tissue processing revenues;
- Receipt of ProCol inventory from Hancock Jaffe, and the receipt of distribution fees and profits resulting from the sale of ProCol;
- Expected payments to Hancock Jaffe pursuant to the ProCol exclusive distribution agreement;
- Expectations regarding 2014 HeRO Graft revenues and revenue variability;
- Potential for competitive products and services to affect the market for the Company's products and services;
- Anticipated payment of quarterly dividends each year;
- Expectations regarding the recoverability and realizability of deferred tax assets and the anticipated benefits of net operating loss carryforwards;
- Estimates of fair value of acquired assets, and its belief that the estimates are reasonable;
- Expectations that the Company will continue to renew certain acquired contracts and procurement agreements for the foreseeable future;
- Assumptions regarding the adequacy of, and competitive advantages conferred by, its intellectual property protections;
- Plans and expectations regarding research and development of new technologies and products;
- Expectations about whether and when it may receive additional payments related to its sale of Medafor stock;
- Expectations that general, administrative, and marketing expenses will increase in 2014, as compared to 2013, before consideration of the effects of litigation and business development expenses;
- Expectations that research and development expenses will increase materially in 2014, as compared to 2013;
- The Company's belief that its sales of PerClot, upon FDA approval, and its derivative products will not infringe the patent held by Bard, that the costs associated with the declaratory judgment action against Bard and certain of its subsidiaries will be material, and that the pace at which those costs will be incurred will be unpredictable;
- Expectations regarding business consolidations in the healthcare industry that could exert downward pressure on demand for Company products and the fees charged by the Company;

- Expectations regarding sales of BioGlue, PerClot, handpieces, and laser consoles and the factors affecting such sales;
- The Company's belief that healthcare policy and law changes may have a material adverse effect on the business;
- The Company's belief that the underlying collateral is sufficient to secure the Company's \$2.0 million loan to ValveXchange;
- The Company's belief regarding the sufficiency of its response to the 2014 CryoLife Form 483 and the Warning Letter, and that any issues related to the FDA's observations in the 2014 CryoLife Form 483 and the Warning Letter will not have a material effect on the Company;
- Expectations regarding the impact of the re-labeling and change in expiration dating with respect to BioGlue 5ml syringes;
- The Company's beliefs and underlying assumptions regarding the seasonal nature of the demand for some of its products and services;
- Adequacy of the Company's financial resources and its belief that it will have sufficient cash to meet its operational liquidity needs for at least the next twelve months;
- Estimates of contingent payments and royalties that may be paid by the Company and the timing of such payments;
- The impact on cash flows of funding business development activities and the potential need to obtain additional borrowing capacity or financing;
- Expectations regarding the source of any future payments related to any unreported product or tissue processing liability claims;
- The anticipated impact of changes in prevailing economic conditions, interest rates, and foreign currency exchange rates;
- Constraints imposed on the Company by its lender under the existing credit facility;
- Plans regarding acquisition and investment opportunities of complementary product lines and companies;
- The anticipated effect of suppliers'/sources' inability to deliver critical raw materials or tissues and/or the Company having to source supply from an alternate supplier;
- Expected impacts of issuance of additional shares and share repurchases on financial results calculated on a per-share basis;
- Issues that may affect the Company's future growth, financial performance, and cash flows; and
- Other statements regarding future plans and strategies, anticipated events, or trends.

These statements are based on certain assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions, and expected future developments as well as other factors it believes are appropriate in the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from the Company's expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risk factors set forth below, the risk factors set forth under Part I, Item 1A of the Company's Form 10-K for the year ended December 31, 2013, and other factors, many of which are beyond the control of the Company. Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by the Company will be realized or, even if substantially realized, that they will have the expected consequences to or effects on the Company or its business or operations. The Company assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

Risks and Uncertainties

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

- We are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product;
- Our BioGlue patent has expired in the U.S. and most of the rest of the world. Competitors may utilize the inventions disclosed in the expired patents in competing products, although the competing product will have to be approved by the appropriate regulatory authority;
- Competitors have obtained FDA approval for indications in which BioGlue has been used off-label and for which we cannot market BioGlue, which has reduced, and could continue to reduce, the addressable procedures for BioGlue;
- Our products and tissues are subject to many significant risks, including being recalled or placed on hold by us, the FDA, or other regulatory bodies and being subjected to adverse publicity, which could lead to decreased use, additional regulatory scrutiny, or product liability lawsuits;
- Regulatory agencies could require us to change or modify our processes, procedures, and manufacturing operations, and such agencies could
 reclassify or reevaluate our clearances and approvals to sell our medical devices and tissue services;
- Our tissues, which are not sterile when processed, and our medical devices allegedly have caused, and may in the future cause, injury to patients, which has exposed, and could in the future expose, us to tissue processing and product liability claims and additional regulatory scrutiny and inspections as a result;
- The FDA may determine that our corrective actions have not, and/or proposed corrective actions will not, adequately address the issues raised in the 2014 CryoLife Form 483 and/or the Warning Letter. If we have failed to respond to the notice of violations in the 2014 CryoLife Form 483 or the Warning Letter to the FDA's satisfaction, we may be subject to additional regulatory action by the FDA, including recalls, injunctions, and/or civil money penalties, and the demand for our products and services could be negatively impacted by adverse publicity with respect to the 2014 CryoLife Form 483 and/or the Warning Letter. In addition, further actions required to be taken in response to the 2014 CryoLife Form 483 and/or the Warning Letter could impact the availability of our products and tissues and our cost structure, including our revenues, financial condition, profitability, and cash flows;
- We will not fully realize the benefit of our investment in our distribution and license and manufacturing agreements with Starch Medical, Inc. unless we are able to obtain FDA approval to distribute PerClot in the U.S., which will require an additional commitment of funds;
- We will not fully realize the benefit of our distribution agreement with Hancock Jaffe unless Hancock Jaffe is able to obtain approval of a PMA with respect to its new manufacturing facility, which is beyond our control;
- If Hancock Jaffe is ultimately unable to obtain approval of a PMA with respect to its new facility, we may be unable to obtain refunds of amounts previously paid to Hancock Jaffe or to obtain sufficient value from pledged collateral, and, therefore, a portion of the amounts we have paid to Hancock Jaffe may have to be written-down or impaired, and such amounts could be material;
- We may ultimately be unsuccessful in our PerClot clinical trials and/or may be unable to obtain FDA approval to market and distribute PerClot in the U.S. Even if we receive FDA approval, we may be unsuccessful in our efforts to sell PerClot in the U.S. as other competing products may have penetrated the market by that time;
- Our declaratory judgment action against Bard and certain of its subsidiaries will be expensive, and if we lose, we may be prohibited from selling PerClot and its derivative products, such as PerClot Topical, or may have to pay substantial royalties or damages related to such sales;
- We have inherited risks and uncertainties related to Cardiogenesis' and Hemosphere's businesses;
- The receipt of impaired materials or supplies that do not meet our standards, the recall of materials or supplies by our vendors or suppliers, or our inability to obtain materials and supplies could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows;
- As a result of the funding issues that have been affecting ValveXchange, our Loan to ValveXchange may become uncollectible, which could have a material, adverse impact on our business. Even if ValveXchange is able to secure additional financing, it may nonetheless default on the Loan in the future, we may need to foreclose on the Loan, and there is no guarantee that the security for the notes will be sufficient to repay the Loan;
- We continue to evaluate expansion through acquisitions, licenses, investments, and other distribution arrangements in other companies or technologies, and such actions involve the risk of unknown liabilities, and could result in the dilution

of our stockholders' value, the consumption of resources that may be necessary to operate our business, the incurrence of debt on unfavorable terms, and unfavorable tax consequences;

- We may not realize the anticipated benefits from acquisitions, and we may be unable to integrate, upgrade, or replace systems acquired in acquisitions, secure the services of key employees, or succeed in the marketplace with the acquisition;
- Our sales are impacted by challenging domestic and international economic conditions and their constraining effect on hospital budgets, and demand for our products and tissues could decrease in the future, which could have a material, adverse impact on our business;
- Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material, adverse impact on us;
- Key growth strategies may not generate the anticipated benefits;
- We may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and our new
 products and services may not achieve market acceptance;
- Extensive government regulation may adversely impact our ability to develop and market products and services, and restrictive laws, regulations, and rules could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows;
- Uncertainties related to patents and protection of proprietary technology may adversely impact the value of our intellectual property or may result in our payment of significant monetary damages and/or royalty payments, negatively impacting our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary technology rights against others;
- Our right to receive additional payments for our Medafor common stock is subject to revenue performance conditions related to the Arista product, as to which we have no control or ability to predict;
- Intense competition may impact our ability to operate profitably;
- If we are not successful in expanding our business activities in international markets, it could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows;
- We are dependent on the availability of sufficient quantities of tissue from human donors;
- Consolidation in the healthcare industry could continue to result in demands for price concessions, limits on the use of our products and tissues, and limitations on our ability to sell to certain of our significant market segments;
- The success of many of our products and tissues depends upon strong relationships with physicians;
- Our existing insurance policies may not be sufficient to cover our actual claims liability, and we may be unable to obtain future insurance policies
 in an amount sufficient to cover our anticipated claims at a reasonable cost or at all;
- We are not insured against all potential losses. Natural disasters or other catastrophes could adversely impact our business;
- Our current plans and ability to continue to pay a quarterly cash dividend may change;
- Our credit facility, which expires in October 2014, limits our ability to pursue significant acquisitions and also may limit our ability to borrow;
- Continued fluctuation of foreign currencies relative to the U.S. Dollar could materially, adversely impact our business;
- Rapid technological change could cause our products and services to become obsolete; and
- We are dependent on our key personnel.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company's interest income and interest expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents of \$32.8 million and restricted cash of \$5.7 million and interest paid on the Company's variable rate line of credit as of March 31, 2014. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended March 31, 2014, affecting the Company's cash and cash equivalents, restricted cash and securities, and line of credit would not have a material effect on the Company's financial position, profitability, or cash flows.

Foreign Currency Exchange Rate Risk

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

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

An additional 10% adverse change in exchange rates from the exchange rates in effect on March 31, 2014 affecting the Company's balances denominated in foreign currencies would not have had a material effect on the Company's financial position or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by the Company for the three months ended March 31, 2014 affecting the Company's revenue and expense transactions denominated in foreign currencies, would not have had a material effect on the Company's financial position, profitability, or cash flows.

Item 4. Controls and Procedures.

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

The Company's management, including the Company's President and CEO and the Company's Executive Vice President of Finance, Chief Operating Officer, and CFO, does not expect that its Disclosure Controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple error or mistake. The Company's Disclosure Controls have been designed to provide reasonable assurance of achieving their objectives.

Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of March 31, 2014, the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

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

Part II - OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

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

Item 1A. Risk Factors.

There have been no material changes to the Risk Factors as previously disclosed in Part I, Item 1A, "Risk Factors" in our 10-K for the year ended December 31, 2013.

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

(c) The following table provides information about purchases by the Company during the quarter ended March 31, 2014 of equity securities that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934:

Issuer Purchases of Equity Securities Common Stock and Common Stock Units

Period	Total Number of Common Shares and Common Stock Units Purchased	Average Price Paid per Common Share		Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	of C Th Purc	Dollar Value Common Shares at May Yet Be hased Under the ns or Programs
01/01/14 - 01/31/14	29,694	\$	9.79		\$	13,476,633
02/01/14 - 02/28/14	99,441		9.82			13,476,633
03/01/14 - 03/31/14						13,476,633
Total	129,135		9.81			13,476,633

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

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

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibit index can be found below.

Exhibit Number	Description
3.1	Amended and Restated Articles of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Form S-3 filed February 22, 2012.)
3.2	Amended and Restated By-Laws. (Incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed July 27, 2011.) (File No. 001-13165)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.) (File No. 001-13165)
4.2	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.) (File No. 001-13165)
10.1*+	Exclusive Supply and Distribution Agreement, dated as of March 26, 2014, by and between CryoLife, Inc. and Hancock Jaffe Laboratories, Inc.
31.1*	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32** 101.INS* 101.SCH* 101.CAL*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002. XBRL Instance Document XBRL Taxonomy Extension Schema Document XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

Filed herewith.

^{**} Furnished herewith.

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

SIGNATURES

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

CRYOLIFE, INC. (Registrant)

/s/ STEVEN G. ANDERSON /s/ D. ASHLEY LEE

STEVEN G. ANDERSON

Chairman, President, and

Chief Executive Officer

(Principal Executive Officer)

Chief Financial Officer

(Principal Financial and Accounting Officer)

April 30, 2014

DATE

CONFIDENTIAL TREATMENT REQUESTED

[***] – CONFIDENTIAL PORTIONS OF THIS AGREEMENT WHICH HAVE BEEN REDACTED ARE MARKED WITH BRACKETS ("[***]"). THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.

EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT

This EXCLUSIVE SUPPLY AND DISTRIBUTION AGREEMENT (the "Agreement") is made and entered into effective as of March 26, 2014 (the "Effective Date") by and between Hancock Jaffe Laboratories, Inc., a corporation organized under the laws of the state of Delaware ("HJL"), with an address at 70 Doppler, Irvine, California 92618 and CryoLife, Inc., a Florida corporation ("CL"), with an address at 1655 Roberts Blvd. NW, Kennesaw, Georgia 30144, (hereinafter sometimes individually or collectively referred to as a "Party" or the "Parties," respectively).

RECITALS

- HJL is engaged in the design, development, manufacture and sale of products for use for vascular access and peripheral vascular indications.
- 2. CL sells and distributes medical devices and processes tissues for use in cardiac and vascular surgeries.
- 3. HJL once manufactured the Products but ceased manufacturing the Products when it moved locations.
- 4. HJL desires to commence manufacturing the Products again and to supply such quantities of Products as CL desires, and CL desires to obtain from HJL a supply of the Products so that CL can exclusively distribute the Products worldwide.
- 5. CL and HJL desire to formalize their relationship by entering into this Agreement for the purpose of developing, manufacturing, supplying and distributing the Products, all as further set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual representations, warranties, covenants and agreements contained herein, the Parties hereto agree as follows:

ARTICLE 1 DEFINITIONS

- 1.1. AAA shall have the meaning set forth in Section 17.1.
- 1.2. Act shall mean the United States Food, Drug and Cosmetic Act and the regulations promulgated thereunder, as amended from time to time
- 1.3. Acquisition Agreement shall have the meaning set forth in Section 16.1.

- 1.4. Actual Quarterly Spend shall have the meaning set forth in Section 5.1.
- 1.5. Additional Product(s) shall mean all improvements to, modifications of or subsequent generations of the Products that do not affect the form, fit or function of the Product and any support product(s) developed by HJL during the term of this Agreement.
- 1.6. Affiliates shall mean, with respect to either Party, those entities controlled by, in control of, or under common control with such person. For the purposes of this definition, "control" means ownership or control, direct or indirect, of more than 50% of the voting capital or equity participation of an entity.
- 1.7. Agreement shall have the meaning set forth in the Preamble.
- 1.8. Applicable Laws shall mean all applicable common law, statutes, ordinances, rules, regulations or orders of any governmental authority, including applicable regulatory laws, rules and regulations, within the Territory.
- 1.9. Breaching Party shall have the meaning set forth in Section 12.1.
- 1.10. CAPA shall have the meaning set forth in Section 2.5.
- 1.11. CE Mark shall mean the Conformité Européenne mark given by a Notified Body that certifies that the Products comply with all Applicable Laws.
- 1.12. Change in Control shall mean (i) any consolidation or merger of either Party with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of such Party immediately prior to such consolidation, merger or reorganization, own less than fifty percent (50%) of such Party's voting power immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions to which either is a Party in which in excess of fifty percent (50%) of such Party's voting power is transferred; or (ii) a sale, lease or other disposition of all or substantially all the assets of either Party.
- 1.13. CL shall have the meaning set forth in the Preamble.
- 1.14. CL Confidential Information shall mean any non-public information about CL, its development of intellectual property and its operations including, but not limited to, any non-public information or scientific or technical data, know-how, or expertise of CL relating to the Products, existing as of the Effective Date or developed during the term of this Agreement and non-public information that relates to its financial statements, marketing or finances, market research, customers, customer lists, markets, product plans, business plans, services, software, developments, inventions, processes, procedures, methods, know-how, designs, data, programs, drawings, and engineering information.
- 1.15. CL Indemnified Party shall have the meaning set forth in Section 12.1.
- 1.16. CL Required Markets shall have the meaning set forth in Section 2.2.
- 1.17. Claims shall have the meaning set forth in Section 12.1.
- 1.18. Confidential Information shall mean, as appropriate, CL Confidential Information and/or HJL Confidential information.
- 1.19. Coronary Indications shall mean uses of any products for indications relating to the creation of a blood

pathway around a blocked artery in the heart.

- 1.20. Disposition shall have the meaning set forth in Section 16.2.
- 1.21. Distribution Fee shall have the meaning set forth in Section 7.5.
- 1.22. Effective Date shall have the meaning set forth in the Preamble.
- 1.23. Existing Inventory shall have the meaning set forth in Section 5.2.
- 1.24. FDA shall mean the Food and Drug Administration of the U.S. Department of Health and Human Services.
- 1.25. FDA Approval shall mean the date on which a Product obtains approval from the FDA to market and sell the Products under the Act.
- 1.26. First Refusal Option shall have the meaning set forth in Section 16.2.
- 1.27. F.O.B. shall have the meaning set forth in Section 6.6.
- 1.28. Force Majeure shall have the meaning set forth in Section 18.1.
- 1.29. Foreign Approval(s) shall have the meaning set forth in Section 2.3.
- 1.30. HJL shall have the meaning set forth in the preamble.
- 1.31. HJL Confidential Information shall mean any non-public information about HJL, its development of Intellectual Property, and its operations including, but not limited to, any non-public information or scientific or technical data, know-how, or expertise of HJL relating to the Products existing as of the Effective Date or developed during the term of this Agreement and non-public information that relates to its financial statements, marketing or finances, market research, customers, markets, product plans, business plans, services, software, developments, inventions, processes, procedures, methods, know-how, designs, data, programs, drawings, and engineering information.
- 1.32. HJL Disposition Notice shall have the meaning set forth in Section 16.2.
- 1.33. HJL Indemnified Party shall have the meaning set forth in Section 12.1.
- 1.34. HJL Intellectual Property shall have the meaning set forth in Section 14.4.
- 1.35. HJL Invention(s) shall mean any invention whether or not patentable, conceived or developed without the use of any CL Confidential Information by employees of HJL, alone or together with any Third Party (including Affiliates, agents or consultants of HJL or a person or entity working in any fashion on the behalf of HJL but excluding CL), during the term of this Agreement, or prior to the Effective Date.
- 1.36. GMP/QSR Regulations shall mean the Good Manufacturing Practices/Quality System Regulations set forth in 21 C.F.R. Section 820.
- 1.37. Indemnifying Party shall have the meaning set forth in Section 12.3.
- 1.38. Initial Build Inventory shall have the meaning set forth in Section 5.1.

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- 1.39. Initial Term shall have the meaning set forth in Section 10.1.
- 1.40. Intellectual Property means (a) discoveries, inventions, improvements, concepts and ideas, whether or not patentable, (b) works of authorship fixed in a tangible medium of expression, (c) trademarks, (d) trade secrets and know-how, (e) all proprietary rights relating thereto, including all applications, registrations, extensions, divisionals and renewals in connection therewith and (f) all documents and information relating to the foregoing.
- 1.41. Manufacturer of Record shall mean the Party who owns the Premarket Clearance and is responsible for compliance with conditions of clearance of the Premarket Clearance and for all communications with the Notified Body regarding CE Mark designations. For purposes of this Agreement, HJL shall be the Manufacturer of Record for all Products.
- 1.42. Manufacturing Reimbursement shall have the meaning set forth in Section 5.1.
- 1.43. MDR shall have the meaning set forth in Section 2.6.
- 1.44. Medical Device Establishment Registration shall have the meaning set forth in Section 2.1.
- 1.45. Net Sales means the total sales of CL from the commercial distribution of Products excluding fees, freight and shipping costs, and reduced by credits and returns.
 - The term "Net Sales" shall not include revenue received by CL (or any of its Affiliates) from transactions with an Affiliate of CL unless such Affiliate is the end user of the Product.
- 1.46. New Product shall mean any improvement to or modification of the Product that affects the form, fit or function and for which a new regulatory submission or clearance from a regulatory body is required.
- 1.47. New Product Development Notice shall have the meaning set forth in Section 4.5.
- 1.48. Non-Breaching Party shall have the meaning set forth in Section 12.1.
- 1.49. Notified Body shall mean a certification organization which the competent national authority of a European member state designates to carry out compliance assessments of the Products in the relevant market.
- 1.50. Nonconforming Product shall have the meaning set forth in Section 6.7.
- 1.51. Option shall have the meaning set forth in Section 16.1.
- 1.52. Option Acquisition Price shall mean: (i) [***] multiplied by CL's Net Sales for the [***] full calendar quarters immediately prior to the date that CL provides HJL with written notice of the exercise of the Option plus the Royalty Payment.
- 1.53. Option Period shall have the meaning set forth in Section 16.2.
- 1.54. Party(ies) shall have the meaning set forth in the preamble.

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- 1.55. Product(s) shall mean Vascular Bioprosthesis for vascular access and peripheral vascular indications that is currently branded as ProCol®, but shall not include products intended for Coronary Indications with a diameter of 3 mm or less and a length of 20 cm or less.
- 1.56. Product Information shall have the meaning set forth in Section 11.1
- 1.57. Profit Sharing Payments shall have the set forth in Section 7.6.
- 1.58. Purchased Assets shall have the meaning set forth in Section 16.1.
- 1.59. Remedial Action shall have the meaning set forth in Section 2.5.
- 1.60. Renewal Period shall have the meaning set forth in Section 10.1.
- 1.61. Requested Delivery Date shall have the meaning set forth in Section 6.5.
- 1.62. Royalty Payment shall mean for the [***] year period following the closing of the acquisition of the assets underlying the Option, the following royalty paid by CL to HJL: an amount equal to [***]% of CL's Net Sales, provided that in no event shall such Royalty Payment exceed \$[***] in any 12 month period or \$[***] in the aggregate. Such Royalty Payment shall be paid quarterly within 60 days after the end of each calendar quarter.
- 1.63. Rules shall have the meaning set forth in Section 17.1.
- 1.64. Shipping Point shall have the meaning set forth in Section 6.6.
- 1.65. Specifications shall mean the documents describing the form, fit and function of the Products that obtain FDA Approval under the FDA's premarket approval process including (i) HJL's design and functionality specifications relating to the Products and (ii) any specifications for manufacturing, testing, storing, packaging, shipping or labeling the Products consistent with regulatory requirements as may be amended or revised from time to time as set forth herein. Current Specifications for each product category have been agreed to by the Parties herein, and they may be changed from time to time by the agreement of the Parties herein.
- 1.66. Technology shall have the meaning set forth in Section 4.2.
- 1.67. Territory shall mean worldwide.
- 1.68. Third Party shall mean any person or entity other than a Party or an Affiliate.
- 1.69. Transfer Prices shall have the meaning set forth in Section 7.1.
- 1.70. United States shall mean the several states of the United States of America and the District of Columbia, and the territories and possessions of the United States, including the Commonwealth of Puerto Rico.

1.71. Vigilance Report shall mean the incident report for death or serious injury required under the post market surveillance system as defined by the European Council Directive 93/42/EEC or the relevant and applicable equivalent of any other regulatory body.

ARTICLE 2 REGULATORY

- 2.1. <u>Medical Device Establishment Registration</u>. HJL shall maintain a Medical Device Establishment Registration (as defined under the Act) as Manufacturer of Record and Specifications developer for the Products, as is required.
- 2.2. <u>U.S. Approval/Clearance</u>. HJL shall be responsible, at its expense, for filing and obtaining and maintaining (including development of and compliance with necessary quality programs) all necessary authorizations from regulatory authorities in the United States including the FDA, necessary for the sale of the Products in the United States ("CL Required Markets"). HJL's obligations under this Section 2.2 shall include the preparation and filing of any required submissions and the establishment and oversight of any required clinical investigations and clinical follow-up relating to future commercial sale of the Products in, at a minimum, the CL Required Markets. HJL will provide CL with drafts of all proposed filings with any U.S. federal, state or foreign regulatory agency for review and comment by CL in advance of filing with the applicable authority.
- 2.3. <u>Foreign Approvals</u>. To the extent mutually agreed, HJL shall be responsible, on a timely basis, for filing, obtaining and maintaining all necessary "device" or "medical" regulatory approvals from foreign regulatory authorities necessary for the commercial sale of the Products in markets other than the United States ("Foreign Approvals"). The expense for obtaining such approvals shall be CL's responsibility. Except as otherwise required by law or agreed by the Parties, HJL shall be primarily responsible for all dealings with the appropriate competent authority such as notification, medical device vigilance and national labeling issues, and HJL shall bear final legal responsibility for the content of all its own labeling, provided however that if it chooses, CL may make such filings and HJL shall supply assistance as reasonably requested by CL.
- 2.4. <u>Manufacturing Compliance</u>. In the event that HJL determines that its manufacturing and/or quality systems, or any portion thereof, are not in compliance with any Applicable Law, it shall immediately notify CL in writing. Within three business days of such determination, HJL shall provide in writing to CL justification for non-compliant processes and an explanation of the controls that will be implemented to improve those processes.
- 2.5. Remedial Actions. Each Party will notify the other immediately, and promptly confirm such notice in writing, if it obtains information indicating that any of the Products may be subject to any recall, field corrective action or other regulatory action (other than a corrective and preventive action ("CAPA") under the Act) with respect to a Product taken either by virtue of applicable federal, state, foreign or other law or regulation or good business judgment (a "Remedial Action"). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action; provided that CL shall have sole responsibility for collecting information from its customers, including customer complaints. HJL will determine in good faith and in consultation with CL whether to commence any Remedial Action with respect to the Product. Each Party will maintain adequate records to permit the Parties to trace the manufacture of the Product and the distribution and use of the Product. In the event that HJL determines that any Remedial Action with respect to the Product should be commenced or that a Remedial Action is required by any governmental authority having jurisdiction over the matter, HJL will control and coordinate all efforts necessary to conduct such Remedial Action. If HJL conducts any Remedial Action related to the Product and HJL is determined to be responsible for the problem requiring the Remedial Action (i.e., a problem arises from faulty manufacture), HJL, at CL's option, will either issue a credit to CL or reimburse CL for the sales price of all CL devices recalled in such Remedial Action and the other

reasonable costs incurred by CL of conducting such Remedial Action. HJL shall have sole responsibility for handling any CAPA's. CL shall cooperate with HJL to the extent reasonably requested by HJL in handling any CAPA, provided that its reasonable costs in assisting with the CAPA will be reimbursed by HJL.

- 2.6. Complaints and Medical Device Reporting. Each Party will comply with applicable provisions of the Medical Device Reporting systems, including the requirements of 21 CFR Part 803, and each Party will cooperate with the other for the efficient compliance therewith. CL and HJL agree to notify the other within two (2) business days of receipt from any customer of any complaint or fileable Medical Device Report ("MDR") relating to the Product. HJL will investigate such complaint or MDRs/Vigilance Reports and forward to CL all information relating to any defects in the performance, design, or quality of the Products. HJL shall investigate all instances of product failure or inadequacy documented by CL and forwarded by CL for investigation. HJL shall provide a written summary of the findings from such investigation to CL within seven days following the date that HJL is informed of such complaint or MDR. HJL shall have sole responsibility for filing the MDR with the appropriate regulatory agency.
- 2.7. <u>Vigilance Reporting</u>. HJL will notify CL in writing if a Vigilance Report is required to be filed with respect to the Product. HJL, at its sole cost and expense, will be responsible for complying with Vigilance Reporting requirements for the Product. HJL will remain responsible for any and all Product investigation as provided in Section 2.6.
- Product, its manufacture and the Product's regulatory and quality status, at CL's expense, as reasonably deemed necessary by CL, but no more frequently than once in any 12 month period, unless CL determines in good faith that exceptional circumstances require more frequent audits. The audit may include, without limitation, records relating to manufacturing compliance with the Specifications, compliance with quality control and inspection reports procedures, compliance with GMP/QSR Regulations, CE Mark certification records and procedures, regulatory compliance, and after the following certifications have been obtained compliance with ISO 13485:1996 and EN 46001 requirements. Such audits will be conducted during HJL's normal business hours, after three business days' prior written notice to HJL by CL. HJL will make its regulatory compliance and quality assurance personnel reasonably available to CL in connection with such audits. If CL recommends any corrective actions to HJL in connection with such audits, HJL will take any corrective action recommended by CL within 30 days of receipt of any corrective action recommendations, if possible, or will inform CL in writing of the reasons why HJL believes such corrective action is not required or cannot be completed within such 30 day period. CL will be given access to audit any corrective action.
- 2.9. <u>Regulatory Inspections</u>. HJL will promptly notify CL of any inspection of its facilities manufacturing the Product or any component part of a Product by the FDA, ISO, CE Mark certification organization or other federal, state, local or other regulatory agency which relates to the manufacture, assembly, packaging or regulatory status of the Product and provide CL with information about the progress and outcome of such inspection, including, without limitation, copies of any notice of observations or warnings, requests for Remedial Action, CAPA's or other adverse findings. [Add initial inspection language].
- 2.10. Additional Quality Requirements. HJL shall comply with those additional quality requirements set forth in Exhibit A.

ARTICLE 3 AUDIT RIGHTS

CL and its Affiliates shall maintain accurate books and records in accordance with generally accepted accounting principles showing sales of the Products by CL and its Affiliates in sufficient detail to enable Net

Sales to be determined. In addition, each Party shall maintain accurate books and records in accordance with generally accepted accounting principles to enable each Party to monitor compliance by the other with the terms of this Agreement. Each Party (or its accountants) shall have the right to inspect such books and records at reasonable intervals (but no more frequently than once in any twelve month period) and upon reasonable prior written notice. Such inspections shall occur during normal business hours at the offices of the Party being inspected and at the expense of the inspecting Party; provided, however, that if such inspection shall reveal an overpayment or underpayment by a Party of amounts actually due of more than five percent (5%), then the Party being inspected shall bear the expense of such inspection. Any deficiencies in payment or overpayments shall be immediately due and payable together with interest at the rate of eighteen percent (18%) per annum from the date or dates such amounts should have been paid.

ARTICLE 4 APPOINTMENT AS EXCLUSIVE DISTRIBUTOR

- 4.1. <u>Scope and Consideration</u>. Subject to the terms and conditions of this Agreement, HJL grants to CL and its Affiliates the exclusive right to market, sell and distribute the Products in the Territory.
- 4.2. Exclusivity. CL's distribution rights under this Agreement shall be exclusive in the Territory for the Products. HJL shall not sell the Products to any party except to CL. In addition, HJL shall not license or transfer the technology, consisting of know-how and manufacturing equipment necessary or helpful for the manufacture of the Products and the process employed in the manufacture thereof (the "Technology"), to any Third Party that would enable or allow such Third Party to manufacture the Products or other products or services competitive with the Products without CL's prior written consent. HJL represents and warrants to CL that HJL has not entered into any other agreements, written or oral, with any Third Party permitting any party other than HJL from manufacturing, selling or distributing Products in the Territory, and covenants and agrees that during the term of this Agreement, HJL will (i) not enter into any such agreement in the Territory or (ii) itself sell, market, promote, manufacture or distribute any Products in the Territory (except in accordance with this Agreement) or any products or services competitive with the Products without CL's prior written consent.
- 4.3. <u>Subdistributors and Subagents</u>. CL may appoint subdistributors or subagents for distribution of the Products in the Territory, and may provide to HJL a list of such subdistributors from time to time. Notwithstanding such appointment of subdistributors, CL shall remain fully responsible for the performance of all of its covenants and obligations hereunder, and any sales by HJL to such subdistributor requested by CL shall be billed by HJL to CL directly.
- 4.4. Additional Products. CL's right to distribute Products under this Agreement includes the right to distribute Additional Products. If HJL, individually or jointly with CL, develops Additional Products during the term of this Agreement, HJL shall notify CL in writing promptly after HJL estimates the date that such Additional Product will be available for commercial sale in the Territory, and this Agreement shall automatically be amended to include any such Additional Products, with CL's written consent.
- 4.5. New Products. If HJL develops a New Product during the term of this Agreement, HJL shall notify CL in writing (a "New Product Development Notice") promptly after HJL estimates the date that such New Product will be available for commercial sale in the Territory, and, subject to CL's written consent, such new Product shall be deemed to be part of this Agreement.
- 4.6. <u>Ownership</u>. Ownership of and rights to New Products, Additional Products and other developments and inventions that are developed jointly by CL and HJL shall be determined in accordance with Applicable Law, including applicable patent law.

ARTICLE 5 MANUFACTURING REIMBURSEMENT AND INITIAL BUILD

5.1. Manufacturing Reimbursement.

- (a) CL shall reimburse HJL for certain of HJL's costs to restart and validate its manufacturing operations at HJL's facility at 70 Doppler, Irvine, California, in an amount of up to \$2,258,070 (such amount shall be the "Manufacturing Reimbursement"). Such Manufacturing Reimbursement shall also be used by HJL to obtain FDA Approval for manufacturing the Products to allow for commercial sale by CL, including the manufacture of commercially saleable units of Products. Such Manufacturing Reimbursement shall be advanced to HJL according to the budget as detailed in Exhibit B every calendar quarter commencing on the Effective Date. In the event the Effective Date is not April 1, 2014, CL shall make an initial Manufacturing Reimbursement payment equal to a pro rata amount of the payments specified in the budget based on the remaining days in that calendar quarter, if any. Following the end of each calendar quarter period, a reconciliation shall be made with HJL and CL of actual expenditures during the quarter. In order to facilitate such reconciliation, HJL shall provide CL with supporting documentation and data along with other information reasonably requested by CL for CL to verify expenditures incurred by HJL (such amount the "Actual Quarterly Spend"). If the Actual Quarterly Spend is within five percent of the quarterly Manufacturing Reimbursement (pro-rated if the Effective Date is not on April 1, 2014), no adjustment to future Manufacturing Reimbursements will be made. If any quarter's Manufacturing Reimbursement is greater than the Actual Quarterly Spend by five percent or more, CL may recoup the excess by offsetting that amount against any future Manufacturing Reimbursement payment or any other future payments otherwise owed to HJL.
- (b) CL may discontinue the Manufacturing Reimbursement at any time if HJL has manufactured 1500 commercially saleable units of Product but has not obtained the necessary FDA Approvals to allow CL to sell such Product. In such case, CL shall only be required to resume such Manufacturing Reimbursement once FDA Approval is obtained thereafter. CL may also discontinue the Manufacturing Reimbursement in the event it becomes reasonably apparent that HJL will not be able to obtain FDA Approval within nine months, or HJL will not be able to satisfy its material obligations under this Agreement for six months or more.
- (c) Notwithstanding anything herein to the contrary, in no event shall CL be required to reimburse HJL more than \$2,258,070 in total or \$650,000.00 in any individual quarter for the Manufacturing Reimbursement.
- (d) HJL shall manufacture and deliver 3800 units of saleable Product to CL and CL is not required to pay any amount for such units except the Manufacturing Reimbursement (such amounts the "Initial Build Inventory").
- 5.2. Existing Inventory. In consideration for the Manufacturing Reimbursement, CL shall own and have the exclusive right to market, distribute and sell all units of Products currently saleable located at HJL's facility (the "Existing Inventory"), or use such inventory as samples in the sales process, a schedule of Existing Inventory along with the shelf life of the Existing Inventory has already been provided by HJL to CL. HJL shall ship such Products as and when directed by CL and CL shall be entitled to all revenues associated with such shipment (although CL will reimburse HJL's shipping fees associated with such shipment).
- 5.3. Initial Build Inventory. In consideration of the Manufacturing Reimbursement, HJL shall manufacture and deliver 3800 units (in addition to the Existing Inventory) of commercially saleable Product to CL as directed by CL. All Product manufactured by HJL shall first be allocated to the Initial Build Inventory and other inventory necessary to validate the manufacturing process described in Section 5.1. The Parties shall mutually agree on the size configurations of the Initial Build Inventory. HJL

shall ship the Initial Build Inventory as and when requested by CL, including to CL for CL to ship and sell to others. CL shall own all such Initial Build Inventory and shall be entitled to all revenues associated with such sales (although CL will reimburse HJL's shipping fees associated with HJL's shipments). HJL will not manufacture more than 900 commercially saleable units of the Products for the Initial Build Inventory in any calendar quarter, or 1500 commercially saleable units of the Product for the Initial Build Inventory in the aggregate, prior to receiving FDA Approval without CL's prior written consent.

5.4. <u>Security Interest</u>. In order to secure HJL's obligations under this Agreement, HJL shall provide CL with a first priority security interest in all Initial Build Inventory and shall take all steps and execute all documents reasonably requested by CL to effectuate same, including entering into a security agreement mutually agreed to by the Parties and executed simultaneously herewith.

ARTICLE 6 SUPPLY AND ORDERS FOR PRODUCTS

- 6.1. Purchase Orders. CL shall submit purchase orders to HJL for the Products pursuant to Section 6.3. once the following has occurred: (i) HJL notifies CL in writing that it has the capability to manufacture the Products in accordance with the Specifications and Applicable Law and (ii) CL determines the Initial Build Inventory shall be exhausted within 90 days, or that it needs additional inventory, Each purchase order shall cover the portion of the forecast that has become a firm order under Section 6.3 of this Agreement and shall, at a minimum, include: (a) identification of the Products ordered; (b) quantity; (c) requested delivery date; and (d) shipping instructions and shipping address. CL may issue additional purchase orders and/or earlier purchase orders other than those described in the first sentence of this Section 6.1.
- 6.2. Acceptance of Orders. Except as otherwise provided in Section 6.4, all purchase orders issued in accordance with this Agreement shall be automatically accepted by HJL. Purchase orders for the Products must be received by HJL at least 30 days prior to delivery date requested. Each purchase order shall be deemed to be an offer by CL to purchase the Products pursuant to the terms of this Agreement and shall give rise to a contract between CL and HJL for the sale of the Products ordered and shall be subject to and governed by the terms of this Agreement solely and to no other terms including the provisions of the Uniform Commercial Code. The terms and conditions of this Agreement shall govern and supersede any additional or contrary terms set forth in CL's purchase order or any HJL or CL acceptance, confirmation, invoice or other document, unless the specific additional or contrary terms are stated in writing and duly signed by the CFO or CEO of CL and an officer of HJL. With each lot of Products manufactured by HJL, HJL shall supply to CL documentation certifying in writing that each shipment of Products complies with (i) the then current Specifications and with the testing procedures described therein; and (ii) all other documentation agreed to by CL and HJL.
- 6.3. <u>Forecasts</u>. Commencing within 10 business days of the occurrence described in the first sentence of Section 6.1, CL shall provide to HJL a written rolling 12-month forecast (with such first forecast to be for less than 12 months if the first forecast is not issued at the beginning of a calendar quarter). The first three months of each forecast shall constitute a firm order to purchase the units of the Products specified in the forecast. The first forecast for the first three months shall not exceed 1500 units without the consent of HJL. The balance of each forecast shall constitute a non-binding good faith estimate of expected orders for Products.
- 6.4. Order Limitations. HJL shall maintain an adequate inventory of the Products and shall notify CL immediately in writing upon becoming aware of any actual or potential interruption in supply. HJL shall not be required to deliver quantities in excess of 120% of forecasted requirements unless HJL

has been given at least 90 days advance written notice of the quantities to be delivered which exceed the forecasted amounts. Notwithstanding the foregoing HJL shall use all commercially reasonable efforts to supply quantities in excess of 120% of forecasted requirements that were given with less than 90 days advance notice.

- 6.5. Modification of Orders. Except as otherwise provided in Section 6.4, no purchase order shall be modified or canceled except upon the mutual agreement of the Parties, which shall not be unreasonably withheld by either Party. Mutually agreed change orders shall be subject to all provisions of this Agreement, whether or not the changed purchase order so states. Notwithstanding the foregoing, any purchase order may be canceled by CL as to any Products which are not delivered within 10 days of the delivery date requested by CL pursuant to a purchase order submitted to HJL under Section 6.1 and accepted by HJL under Section 6.2 (the "Requested Delivery Date"), and any such cancellation shall not limit or affect any contract remedies available to CL with respect thereto.
- 6.6. Shipment. All Products sold by HJL to CL shall be shipped by HJL free on board ("F.O.B.") HJL's facility (the "Shipping Point") addressed to CL's address (or such other address as set forth by CL). All shipments of Existing Inventory and Initial Build Inventory shall be shipped by HJL FOB Shipping Point also as directed by CL. HJL shall bear all risk of loss prior to HJL's delivery of the Products to a common carrier at the Shipping Point, and shall have no further responsibility for the Products after it has delivered the Products to the common carrier. CL assumes all risk of loss upon HJL's delivery of the Products to a common carrier at the Shipping Point. CL shall pay all loading, freight, shipping, insurance, forwarding and handling charges, fees, storage, and all other charges applicable to the Products after they are delivered by HJL to the common carrier at the Shipping Point.
- 6.7. Inspection. HJL will inspect and test the Product as required by the Specifications, including the Existing Inventory and Initial Build Inventory. CL will inspect all incoming Product. Upon notification to HJL, CL will have the right to reject any lot that contains Product that does not meet the Specifications ("Nonconforming Product"). CL will provide HJL with information as to the reason for the rejection of the Nonconforming Product including a description of the test procedure and results, if any, on which the rejection is based (i) within 60 days of receipt therefor with respect to nonconformities that can be discovered with reasonable diligence, and (ii) for all other Nonconforming Products, within 45 days after CL discovered or was informed by a Third Party or should have discovered the nonconformity. HJL will instruct CL as to the disposal or return of Nonconforming Product. In the event of Nonconforming Product(s), HJL will be responsible for return shipping charges. CL may issue a debit memorandum to HJL, which HJL will honor promptly for CL's benefit, for the purchase price, freight and related costs of the Nonconforming Product and, HJL will promptly replace the Nonconforming Product and invoice CL for the Product shipped to replace the Nonconforming Product at the time of shipment of the replacement product.

6.8. Process or Material Changes.

- (a) No material changes, modifications, deviations or exceptions to the Specifications, materials or fabrication manufacturing or packaging processes may be made without CL's consent and 60 days prior written notice by HJL to CL.
- (b) Any such material changes, modifications, deviations or exceptions proposed to be implemented by HJL shall be subject to prior review by CL for safety, regulatory issues and efficacy and shall not be implemented for at least such 60 day period or longer as required to address CL's concerns, if any.
- (c) HJL shall provide, at its sole cost and expense, a limited number of samples of the Product incorporating the proposed change for such prior evaluation during the 60 day period.

- 6.9. Packaging, Sterilization and Labeling. HJL shall be responsible for packaging, labeling, instructions for use, and any necessary sterilization of Products purchased under this Agreement. HJL shall deliver the text of proposed packaging, labeling, and instructions for use to CL for its review and comment prior to printing. HJL shall prepare packaging, labeling and instructions for use in all foreign languages that CL reasonably requests. HJL shall be responsible for the costs of translating the labels and instructions for use into any foreign language. CL hereby grants HJL a limited, non-exclusive, license to use CL's name and the CL trademark and design in accordance with CL's instructions, solely for purposes of packaging and labeling Products sold by HJL to CL or its Affiliates under this Agreement.
- 6.10. <u>Subcontracts and Suppliers</u>. If CL is required to place its CE Mark certification on the Product, HJL will promptly supply CL a list of HJL's subcontractors and suppliers contributing to the manufacture of the Product. After HJL has supplied CL with such list, HJL shall provide CL with at least 30 days' notice of any proposed change in such subcontractors and suppliers and will allow audits of its subcontractors and suppliers.

ARTICLE 7 PRICES AND PAYMENTS

- 7.1. <u>Transfer Prices</u>. The purchase price of all Products sold to CL hereunder, F.O.B. Shipping Point, ("Transfer Prices") shall be as agreed by the Parties in a separate document containing Transfer Prices and other miscellaneous terms. For avoidance of doubt the Parties hereto provide however that Existing Inventory and Initial Build Inventory are owned by CL due to the Manufacturing Reimbursement.
- 7.2. <u>Payment Terms</u>. HJL will invoice CL upon delivery of Products. Invoices for Products shall be due and payable in full within 37 days from the date of invoice.
- 7.3. <u>Taxes</u>. The Transfer Prices for Products do not include any sales, use, value added or similar taxes, customs duties, or tariffs imposed by any governmental authority or agency on Products or any components thereof that are imposed on CL by any country in the Territory. CL shall pay or reimburse HJL for all such amounts incurred in connection with CL's purchase of Products; provided, however, that HJL shall pay all income, excise or franchise taxes imposed upon the manufacturing activities or income of HJL.
- 7.4. Resale Prices. CL may resell the Products at such prices, as CL in its sole discretion, shall determine.
- 7.5. <u>Distribution Fee.</u> CL shall retain a certain amount of the sales price of each Product as a distribution fee to compensate CL for its sales and marketing costs (the "Distribution Fee") as agreed to separately by the Parties.
- 7.6. <u>Profit Sharing Payments</u>. Within 60 days after each calendar quarter during which Product sales to a Third Party occur by CL under this Agreement (excluding sales of the Initial Build Inventory and Existing Inventory), CL will pay to HJL a profit sharing payment that will compensate HJL for, among other things, HJL's training of CL personnel, sales, marketing, regulatory and clinical support for the Product ("Profit Sharing Payment") based on the following formula:

Net Sales of the Products, less each of the following attributable to the sales of the Products: (i) the Distribution Fee and (ii) the Transfer Prices. The result shall be divided by two to determine the Profit Sharing Payment earned by HJL.

Such Profit Sharing Payment shall be accompanied by a report setting forth in reasonable detail the calculation of the Profit Sharing Payment.

ARTICLE 8 GENERAL RIGHTS AND OBLIGATIONS OF CL

- 8.1. <u>Sales and Marketing</u>. CL will provide its standard level of sales and marketing support for the Products and will use commercially reasonable efforts to promote, market, sell and to distribute the Products in the Territory. CL will develop and produce brochures and other marketing and sales literature for the Product as it deems appropriate.
- 8.2. Post-Marketing Studies. CL may, in its sole discretion and at its expense, pursue authorship and publication of post-marketing or white paper studies to increase market awareness of the Products. HJL will assist CL by providing marketing and other materials and manufacturing information reasonably necessary to support such studies. CL shall provide HJL with sufficient opportunity to review any such proposed publications and CL shall agree not to publish HJL Confidential Information or publish any information that will affect HJL's ability to seek patent protection on the Product or related technology or know-how. HJL shall inform CL promptly in the event that HJL becomes aware of (i) post-market clinical studies being conducted involving the Product, or (ii) literature or unpublished reports of data from any clinical or non-clinical laboratory studies involving the Product.
- 8.3. <u>Marketing Materials</u>. CL shall be responsible for the preparation of sales and marketing materials for the Products, including (subject to Section 6.9), the translation, adaptation and/or modification of HJL's sales and marketing materials, as deemed appropriate by CL, to reflect local culture or business practices and languages, and to reflect CL as the exclusive distributor of the Product. HJL will cooperate with CL in the preparation of CL's sales and marketing materials.
- 8.4. <u>Alteration of Products</u>. CL, its Affiliates and agents shall not, in any way, alter the Products or remove, cover, change, alter or add to the labels attached to the Products by HJL, except with HJL's prior written approval.
- 8.5. Import and Export Approvals. CL shall be responsible for obtaining all import and export licenses and permits (other than regulatory approvals described in Article 2) as may be required to export the Products from the United States and to import the Products into such countries as are selected by CL in accordance with then-prevailing laws and regulations of such countries. All such filings and registrations of the Products shall be in the name of CL, whenever feasible in accordance with prevailing laws and regulations. HJL shall cooperate fully with CL in its efforts to obtain any such approvals.

ARTICLE 9 GENERAL RIGHTS AND OBLIGATIONS OF HJL

9.1. Manufacture and Supply of Products. HJL shall exercise all reasonable and appropriate actions to develop the capability to manufacture the Products in commercially appropriate quantities in accordance with the Specifications and Applicable Law, including obtaining FDA Approval. Thereafter, during the term of this Agreement, HJL shall manufacture and sell Products to CL in accordance with the Specifications and the terms and conditions set forth in this Agreement. If HJL (i) is unable to provide Product to CL within 90 days of the delivery/due date in any order or in accordance with this Agreement, (ii) does not obtain FDA Approval to manufacture the Product within nine months from the Effective Date of this Agreement, or (iii) is unable meet the volume requirements established in accordance with this Agreement, then CL may manufacture the Products itself or through a Third Party

and HJL shall provide all documentation and reasonable assistance necessary for CL to manufacture or have manufactured the Products. HJL shall escrow the instructions, know-how and Specifications required to manufacture the Product with a Third Party reasonably acceptable to both Parties. The escrow agreement shall provide that if any of the foregoing occurs, then CL shall have access to the escrowed information and CL may manufacture or have manufactured the Product either itself or by a Third Party.

- 9.2. <u>Training and Support</u>. HJL shall (a) assist, at no charge, in the training of CL's sales personnel representing the Products with respect to the promotion and use of the Products; and (b) travel, at CL's sole cost and expense, with CL's sales personnel to assist in problem solving, market needs identification and general market development, in each case as may be reasonably requested by CL. Travel, hotel and any other direct expenses must be pre-approved by CL and will be billed at cost. It is expected that air travel will be in coach class only and moderately priced hotels will be used. CL's corporate travel department is available upon a request to the appropriate business contact at CL in the event there is difficulty meeting these requirements. Rental cars may be used if less expensive than alternate means of transportation. Any additional expenses incurred for the purpose of delivering the activities in this Section must be approved in writing by CL.
- 9.3. <u>Marketing Samples</u>. HJL will provide to CL at no charge, non-sterile samples of the Products in a variety of sizes related to its start-up of the manufacturing of the Products, but at a minimum, no less than 50 samples. CL will provide such samples to its sales force and customers at no charge. At CL's request, HJL shall also (i) provide to CL at no cost any Products in HJL's possession or control which do not meet the Specifications for use solely as non-useable samples, and (ii) sell to CL additional non-sterile samples at 50% of the Transfer Price.
- 9.4. Marketing, Artwork and Sales Leads. HJL shall provide reasonable support to CL as needed in the marketing and sale of the Products, including contacting key opinion leaders and assisting with the launch of the Product and providing training. HJL shall provide camera ready artwork and copies of all advertising and marketing support materials in its possession or control that are necessary or helpful for the sale and marketing of the Products in the Territory. HJL shall forward to CL all leads for sales of Products in the Territory.
- 9.5. <u>Information Provided</u>. During the period from the Effective Date until FDA Approval is received, in order to keep CL fully informed of the progress and activity of HJL in furtherance of this Agreement, HJL shall (i) make its management and other personnel reasonably available to CL to meet in person or by teleconference as requested by CL, and (ii) allow CL reasonable access to the premises of HJL upon reasonable notice.

ARTICLE 10 TERM AND TERMINATION

- 10.1. <u>Term.</u> This Agreement shall take effect as of the date first above written and shall continue in force for a period of three years (the "Initial Term") from the Effective Date. Thereafter, this Agreement shall automatically renew for up to two consecutive one year terms (each a "Renewal Period"), unless CL gives written notice of termination to the other at least six months prior to the end of the Initial Term or a Renewal Period, as applicable.
- 10.2. <u>Termination</u>. Notwithstanding the provisions of Section 10.1, this Agreement may only (to the exclusion of any otherwise Applicable Law) be terminated in accordance with the following provisions:
 - (a) Either Party may terminate this Agreement at any time by giving notice in writing to the other Party, which notice shall be effective upon dispatch, should the other Party file a petition of any type as to its bankruptcy, be declared bankrupt, become insolvent, make an assignment for the

benefit of creditors, go into liquidation or receivership, or otherwise lose legal control of its business.

- (b) CL may terminate this Agreement by giving notice in writing to HJL should an event of Force Majeure, as defined below, continue for more than six months.
- (c) CL may terminate this Agreement by giving 30 days' notice in writing to HJL, which notice shall be effective upon dispatch, if there shall occur a Change in Control of HJL.
- 10.3. <u>Rights and Obligations on Termination</u>. In the event of termination of this Agreement for any reason, the parties shall have the following rights and obligations:
 - (a) Termination of this Agreement shall not release either Party from the obligation to make payment of all amounts then or thereafter due and payable.
 - (b) The terminating Party shall have the right, at its option, to cancel any or all purchase orders that provide for delivery after the effective date of termination.
 - (c) CL shall be permitted to resell any inventory of Products on hand at the time of termination and for a period of 18 months thereafter.
 - (d) CL may satisfy any tenders and other contractual commitments which extend beyond the effective date of termination, and HJL shall continue to comply with all of its obligations under this Agreement necessary or appropriate to allow CL to satisfy such commitments including providing appropriate Products to CL at the Transfer Prices set forth herein as if the Agreement were still in effect.
 - (e) HJL shall not use CL's model numbers for the Products except for any Products sold to CL, and shall identify the Products only by model numbers that are not confusingly similar to CL's designated model numbers.
 - (f) CL's and HJL's obligations pursuant to Sections 2.6, 2.8, 2.9, 2.10, 8.4, 8.5 and Articles 1, 3, 7, and 11 19 shall survive termination of this Agreement. All other provisions of this Agreement shall terminate upon termination of this Agreement.

ARTICLE 11 PRODUCT WARRANTIES

11.1. Warranty. HJL warrants to CL that: (i) the Products, including the Existing Inventory and Initial Build Inventory, delivered to CL under this Agreement will be saleable and useable in a clinical setting and will conform to the then current and agreed Specifications for Products; (ii) the Products, including the Existing Inventory and Initial Build Inventory, will be free from defects in design, manufacturing, materials and workmanship under normal intended use and service, in accordance with all Applicable Laws and requirements including, but not limited to, the Act and GMP/QSR Regulations; (iii) the Products, including the Existing Inventory and Initial Build Inventory, have been manufactured, tested, stored, packaged, labeled and shipped in compliance with the Specifications and all Applicable Laws including, but not limited to, the Act and GMP/QSR Regulations; (iv) the Product information (including instructions and information relating to the storage, handling, maintenance, transportation and implantation of the Product labeling) and related Product information provided by HJL ("Product Information") shall be accurate and complete in all respects; (v) the Products shall have a shelf life of at least 54 months with at least 42 months shelf life remaining when received by CL (not including the Existing Inventory); (vi) HJL's manufacturing facility is and at the time of manufacture shall be in compliance with all GMP/QSR Regulations and ISO 13485:1996, EN 46001 requirements; (vii) HJL has and at the time of manufacture shall have all approvals and consents required to mark

the Products with a CE Mark; and (viii) the Products, including the Existing Inventory and Initial Build Inventory, are free and clear of any liens, security interests or encumbrances of any nature whatsoever. CL shall have available the remedies provided for in Section 6.7 in the event any Products do not meet the foregoing warranties prior to returning any Products alleged to be defective, CL shall notify HJL in writing of the claimed defect and shall include the lot and serial number of such Products, as well as the number and date of the invoice therefor.

- 11.2. <u>Limited Warranty</u>. THE WARRANTIES SET FORTH IN SECTION 11.1 ARE INTENDED SOLELY FOR THE BENEFIT OF CL. ALL CLAIMS THEREUNDER SHALL BE MADE BY CL AND MAY NOT BE MADE BY CL'S CUSTOMERS. THE WARRANTIES SET FORTH IN SECTION 11.1 ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY HJL, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. THE SOLE AND EXCLUSIVE REMEDIES OF CL FOR BREACH OF THE WARRANTY DESCRIBED IN SECTION 11.1 SHALL BE LIMITED TO THE REMEDIES PROVIDED IN THIS AGREEMENT.
- 11.3. <u>CL Warranty Obligations</u>. CL shall not make any representations or warranties with respect to HJL's liability therefore except as set forth in this Article.

ARTICLE 12 REPRESENTATIONS, WARRANTIES AND INDEMNIFICATION

12.1. Indemnification.

- (a) Cross Indemnity. HJL and CL each (when indemnifying such party is the "Breaching Party") hereby agree to indemnify, defend and hold the other (the "Non-Breaching Party") harmless from and against all suits, actions, claims, demands, causes of action, judgments, liabilities and expenses (including court costs and reasonable attorneys' fees) ("Claims") which arise or result from the Breaching Party's misrepresentations of any representation contained herein, or default in the observance or performance of any term or provision of this Agreement. Further, the Breaching Party agrees to indemnify, defend and hold the Non-Breaching Party harmless from and against all Claims which arise or result from activities on the part of the Non-Breaching Party, based on actual or alleged violations by the Breaching Party of Applicable Laws.
- (b) Products Liability. HJL hereby agrees to defend, indemnify and hold CL and its Affiliates (each a "CL Indemnified Party") harmless from and against all Claims which arise out of or result from personal injury or death incident to the use of any Products to the extent resulting from: (i) an inadequacy in the Product Information, (ii) the failure of the Products to meet the Specifications or (iii) the failure of the Products to be manufactured, tested, stored packaged, labeled and shipped in compliance with all Applicable Laws.
 - CL hereby agrees to defend, indemnify and hold HJL and its Affiliates (each a "HJL Indemnified Party") harmless from and against all Claims which arise out of or result from personal injury incident to the use of any Products to the extent resulting from the negligent or wrongful acts or omissions of CL.
- 12.2. Insurance Requirements. CL and HJL shall each possess insurance in the amounts and types set forth below.
 - (a) <u>HJL Insurance Requirements</u>. HJL will carry product liability insurance covering any loss, damage, expense or liability incurred or suffered by any party other than HJL arising out of any use of a Product as agreed to by the Parties. Such policy or policies, which may include umbrella or excess liabilities coverage, shall (i) have aggregate limits of liability as agreed to by

the Parties with respect to any incident or occurrence and of not less than an amount agreed to by the Parties in the aggregate on the Effective Date; (ii) provide for a deductible or retained amount agreed to by the parties; and (iii) provide that such policy may not be canceled except upon written notice in accordance with policy provisions. Upon request, HJL shall provide such evidence of the effectiveness of such insurance to CL.

- (b) <u>CL Insurance Requirements</u>. CL will carry product liability insurance covering any loss, damage, expense or liability incurred or suffered by a party other than CL arising out of any use of a Product as agreed to by the Parties. Such policy or policies, which may include umbrella or excess liability coverage shall (i) have aggregate limits of liability agreed to by the Parties with respect to any incident or occurrence and of not less than an amount agreed to by the Parties in the aggregate; (ii) provide for a deductible or retained amount agreed to by the Parties; and (ii) provide that such policy may not be canceled except upon written notice to both HJL in accordance with the policy provisions. Upon request, CL shall provide evidence of the effectiveness of such insurance to HJL.
- 12.3. Third Party Claims. If a Claim by a Third Party is made against an Indemnified Party (whether a HJL Indemnified Party or a CL Indemnified Party) and if the Indemnified Party intends to seek indemnity with respect thereto from the other Party (the "Indemnifying Party") under this Article 12, such Indemnified Party shall promptly notify the Indemnifying Party of such Claim; provided, however, that the failure to give timely notice shall not affect the rights of the Indemnified Party so long as such failure to give timely notice does not adversely affect the Indemnifying Party's ability to defend such Claim against a Third Party. The Indemnifying Party shall be entitled to assume the defense thereof, with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party. The Indemnifying Party shall have control of the defense of any such action, including any appeals and negotiations for the settlement or compromise thereof and shall have authority to enter into a binding settlement or compromise; provided that, the Indemnifying Party shall not enter into any settlement or compromise or take any other action with respect to the Claim which may adversely affect the Indemnified Party without the Indemnified Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnified Party may participate, at its own cost and expense, in the defense of any such Claim; provided, however, that such defense shall be controlled by the Indemnifying Party.
- 12.4. <u>Cooperation as to Indemnified Liability</u>. Each Party hereto shall reasonably cooperate with other parties with respect to access to books, records, or other documentation within such Party's control, if deemed reasonably necessary or appropriate by any Party in the defense of any Claim, which may give rise to indemnification hereunder.
- 12.5. CL's Representations and Warranties. CL hereby represents and warrants to HJL that as of the date hereof:
 - (a) CL is a corporation duly organized, validly existing and in good standing under the laws of Florida, and this Agreement has been duly authorized by all necessary corporate action.
 - (b) This Agreement is the legal, valid and binding obligation of CL, enforceable against CL in accordance with its terms.
 - (c) Neither the execution and delivery of this Agreement nor the compliance with the terms and conditions hereof will conflict with, result in a breach or violation by CL of or constitute a default under any of the terms, conditions or provisions of any contract, agreement or other instrument to which CL is or may be bound or affected.
 - (d) CL has full right, power and authority to enter into this Agreement and to grant to HJL the rights granted and to be granted hereunder.

- (e) CL is not under any obligations inconsistent with the provisions of this Agreement.
- 12.6. HJL's Representations and Warranties. HJL hereby represents and warrants to CL that as of the date hereof:
 - (a) HJL is a corporation duly organized, validly existing and in good standing under the laws of Delaware, and this Agreement has been duly authorized by all necessary corporate action.
 - (b) This Agreement is the legal, valid and binding obligation of HJL, enforceable against HJL in accordance with its terms.
 - (c) Neither the execution and delivery of this Agreement nor the compliance with the terms and conditions hereof will conflict with, result in a breach or violation by HJL of or constitute a default under any of the terms, conditions or provisions of any contract, agreement or other instrument to which HJL is or may be bound or affected.
 - (d) HJL is the sole and exclusive owner of the HJL Inventions and HJL Confidential Information, free and clear of any security interests, claims, encumbrances or charges of any kind, and has full right, power and authority to enter into this Agreement and to grant to CL the rights granted and to be granted hereunder.
 - (e) To the best of HJL's knowledge, HJL Inventions are valid and enforceable, and the rights and licenses granted under this Agreement do not infringe any patent, copyright, trademark, license or other Intellectual Property right of any Third Party and do not misappropriate any trade secret of any Third Party.
 - (f) All proprietary technical information developed by and belonging to HJL that has not been patented has been kept confidential.
 - (g) Except as otherwise set forth on Exhibit C, HJL has not patented or applied for patent protection on any the technology it proposes to use in developing the Product.
 - (h) HJL is not under any obligations inconsistent with the provisions of this Agreement.

ARTICLE 13 CONFIDENTIAL INFORMATION

- 13.1 Confidentiality. Except as otherwise specifically provided in this Agreement, CL and HJL each agree that during the term of this Agreement and for a period of five years thereafter, it will: (i) not use any of the other Party's Confidential Information, for any purpose other than as permitted or required for performance by such Party under this Agreement; (ii) not disclose or provide any of the other Party's Confidential Information to any Third Party; and (iii) to take all reasonably necessary measures to prevent any such disclosure by its employees, agents, contractors or consultants (who shall only be advised of such Confidential Information on a need to know basis in furtherance of this Agreement). Each Party shall advise its employees, agents, contractors and consultants of the requirements of this Article 13 prior to any disclosure of the other Party's Confidential Information to them and shall be responsible to ensure their compliance with such provisions. Any such employee, agent, contractor or consultant must be subject to a contractual restriction on use and disclosure of the Confidential Information consistent with the terms of this Article 13. Upon request of the other Party or termination of this Agreement, each Party shall return all such Confidential Information to the other Party except for one copy which may be retained for archival purposes otherwise subject to this Article 13.
- 13.2 Existence of Agreement. The existence of this Agreement and the participation of the Parties in it

shall be deemed to be Confidential Information subject to the provisions of this Article 13. Any publication, public reference or other transfer of information into the public sector regarding the relationship as defined in the Agreement or any of the terms contained in the Agreement shall be prohibited without prior written consent of the other Party.

- 13.3 Exclusions to Confidential Information . Confidential Information of either Party shall exclude information that:
 - (a) was already in the possession of receiving Party prior to its receipt from the disclosing Party (provided that the receiving Party is able to provide the disclosing Party with reasonable documentary proof thereof);
 - (b) is or becomes part of the public domain by reason of acts not attributable to the receiving Party;
 - (c) is or becomes available to receiving Party from a source other than the disclosing Party which source, to the best of receiving Party's knowledge, has rightfully obtained such information and has no obligation of non-disclosure or confidentiality to the disclosing Party with respect thereto;
 - (d) is made available by the disclosing Party to a Third Party unaffiliated with the disclosing Party on an unrestricted basis;
 - (e) is independently developed by the receiving Party completely without reference to any Confidential Information of the disclosing Party, as evidenced by the receiving Party's written records; or
 - (f) has been or must be publicly disclosed by reason of legal accounting or regulatory requirements beyond the reasonable control, and despite the reasonable efforts of the receiving Party.
- 13.4 <u>Required Disclosures</u>. In the event of any disclosures pursuant to Section 13.3(f) the receiving Party shall provide (i) prompt prior written notice that is reasonable under the circumstances to the disclosing Party, and (ii) reasonable assistance to the disclosing Party in order to obtain a protective order or otherwise prevent public disclosure of such Confidential Information at the disclosing Party's expense. If the disclosing Party fails to obtain a protective order or other appropriate remedy, the receiving Party will furnish only that portion of the Confidential Information that is legally required to be disclosed as advised by its legal counsel.

ARTICLE 14 PATENTS AND INTELLECTUAL PROPERTY RIGHTS

- 14.1. <u>Defense of Claims</u>. HJL shall, at its own expense, defend any Claim instituted or asserted against CL which is based on an allegation that any Product constitutes an infringement of any Intellectual Property right protected under the laws of the United States, any state of the United States, or any other nation. HJL shall have control of the defense of any such Claim, including any appeals and negotiations for the settlement or compromise thereof and shall have full authority to enter into a binding settlement or compromise; provided that, HJL shall not enter into any settlement or compromise which may adversely affect CL without CL's consent, which consent shall not be unreasonably withheld, conditioned or delayed. HJL shall indemnify CL against any award of damages and costs made against CL as a result of any such action. Notwithstanding the foregoing, CL may participate, at its own cost and expense, in the defense of any such Claim; provided, however, that such defense shall be controlled by HJL.
- 14.2. <u>Limitation of Liability</u>. HJL shall have no liability of any kind to CL under Section 14.1 to the extent any such Claim is based upon or arises out of (a) the use of any Product in combination with an apparatus or device not manufactured, supplied or approved by HJL, (b) the use of any Product in a manner for

which it was not designed or intended to be used based upon the Product Information, or (c) any modification of any Product by CL or any Third Party which causes it to become infringing.

- 14.3. Potential Infringement Remediation. If any Product is held to constitute an infringement or misappropriation of any Third Party's Intellectual Property rights, if HJL and CL concur that any Product constitutes such an infringement or misappropriation, or if CL is advised by its legal counsel that any Product potentially infringes or misappropriates any Third Party's Intellectual Property right, HJL shall at its expense either: (i) procure the right for CL to continue distributing the Products in accordance with this Agreement at no additional cost to CL (ii) replace the Product with a non-infringing and non-misappropriating equivalent product conforming to the Specifications at no additional cost to CL, or (iii) modify the Product to make it non-infringing and non-misappropriating while conforming to the Specifications at no additional cost to CL. In the event that HJL is unable to or does not secure sufficient rights to permit CL to sell or market the Products in the manner contemplated by this Agreement within a reasonable time, HJL shall, at CL's option, promptly repurchase the entire Product inventory held by CL and its subdistributors at the original purchase price (including shipping, customs and related costs), and CL shall be immediately released of its obligation under this Agreement to sell, market and promote the Products without waiving any rights available against HJL for such a breach of this Agreement.
- 14.4. Intellectual Property. HJL represents and warrants to CL that: (a) HJL owns, possesses, or licenses all rights to use all Intellectual Property and know-how used in the development, manufacture or sale of the Products ("HJL Intellectual Property"); (b) no Claim is pending or threatened to the effect that the Product or HJL's use of HJL Intellectual Property infringes upon or conflicts with the any Third Party's Intellectual Property rights, and, to the best of HJL's knowledge, there is no basis for any such Claim; (c) no Claim is pending or threatened to the effect that any such HJL Intellectual Property is invalid or unenforceable by HJL, and, to the best of HJL's knowledge, there is no basis for any such Claim (whether or not pending or threatened); (d) all proprietary technical information developed by and belonging to HJL which has not been patented has been kept confidential; (e) the HJL Intellectual Property is not being and has not been actually or potentially infringed by any company, person or entity; (f) HJL has not granted any license or other right that would be inconsistent with or conflict with the grant of the rights granted to CL under this Agreement.
- 14.5. <u>Protection of HJL's Intellectual Property</u>. HJL shall be responsible for filing and prosecuting all U.S. and foreign patent, copyright and trademark applications it deems necessary or appropriate to protect HJL Intellectual Property.
- 14.6. Each Party shall promptly notify the other Party of any and all actual or potential infringements of the HJL Inventions of which such Party becomes aware within the Territory. HJL shall, at its own cost, take any and all actions, legal or equitable, necessary to prevent such infringements and to eliminate or minimize the consequences of any such infringement. At HJL's request and expense, CL will provide reasonable assistance to HJL in taking action against any such infringements. If HJL fails to take appropriate action against such infringements within 60 days after notice, CL may take such actions at HJL's expense as CL deems necessary and appropriate, including but not limited to filing a lawsuit against the infringing or potentially infringing Third Party (and/or their patents) in HJL's name or its own name and/or requesting that patent offices (or their equivalents) reconsider the validity of Third Party patents and HJL shall reasonably assist CL.

ARTICLE 15 TRADEMARKS

15.1. <u>License</u>. HJL hereby grants to CL a non-exclusive, non-transferable, and royalty-free right and license to use those HJL trademarks, trade names and logotypes identified on Exhibit C in connection

with the sale, distribution, promotion and advertising of the Products as long as such trademarks are used by CL in accordance with HJL's standards, specifications and instructions of which CL has been advised in writing, but in no event beyond the term of this Agreement, subject to any post termination rights provided for herein. CL shall not acquire any right, title or interest under the laws of any nation in such trademarks, trade names or logotypes of HJL other than the foregoing limited license and shall not attempt to assert or register any such right, title or interest. CL shall not use any of HJL's trademarks, trade names or logotypes as part of CL's corporate or trade names or permit any Third Party to do so without the prior written consent of HJL. CL shall permit HJL to inspect any material on which HJL's trademarks, trade names and logo types appear, and CL agrees to make any changes in future materials reasonably required by HJL. CL shall in addition have the right to promote and sell the Products under trademarks, trade names and logotypes of CL selected by CL, which trademarks, trade names and logotypes shall be and shall remain the property of CL.

- 15.2. Infringement. CL shall promptly notify HJL of any use by any Third Party of HJL's trademarks, trade names or logotypes or any use by such Third Parties of similar marks which may constitute an infringement or passing off of HJL's trademarks, trade names or logotypes of which CL has knowledge. HJL reserves the right in its sole discretion to institute any proceedings against such Third Party infringers and CL shall refrain from doing so. CL agrees to provide reasonable cooperation to HJL in any action taken by HJL against such Third Parties, provided that all expenses of such action shall be borne by HJL and all damages which may be awarded or agreed upon in settlement of such action shall accrue to HJL.
- 15.3. Termination of Use. CL acknowledges HJL's proprietary rights in and to HJL's trademarks, trade names and logotypes, and CL hereby waives all right to any trademarks, trade names and logotypes now or hereafter originated by HJL. CL shall not adopt, use or register any words, phrases or symbols which are identical to or confusingly similar to any of HJL's trademarks. Upon termination of this Agreement, CL shall cease using HJL's trademarks, trade names and logotypes in any manner, subject to CL's right, if any, to continue to sell Products held in inventory or if CL purchases or otherwise licenses such rights to the trademarks, trade names and logotypes pursuant to a separate agreement or agreements, in which case such agreement(s) shall control.

ARTICLE 16 OPTION TO PURCHASE AND RIGHT OF FIRST REFUSAL

16.1. Option to Purchase. HJL grants to CL the exclusive right and option (the "Option") to allow CL to acquire all assets (the "Purchased Assets") of HJL relating to the Products and the HJL Intellectual Property, all documents and information relevant thereto and all equipment and tooling necessary or helpful for the manufacture of the Products as forth in this Section. This Option shall survive the acquisition of HJL or substantially all of HJL's assets or a Change in Control of HJL. The Option may be exercised by CL any time commencing 25 months after the Effective Date of this Agreement, or sooner in the event HJL or substantially all of HJL's assets are acquired by CL delivering written notice to HJL. The agreement to acquire the Purchased Assets (the "Acquisition Agreement") free and clear of all liens and encumbrances shall be negotiated in good faith promptly by both Parties at such time as CL exercises the Option. The Acquisition Agreement shall include, without limitation, representations, warranties, covenants and indemnities that are usual and customary in a transaction of this nature as such may be mutually agreed upon between the Parties, including: (i) covenants by HJL not to compete directly or indirectly with the Products in the Territory for a period of five years, (ii) to assist CL with training, the transfer of all HJL Intellectual Property relating to the Products, (iii) the sale and marketing of the Products during a transition period of the transfer of the Products and (iv) those items set forth on Exhibit D attached hereto. Subject to the satisfaction of all conditions precedent contained in the Acquisition Agreement, CL's obligation to execute, deliver and perform the Acquisition Agreement shall be conditioned upon approval of the transaction by the CL Board of

Directors and any requirements of Applicable Laws. As consideration for the purchase of the Purchased Assets, CL shall pay to HJL at the closing of the transaction the Option Acquisition Price. The Parties acknowledge that they may need to enter in a post-closing supply agreement whereby HJL will continue to manufacture the Products for CL at a transfer price to be agreed (which shall not include any profit sharing provision) in which case there should be a corresponding reduction in the Option Acquisition Price.

16.2. Right of First Refusal.

- (a) If HJL receives any bona fide offer(s) to purchase in one transaction or series of transactions, or reaches an agreement in principal (subject to CL's rights under this Article) with, or otherwise determines that it is willing to accept an offer from, any Third Party, which agreement(s) or offer(s) includes terms and provisions regarding the sale, license or other transfer of any HJL Intellectual Property and/or all equipment, facilities and tooling used in the development, manufacture, processing, packaging, sterilization, or sale of products for Coronary Indications (whether as an entire product line, or as one, several or all of the Products, but excluding any transaction involving a Change in Control of HJL) (in each case a "Disposition"), then HJL shall, within five business days after receipt of any such offer or agreement in principal, or after such determination, notify CL in writing thereof ("HJL Disposition Notice"). Any HJL Disposition Notice shall (i) specify the pricing, terms, conditions, timing and all material provisions with respect to the proposed transaction, (ii) identify the proposed party or parties to such transaction, and (iii) include a copy of the proposed agreement in principal or offer for the proposed transaction between HJL and the proposed Third Party or parties.
- (b) CL shall have the irrevocable right and option (the "First Refusal Option"), exercisable in writing to HJL any time within 60 days after CL's receipt of the HJL Disposition Notice (the "Option Period"), to elect to enter into such proposed transaction upon the same or comparable pricing (or the monetary equivalent of any non-monetary consideration), terms, conditions and other material provisions as set forth in HJL's Disposition Notice. If the consideration proposed to be paid for the Disposition is in property, services or other non-cash consideration, the fair market value of the non-cash portion of the consideration shall be determined in good faith by HJL's Board of Directors and set forth in the HJL Disposition Notice (such amount to be subject to agreement by CL). If CL cannot for any reason pay in the same form of non-cash consideration, CL shall pay the cash value equivalent thereof (unless in the case of stock consideration, HJL consents to CL providing capital stock of CL of an equal value as mutually determined by HJL's and CL's Board of Directors). If CL elects to exercise its First Refusal Option, HJL and CL shall use their best efforts to consummate such proposed transaction within 60 days following exercise of the First Refusal Option by CL.
- (c) If CL fails to exercise its First Refusal Option to enter into such proposed transaction, HJL and the proposed party identified in the HJL Disposition Notice may complete such proposed transaction upon the pricing, terms, conditions and material provisions specified in the HJL Disposition Notice; provided that, if (i) HJL and such Third Party fail to complete such transaction within 90 days after the expiration of CL's First Refusal Option, (ii) if any of the pricing, terms, conditions or other material provisions contained in HJL's Disposition Notice are modified so as to be less favorable to HJL, or (iii) if the identity of such Third Party changes, provided that an Affiliate of such third party shall not be considered a change of identity of such Third Party, then, in any such event, HJL shall provide a new HJL Disposition Notice to CL, and CL shall have a new First Refusal Option pursuant to the procedures above with respect to such delayed or modified proposed transaction.
- 16.3. <u>Failure to Agree</u>. In the event the Parties are not able to reach agreement on all or any part of this Article 16, the matter in dispute (including determining the appropriate representations, warranties, covenants and indemnities for the Acquisition Agreement and finalizing the remainder of the terms of the Acquisition Agreement if the Parties are able to reach agreement on certain or all terms) shall be resolved by binding arbitration in accordance with Article 17 below.

ARTICLE 17 ARBITRATION

- 17.1. <u>Disputes.</u> Any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, shall be finally settled by arbitration in accordance with the Commercial Arbitration Rules (the "Rules") of the American Arbitration Association ("AAA") in effect on the date of this Agreement by a single arbitrator who shall be experienced in the medical device industry and who shall be appointed in accordance with the Rules and such arbitration shall be administered by AAA with a single arbitrator selected from a list of arbitrators proposed by AAA in accordance with the Rules. The arbitrator shall allow such discovery as is appropriate and consistent with the purposes of the arbitration in accomplishing fair, speedy and cost-effective resolution of disputes. The costs of the arbitration including the arbitrators' fees shall be shared equally by the Parties. Judgment upon the award rendered in any such arbitration may be entered in any court of competent jurisdiction, or application may be made to such court for a judicial acceptance of the award and enforcement, as the law of such jurisdiction may require or allow. The place of arbitration shall be Atlanta, Georgia.
- 17.2. <u>Governing Law</u>. This Agreement shall be governed by, and interpreted and construed in accordance with the laws of the State of Georgia.

ARTICLE 18 FORCE MAJEURE

- 18.1. <u>Force Majeure Definition</u>. Force Majeure shall mean any event or condition, not existing as of the date of this Agreement, not reasonably foreseeable as of such date and not reasonably within the control of either Party, which prevents in whole or in material part the performance by one of the Parties of its obligations hereunder or which renders the performance of such obligations so difficult or costly as to make such performance commercially unreasonable. Without limiting the foregoing, the following shall constitute events or conditions of Force Majeure: riots, civil or military disturbances, war, epidemics, fire, flood, hurricane, typhoon, earthquake, lightning, and explosion.
- 18.2. Notice. Upon giving notice to the other Party, a Party affected by an event of Force Majeure shall be released without any liability on its part from the performance of its obligations under this Agreement, except for the obligation to pay any amounts due and owing hereunder, but only to the extent and only for the period that its performance of such obligations is prevented by the event of Force Majeure. Such notice shall include a description of the nature of the event of Force Majeure, its cause and possible consequences. The Party claiming Force Majeure shall promptly notify the other Party of the termination of such event.
- 18.3. <u>Suspension of Performance</u>. During the period that the performance by one of the Parties of its obligations under this Agreement has been suspended by reason of an event of Force Majeure, the other Party may likewise suspend the performance of all or part of its obligations hereunder, except for the obligation to pay any amounts due and owing hereunder, to the extent that such suspension is commercially reasonable.

ARTICLE 19 MISCELLANEOUS

19.1. <u>Relationship</u>. This Agreement does not make either Party the employee, agent or legal representative of the other for any purpose whatsoever. Neither Party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name

of the other Party. In fulfilling its obligations pursuant to this Agreement each Party shall be acting as an independent contractor.

- 19.2. <u>Assignment</u>. Except as otherwise provided in this Agreement, neither Party may assign or otherwise transfer its rights and obligations under this Agreement without the prior written consent of the other Party. Notwithstanding any other provision in this Agreement to the contrary, and subject to CL's rights as set forth in Article 16, either Party may assign this Agreement to a company controlling, controlled by or under common control with the assigning Party, or to its successor in connection with a Change in Control of such Party. Any prohibited assignment shall be null and void. All terms and conditions of this Agreement shall be binding on and inure to the benefit of the successors and permitted assigns of the Parties.
- 19.3. Notices. Notice permitted or required to be given under this Agreement shall be deemed sufficient if given in writing by commercial air delivery service or by registered or certified air mail, postage prepaid, return receipt requested, addressed to the respective addresses of the Parties set forth below or at such other address as the respective Parties may designate by like notice from time to time. Notices so given shall be effective upon the earlier of: (a) receipt by the Party to which notice is given; (b) on the seventh business day following the date such notice was deposited in the mail; or (c) when received. Notices shall be given as follows:

If to HJL: Hancock Jaffe Laboratories, Inc.

70 Doppler Irvine, CA 92618 Attn: Norman Jaffe

If to CL: CryoLife, Inc.

1655 Roberts Blvd. NW Kennesaw, GA 30144

Attn: CEO

With a copy to CL's General Counsel at the same address

- 19.4. Entire Agreement. This Agreement, including the exhibits attached hereto and incorporated as an integral part of this Agreement, constitutes the entire agreement of the Parties with respect to the subject matter hereof, and supersedes all previous proposals, oral or written, and all negotiations, conversations or discussions heretofore had between the Parties related to this Agreement.
- 19.5. <u>Amendment</u>. This Agreement shall not be deemed or construed to be modified, amended, rescinded, canceled or waived, in whole or in part, other than by written amendment signed by the Parties hereto, except as expressly provided in this Agreement.
- 19.6. <u>Severability</u>. In the event that any of the terms of this Agreement are in conflict with any rule of law or statutory provision or otherwise unenforceable under the laws or regulations of any government or subdivision thereof, such terms shall be deemed stricken from this Agreement, but such invalidity or unenforceability shall not invalidate any of the other terms of this Agreement and this Agreement shall continue in force, unless the invalidity or unenforceability of any such provisions of this Agreement substantially violates, comprises an integral part of or is otherwise inseparable from the remainder of this Agreement.
- 19.7. <u>Counterparts</u>. This Agreement shall be executed in two or more counterparts, and each such counterpart shall be deemed an original hereof.

- 19.8. Waiver. No failure by either Party to take any action or assert any right hereunder shall be deemed to be a waiver of such right in the event of the continuation or repetition of the circumstances giving rise to such right.
- 19.9. Use of Certain Words. Throughout this Agreement, the use of the words "and" or "or" shall be deemed to refer to "and/or" and the use of the word "including" shall be deemed to refer to "including but not limited to."
- 19.10. Publications. HJL and CL may pursue publication of the results of any clinical study or trial conducted with respect to Products including white paper publications by CL to expand market usage for Products. The Party seeking to publish shall provide the nonpublishing Party with sufficient opportunity to review any such proposed publications and make recommendations as to revisions to any such proposed publication. Notwithstanding the foregoing, neither Party shall publish the other Party's Confidential Information, without the express written consent of the non-publishing Party, which consent may not be unreasonably withheld, conditioned or delayed, or publish any information that will affect the non-publishing Party's rights under this Agreement or ability to seek patent protection.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed on the date first above written.

CryoLife, Inc.	Hancock Jaffe Laboratories, Inc.
By: <u>/s/ D.A. Lee</u>	By: <u>/s/ Norman Jaffe</u>
Name: <u>D. Ashley Lee</u>	Name: Norman Jaffe
Title: EVP, COO and CFO	Title: President

EXHIBIT A

ADDITIONAL QUALITY REQUIREMENTS

- 1. All Products shall be assigned a specific HJL lot and/or serial number. This number(s) shall be clearly identified on the Product and/or its packaging, as well as on traceability records.
- 2. HJL shall assign a quality representative for the duration of this Agreement. This individual shall be responsible for overseeing HJL activities that impact the Products and acting on HJL's behalf in matters associated with Product quality.
- 3. HJL shall validate all instruments and equipment used during the production of Products in accordance with the Specifications and Applicable Laws.
- 4. In all events, HJL shall provide reasonable resources, maintain copies of all documentation, and perform failure investigation and reasonable corrective and/or preventive actions with respect to any and all complaints.
- 5. HJL shall define, implement, and maintain a CAPA process. This process should include a disciplined approach to determining the root cause of problems and issues and developing, implementing, and verifying the solutions needed to resolve them. HJL's CAPA process shall include provisions for recording the following information associated with or having an impact upon the Products:
 - Product statement
 - Root cause investigation method and results
 - Solution description and associated implementation plan
 - Verification of implementation and effectiveness

CAPA records shall be retained as required by Applicable Laws and shall be made available to CL upon request.

EXHIBIT B

HJL BUDGET

Confidential

ProCol® Manufacturing Budget Projection 2014	January	February	March	April	May	June	July	August	September	October	November	December	TOTAL
Direct and Indirect Labor	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Raw Materials (Tissue)	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Supplies for Production	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Packaging				[***]				[***]					[***]
Facilities	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Quality Tests, Audits, Outside Services	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Insurance	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Administrative	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
TOTAL	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
irect Labor - Includes Benefits	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Employees	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	
direct Labor - Includes Benefits	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
Employees	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	
Units / QTR			[***]			[***]			[***]			[***]	[***]
verage ASP =[***]		!						Ų			!		

2014 Budget Provided by Hancock Jaffe to estimate 1st year costs of bringing ProCol Online

EXHIBIT C

 $\ensuremath{\mathsf{HJL}}$ has no existing patents on technology it uses with the Product.

HJL TRADEMARKS

HJL Trademarks:

ProCol®

CERTIFICATIONS

- I, Steven G. Anderson, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2014

/s/ STEVEN G. ANDERSON

Chairman, President, and Chief Executive Officer

- I, David Ashley Lee, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of CryoLife, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2014

/s/ D. ASHLEY LEE

Executive Vice President, Chief Operating Officer, and Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CryoLife, Inc. (the "Company") on Form 10-Q for the quarter ending March 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Steven G. Anderson, the Chairman, President, and Chief Executive Officer of the Company, and David Ashley Lee, the Executive Vice President, Chief Operating Officer, and Chief Financial Officer of the Company, hereby certifies, pursuant to and for purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ STEVEN G. ANDERSON

STEVEN G. ANDERSON Chairman, President, and Chief Executive Officer April 30, 2014 /s/ D. ASHLEY LEE

D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and
Chief Financial Officer
April 30, 2014