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

FORM 10-Q

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

For the quarterly period ended September 30, 2010

OR

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

For the transition period from _____ to _____

Commission file number: 1-13165

CRYOLIFE, INC.
(Exact name of registrant as specified in its charter)

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

(770) 419-3355
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

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

Yes ☐ No ☐

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

Large accelerated filer ☐ Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

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

Yes ☐ No ☒

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

Class	**Outstanding at October 29, 2010**
Common Stock, $0.01 par value per share	28,131,665 shares

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(Unaudited)		(Unaudited)	
Revenues:				
Preservation services	$15,111	$15,033	$45,699	$42,672
Products	13,175	12,806	41,276	39,669
Other	157	380	448	729
Total revenues	**28,443**	**28,219**	**87,423**	**83,070**
Cost of preservation services and products:				
Preservation services	8,911	8,903	27,322	24,421
Products	4,310	2,275	9,318	6,478
Total cost of preservation services and products	**13,221**	**11,178**	**36,640**	**30,899**
Gross margin	**15,222**	**17,041**	**50,783**	**52,171**
Operating expenses:				
General, administrative, and marketing	11,376	12,386	36,863	37,440
Research and development	1,354	1,461	3,886	3,854
Write-down of acquired in-process research and development	3,749	—	3,749	—
Total operating expenses	**16,479**	**13,847**	**44,498**	**41,294**
Operating (loss) income	**(1,257)**	**3,194**	**6,285**	**10,877**
Interest expense	29	58	145	168
Interest income	(6)	(10)	(16)	(73)
Gain on valuation of derivative	(143)	—	(1,345)	—
Other than temporary investment impairment	3,638	—	3,638	—
Other (income) expense, net	(187)	8	44	100
(Loss) income before income taxes	**(4,588)**	**3,138**	**3,819**	**10,682**
Income tax (benefit) expense	(1,557)	1,276	1,990	4,369
Net (loss) income	**$ (3,031)**	**$ 1,862**	**$ 1,829**	**$ 6,313**
(Loss) income per common share:				
Basic	**$ (0.11)**	**$ 0.07**	**$ 0.07**	**$ 0.22**
Diluted	**$ (0.11)**	**$ 0.07**	**$ 0.06**	**$ 0.22**
Weighted-average common shares outstanding:				
Basic	27,783	28,145	28,086	28,074
Diluted	27,783	28,382	28,356	28,261

See accompanying Notes to Summary Consolidated Financial Statements.

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

	September 30, 2010 (Unaudited)	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,002	$ 30,121
Restricted securities	5,316	—
Receivables, net	15,217	14,636
Deferred preservation costs	32,350	36,445
Inventories	6,298	6,446
Deferred income taxes	5,694	5,694
Prepaid expenses and other current assets	2,704	2,186
Total current assets	**98,581**	**95,528**
Property and equipment, net	13,280	14,309
Investment in equity securities	2,608	3,221
Restricted securities	—	5,000
Patents, net	3,345	4,248
Trademarks and other intangibles, net	5,520	2,724
Deferred income taxes	8,887	8,075
Other long-term assets	2,284	754
Total assets	**$ 134,505**	**$ 133,859**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,554	$ 2,954
Accrued compensation	2,858	3,361
Accrued procurement fees	3,072	3,228
Accrued expenses and other current liabilities	6,160	6,302
Deferred income	2,198	2,646
Derivative liability	—	725
Notes payable	405	—
Total current liabilities	**18,247**	**19,216**
Line of credit	—	315
Other long-term liabilities	3,880	3,882
Total liabilities	**22,127**	**23,413**
Shareholders' equity:		
Preferred stock	—	—
Common stock (issued shares of 29,945 in 2010 and 29,475 in 2009)	299	295
Additional paid-in capital	132,816	128,427
Retained deficit	(10,523)	(12,352)
Accumulated other comprehensive loss	(9)	(38)
Treasury stock at cost (shares of 1,778 in 2010 and 1,000 in 2009)	(10,205)	(5,886)
Total shareholders' equity	**112,378**	**110,446**
Total liabilities and shareholders' equity	**$ 134,505**	**$ 133,859**

See accompanying Notes to Summary Consolidated Financial Statements.

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

	Nine Months Ended September 30,	
	2010	2009
	(Unaudited)	
Net cash from operating activities:		
Net income	$ 1,829	$ 6,313
Adjustments to reconcile net income to net cash from operating activities:		
Depreciation and amortization	2,908	3,179
Deferred income taxes	(801)	3,919
Other than temporary investment impairment	3,638	—
Non-cash compensation	1,938	1,795
Write-down of acquired in-process research and development	3,749	—
Write-down of deferred preservation costs and inventories	1,965	392
Write-down of intangible asset	856	—
Gain on valuation of derivative	(1,345)	—
Other non-cash adjustments to income	(922)	154
Changes in operating assets and liabilities:		
Receivables	(738)	(1,425)
Deferred preservation costs	4,188	(2,079)
Inventories	(1,693)	665
Prepaid expenses and other assets	(2,108)	(899)
Accounts payable, accrued expenses, and other liabilities	358	(1,857)
Net cash flows provided by operating activities	**13,822**	**10,157**
Net cash from investing activities:		
Acquisition of Starch Medical intangible assets	(5,392)	—
Capital expenditures	(1,475)	(1,341)
Purchases of restricted securities and investments	(2,705)	(564)
Sales and maturities of marketable securities	—	1,130
Other	(369)	(542)
Net cash flows used in investing activities	**(9,941)**	**(1,317)**
Net cash from financing activities:		
Principal payments on debt	(315)	—
Proceeds from financing of insurance policies	1,475	1,272
Principal payments on capital leases and short-term notes payable	(1,120)	(886)
Proceeds from exercise of stock options and issuance of common stock	236	891
Purchase of treasury stock	(4,295)	(282)
Other	1,013	—
Net cash flows (used in) provided by financing activities	**(3,006)**	**995**
Increase in cash and cash equivalents	**875**	**9,835**
Effect of exchange rate changes on cash	6	10
Cash and cash equivalents, beginning of period	30,121	17,201
Cash and cash equivalents, end of period	**$31,002**	**$27,046**
Supplemental disclosures of cash flow information - non-cash investing activities:		
Issuance of common stock for acquisition of Starch Medical intangible assets	$ 989	$ —

See accompanying Notes to Summary Consolidated Financial Statements.

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

1. Basis of Presentation

The accompanying summary consolidated financial statements include the accounts of CryoLife, Inc. and its subsidiaries ("CryoLife," the "Company," "we," or "us"). All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying Summary Consolidated Balance Sheet as of December 31, 2009 has been derived from audited financial statements. The accompanying unaudited summary consolidated financial statements as of and for the three and nine months ended September 30, 2010 and 2009 have been prepared in accordance with (i) accounting principles generally accepted in the U.S. for interim financial information and (ii) the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission ("SEC"). Accordingly, such statements do not include all of the information and disclosures required by accounting principles generally accepted in the U.S. for a complete presentation of financial statements. In the opinion of management, all adjustments (including those of a normal, recurring nature) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. 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, 2009.

2. Financial Instruments

Financial instruments measured at fair value are recorded in accordance with the fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;
- Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data; and
- Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available.

A summary of the Company's financial instruments measured at fair value as of September 30, 2010 is as follows (in thousands):

	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
U.S. Treasury money market funds	$ —	$1,854	$ —	$ 1,854
U.S. Treasury debt securities	16,548	—	—	16,548
Restricted securities:				
Money market funds	—	316	—	316
U.S. Treasury debt securities	5,000	—	—	5,000
Total assets	$21,548	$2,170	$ —	$23,718

Changes in fair value of level 3 liabilities are listed in the table below (in thousands). Refer to Note 5 for further discussion of the derivative liability.

	Derivative Liability
Balance as of December 31, 2009	$ 725
Total gains unrealized included in earnings	(1,345)
Purchases	620
Balance as of September 30, 2010	$ —

3. Cash Equivalents and Restricted Securities

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

	Cost Basis	Unrealized Holding Gains	Estimated Market Value
September 30, 2010			
Cash equivalents:			
U.S. Treasury money market funds	$ 1,854	$ —	$ 1,854
U.S. Treasury debt securities	16,548	—	16,548
Restricted securities:			
Money market funds	316	—	316
U.S. Treasury debt securities	5,000	—	5,000
December 31, 2009			
Cash equivalents:			
U.S. Treasury money market funds	$18,754	$ —	$18,754
U.S. Treasury debt securities	8,999	—	8,999
Restricted securities:			
U.S. Treasury money market funds, long-term	5,000	—	5,000

As of September 30, 2010 $316,000 of the Company's money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating to international tax obligations. As of September 30, 2010 $5.0 million of the Company's U.S. Treasury debt securities and as of December 31, 2009 $5.0 million of the Company's U.S. Treasury money market funds were designated as restricted securities due to a financial covenant requirement under the Company's credit agreement with General Electric Capital Corporation ("GE Capital") as discussed in Note 9.

There were no material realized gains or losses on cash equivalents in the nine months ended September 30, 2010 and 2009. At September 30, 2010 $5.0 million of restricted securities had a maturity date within 90 days and $316,000 of restricted securities had a maturity date of between 90 days and one year. As of December 31, 2009 none of the Company's restricted securities had a maturity date.

4. Starch Medical Agreements

Overview

On September 28, 2010 CryoLife entered into a worldwide distribution agreement (the "Distribution Agreement") and a license and manufacturing agreement (the "License Agreement") with Starch Medical Inc. ("SMI") of San Jose, California for PerClot®, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, spinal, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. Under the terms of the agreements, CryoLife received the worldwide rights, excluding China, Taiwan, Hong Kong, Macau, North Korea, Iran, and Syria, to commercialize PerClot for all approved surgical indications and a license to manufacture the PerClot product, exclusive of rights to sell PerClot with an endoscope. CryoLife also received an assignment of the PerClot trademark from SMI as part of the terms of the agreements. CryoLife plans to file an Investigational Device Exemption with the U.S. Food and Drug Administration ("FDA") to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S.

The Distribution Agreement contains certain minimum purchase requirements and has a term of 15 years. CryoLife may begin manufacturing PerClot from plant starch modified by SMI under the terms of the License Agreement, which is anticipated to occur sometime in 2011 or 2012. Following the start of manufacturing and U.S. regulatory approval, CryoLife may terminate the Distribution Agreement. CryoLife will pay royalties to SMI at stated rates on net revenues of products manufactured under the License Agreement. In addition to allowing CryoLife to manufacture PerClot, the License Agreement grants CryoLife a three-year option to purchase certain remaining related technology from SMI.

As part of the transaction, CryoLife paid SMI $6.75 million in cash, which includes $1.5 million in cash for prepaid royalties, and approximately 209,000 shares of restricted CryoLife common stock. CryoLife will pay additional contingent amounts of up to $2.75 million to SMI if certain FDA regulatory and other commercial milestones are achieved.

Accounting for the Transaction

CryoLife accounted for the agreements discussed above as an asset acquisition. The initial consideration aggregated approximately $8.0 million, including $6.75 million in cash, restricted common stock valued at approximately $1.0 million, and direct transaction costs. CryoLife recorded a non-current asset for the $1.5 million in prepaid royalties and allocated the remaining consideration to the individual intangible assets acquired based on their relative fair values as determined by a valuation study. As a result, CryoLife recorded intangible assets of $319,000 for the PerClot trademark, $2.4 million for the PerClot distribution and manufacturing rights in certain international countries, and $3.7 million for the PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This $3.7 million is considered in-process research and development as it is dependant upon regulatory approvals which have not yet been obtained. Therefore, CryoLife expensed the $3.7 million as in-process research and development upon acquisition. The PerClot trademark acquired by the Company has an indefinite useful life; therefore, that asset will not be amortized, but will instead be subject to periodic impairment testing. The $2.4 million intangible asset will be amortized over its useful life of 15 years. See additional disclosures in Note 7 below.

CryoLife expects to record future contingent payment amounts of up to $2.75 million initially as research and development expense or, after FDA approval or issuance of a patent, as acquired intangible assets. The common stock issued to SMI will be held by CryoLife until March 31, 2012, when the restricted provisions of the stock lapse.

5. Medafor Matters

Overview

CryoLife began distributing HemoStase® ("HemoStase") in 2008 for Medafor, Inc. ("Medafor"), a privately held company incorporated in Minnesota, under a private label exclusive distribution agreement between the parties (the "EDA"). In November 2009 and in 2010 the Company executed stock purchase agreements to purchase a total of approximately 2.4 million shares of common stock in Medafor for $4.9 million. The carrying value of this investment as of June 30, 2010 was $6.2 million or $2.61 per share, which included the purchase price and adjustments to record certain of the stock purchase agreements' embedded derivative liabilities at the fair market value on the purchase date, as discussed further below. As Medafor's common stock is not actively traded on any public stock exchange and as Medafor is a privately held company for which financial information is not readily available, the Company accounted for this investment using the cost method and recorded it as the long-term asset, investment in equity securities, on the Company's Summary Consolidated Balance Sheets.

Recent Events

On March 18, 2010 Medafor announced that it was treating the EDA as terminated and ceased shipments of HemoStase to CryoLife. CryoLife thereafter moved the U.S. District Court for the Northern District of Georgia, Atlanta Division (the "Court") to preliminarily enjoin Medafor from proceeding with its termination. Shortly thereafter, Medafor informed CryoLife that, although Medafor had terminated the EDA, it would continue to act as if the EDA were in effect for a short period of time. Medafor resumed shipments of HemoStase in late June of 2010. On September 20, 2010, the Court issued an order denying CryoLife's request for the preliminary injunction. On September 27, 2010, Medafor sent CryoLife a letter stating that it was fully and finally terminating the EDA based upon CryoLife's alleged repudiation, although it had never rescinded its prior termination. This was the sixth time that Medafor notified CryoLife that it either had terminated the EDA or was going to terminate the EDA.

Based on this communication and subsequent communications CryoLife has received from Medafor, CryoLife does not believe that Medafor will make any further inventory shipments to CryoLife. CryoLife was Medafor's largest distributor in 2009 and 2008, accounting for 19% and 15% of Medafor's total revenues, respectively. See further discussion of these recent events in "Legal Action" below.

On September 28, 2010 CryoLife announced that it had entered into a worldwide Distribution Agreement and License Agreement with SMI for PerClot, a competing hemostatic agent used in surgery, as discussed in Note 4 above.

Investment in Medafor Common Stock

During the three months ended September 30, 2010, the Company reviewed available information, including the events described in the paragraphs above, to determine if factors indicated that a decrease in value of the investment in Medafor common stock had occurred. CryoLife determined that the available information, particularly Medafor's termination of its largest distributor, indicated that the Company should evaluate its investment in Medafor common stock for impairment.

CryoLife used a market based approach for the valuation, including comparing Medafor to a variety of comparable publicly traded companies, recent merger targets, and company groups. CryoLife considered both qualitative and quantitative factors that could effect the valuation of Medafor's common stock. Based on its analysis, the Company believes that its investment in Medafor was impaired and that this impairment was other than temporary. Therefore, CryoLife recorded a non-operating expense, other than temporary investment impairment, of $3.6 million to write-down its investment in Medafor common stock. The carrying value of the Company's 2.4 million shares of Medafor common stock after this write-down was $2.6 million or $1.09 per share as of September 30, 2010.

The Company will continue to evaluate the carrying value of this investment if changes to the factors discussed above or additional factors become known that indicate the Company should evaluate its investment in Medafor common stock for further impairment. If the Company subsequently determines that the value of its Medafor common stock has been impaired further or if the Company decides to sell its Medafor common stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in Medafor could be material.

Medafor Derivative

Per the terms of certain of the stock purchase agreements for the Medafor shares discussed above, in the event that CryoLife acquires more than 50% of the diluted outstanding stock of Medafor or merges with Medafor within a three-year period from each respective agreement date (a "Triggering Event"), CryoLife is required to make a future per share payment (the "Purchase Price Make-Whole Payment") to such sellers. The payment would be equal to the difference between an amount calculated using the average cost of any subsequent shares purchased, as defined in each respective agreement, and the price of the shares purchased pursuant to each applicable stock purchase agreement. The Company was required to account for these Purchase Price Make-Whole Payment provisions as embedded derivatives (collectively the "Medafor Derivative").

CryoLife performed a valuation of the Medafor Derivative using a Black-Scholes model to estimate the future value of the shares on the purchase date. Management's assumptions as to the likelihood of a Triggering Event occurring coupled with the valuation of the Purchase Price Make-Whole Payment were then used to calculate the derivative liability. The fair value of the Medafor Derivative was initially recorded as an increase to the investment in equity securities and a corresponding derivative liability on the Company's Summary Consolidated Balance Sheet. The Medafor Derivative is revalued quarterly, and any change in the value of the derivative subsequent to the purchase date is recorded in the Company's Summary Consolidated Statement of Operations.

As of September 30, 2010 the Company believed that the likelihood of a Triggering Event was zero. As a result, the Company recorded a gain on the change in the value of derivative on the Summary Consolidated Statement of Operations of $143,000 and $1.3 million for the three and nine months ended September 30, 2010, respectively. The non-cash gain on valuation of the Medafor Derivative was substantially due to changes during these periods in the Company's estimates of the likelihood of a Triggering Event occurring.

The gain on valuation of the Medafor Derivative was recorded as a decrease in the derivative liability on the Summary Consolidated Balance Sheet. This decrease in the liability was partially offset by an increase of $620,000 related to additional purchases of Medafor common stock during the nine months ended September 30, 2010. See also the disclosure of the change in fair value of the derivative liability in Note 2. The value of the Medafor Derivative was zero and $725,000 as of September 30, 2010 and December 31, 2009, respectively.

HemoStase Inventory

Based on Medafor's termination of the EDA in late September 2010 and the determination that Medafor would no longer be shipping HemoStase to CryoLife, the Company performed a review of its HemoStase inventory to determine if the carrying value of the inventory had been impaired.

Per its review of the EDA, the Company expects to continue to sell HemoStase for a six month period following the most recent termination of the EDA. As a result, the Company determined that the carrying value of the HemoStase inventory was

impaired and increased its cost of products by $1.6 million to write-down related finished goods inventory in the three months ended September 30, 2010. The Company believes that the remaining value of $1.7 million of HemoStase inventory after the write-down is recoverable over the six-month selling period following the termination of the EDA.

The amount of this write-down reflects management's estimate based on information currently available. Management will continue to evaluate the recoverability of its HemoStase inventory as more information becomes available and may record additional write-downs if it becomes clear that additional impairments have occurred. The write-down creates a new cost basis which cannot be written back up if the inventory becomes saleable. The cost of products in future periods may be favorably impacted if the Company is able to sell more HemoStase than the amounts estimated as discussed above.

Legal Action

CryoLife's Lawsuit and Claims with Medafor

As previously reported in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2009, and CryoLife's Forms 10-Q for the quarters ended March 31, 2010, and June 30, 2010, CryoLife filed a lawsuit against Medafor in 2009 in the Court, alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia's Racketeer Influenced and Corrupt Organizations Act ("Georgia RICO"). The lawsuit arises out of the EDA, which gave CryoLife the right to distribute a product manufactured by Medafor under the name HemoStase. The Court dismissed CryoLife's Georgia RICO claim on August 9, 2010. On October 20, 2010 CryoLife filed supplemental claims against Medafor for additional breaches of contract, including those related to Medafor's wrongful termination of the EDA.

CryoLife's Potential Damages

The Company seeks to recover its damages from Medafor, accompanied by preliminary and permanent injunctive relief, punitive damages, and reimbursement of its attorneys' fees. In addition, the Company will seek damages related to Medafor's wrongful termination of the EDA, which will be based upon the Company's lost profits for the period of time during which the EDA would have continued in effect but for Medafor's termination of it. The amount of these damages will be determined through discovery in the lawsuit. No trial date has been set.

Medafor's Counter-claims

On September 8, 2010 Medafor answered CryoLife's complaint and filed a counter-complaint against CryoLife, alleging claims for, among other things, breach of contract, breach of the implied duty of good faith and fair dealing, violation of the Georgia trade secrets act, tortious interference with business relationships, libel, violation of the uniform deceptive trade practices act, fraud and negligent misrepresentation. In addition, Medafor requested that the Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Uniform Commercial Code.

Background on Current Status of the EDA – Medafor's Decision to Terminate the EDA Due to CryoLife's Alleged Repudiation

As previously reported in CryoLife's Current Report on Form 8-K dated March 19, 2010, and CryoLife's Forms 10-Q for the quarters ended March 31, 2010 and June 30, 2010, Medafor informed CryoLife on March 18, 2010 of its contention that CryoLife had repudiated the EDA, thereby entitling Medafor to terminate the EDA. Medafor asserted that it had made a valid statutory demand, in a February 10, 2010 letter to CryoLife, for "adequate assurances" of CryoLife's future performance under the EDA, and that CryoLife had repudiated the EDA by failing to respond in a timely manner. On March 22, 2010 CryoLife informed Medafor that it disputed Medafor's assertions, and that Medafor had no right to terminate the EDA. CryoLife then filed a motion for preliminary injunction, asking the Court to enjoin Medafor from proceeding with its termination of the EDA.

As previously reported in CryoLife's Current Report on Form 8-K dated September 20, 2010, the Court, on September 20, 2010, issued an order denying CryoLife's request for a preliminary injunction against Medafor. Although the order denied the preliminary injunction, it did not address the merits of the parties' respective positions on the underlying issues, which the Court viewed as more appropriately addressed at summary judgment.

As previously reported in CryoLife's Current Report on Form 8-K dated September 28, 2010, on September 27, 2010, Medafor sent CryoLife a letter stating that it had fully and finally terminated the EDA based upon CryoLife's alleged repudiation. This was Medafor's sixth termination or termination attempt with respect to the EDA.

Medafor's Letters to CryoLife Asserting Additional Claims

On September 29, 2010 Medafor notified CryoLife that it was Medafor's position that CryoLife's interactions with Starch Medical, Inc. had resulted in numerous breaches of the EDA by CryoLife that could not be cured. Medafor additionally informed CryoLife that Medafor believed these alleged breaches were additional bases for termination of the EDA. Finally, Medafor informed CryoLife that Medafor would promptly move to amend its counter-claim to add additional claims for breach of contract and fraud, and for conspiracy and aiding and abetting, and other undefined claims.

On October 1, 2010 Medafor notified CryoLife that it was Medafor's position that CryoLife's continued selling of HemoStase tortiously interferes with Medafor's customer relationships and violates the Lanham Act and Georgia's Deceptive Trade Practices Act. Medafor informed CryoLife that if CryoLife continued to sell HemoStase, Medafor would amend its counter-claim to add claims for violations of the Lanham Act and Georgia's Deceptive Trade Practices Act, and other undefined claims.

As of November 4, 2010 Medafor has not amended its counter-claims, although CryoLife expects Medafor to do so by November 12, 2010.

Summary of Medafor's Potential Damages Claims

Pursuant to its counter-claims to date, Medafor seeks to recover its alleged damages from CryoLife, including rescinding the EDA to restore to Medafor all of the benefits that CryoLife has received under the EDA, compensatory damages, injunctive relief, prejudgment interest, punitive damages, and attorneys' fees and expenses.

Current Status of the Lawsuit

No trial date has been set. Discovery began on October 8, 2010. CryoLife has filed Rule 12(e) and (f) motions, requesting that the Court compel Medafor to make more definitive claims with regards to its counter-claims for libel, violations of the Uniform Deceptive Trade Practices Act, and rescission and to strike several of Medafor's affirmative defenses to CryoLife's claims. Medafor filed a motion in response to CryoLife's Rule 12(e) and (f) motions generally opposing CryoLife's requests. CryoLife may also file a Rule 12(c) motion for judgment on the pleadings in order to have the Court dismiss certain claims made by Medafor. CryoLife intends to vigorously prosecute the case and defend itself and contest the matter.

Contingency Related to the Lawsuit and Claims

CryoLife intends to vigorously defend itself and contest the matter. Given the early stage of this case, the Company does not believe at this time that there is a reasonable probability that a loss will occur. Due to the early stage of the case, CryoLife does not currently believe that it is possible to reasonably estimate the amount of loss or a range of losses on the current counter-claims made by Medafor or any future additional counter-claims that may be made by Medafor. The parties have not discussed settlement in any meaningful way.

6. Inventories

Inventories are comprised of the following (in thousands):

	September 30, 2010	December 31, 2009
Raw materials	$ 3,347	$ 4,144
Work-in-process	295	278
Finished goods	2,656	2,024
Total inventories	$ 6,298	$ 6,446

As discussed in Note 5 above, during the quarter ended September 30, 2010, CryoLife wrote-down $1.6 million in HemoStase finished goods inventory due to an impairment. The $2.7 million in finished goods inventory in the table above includes $1.7 million of HemoStase inventory.

7. Intangible Assets

The Company's intangible assets consist of procurement contracts and agreements, trademarks, patents, customer lists, non-compete agreement, and distribution and manufacturing rights acquired in the SMI transaction discussed in Note 4 above.

Indefinite Lived Intangible Assets

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. Accordingly, the Company's indefinite lived intangible assets do not amortize, but are instead subject to periodic impairment testing. As of September 30, 2010 and December 31, 2009 the carrying values of the Company's indefinite lived intangible assets are as follows (in thousands):

	September 30, 2010	December 31, 2009
Procurement contracts and agreements	$ 2,013	$ 2,013
Trademarks	769	435

Definite Lived Intangible Assets

The Company generally amortizes its definite lived intangible assets over their expected useful lives using the straight-line method. As of September 30, 2010 and December 31, 2009 gross carrying values, accumulated amortization, and approximate amortization periods of the Company's definite lived intangible assets are as follows (in thousands):

	Gross Carrying Value	Accumulated Amortization	Amortization Period
September 30, 2010			
Patents	$5,830	$ 2,485	17 Years
Customer lists	579	520	3 Years
Non-compete agreement	381	143	10 Years
Distribution and manufacturing rights	2,441	—	15 Years
December 31, 2009			
Patents	$6,403	$ 2,155	17 Years
Customer lists	574	565	3 Years
Non-compete agreement	381	114	10 Years

Amortization Expense

The following is a summary of amortization expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Amortization expense	$ 132	$ 142	$ 395	$ 413

As of September 30, 2010 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	Remainder of 2010	2011	2012	2013	2014	2015
Amortization expense	$ 173	$685	$671	$583	$489	$464

8. Deferred Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company generated deferred tax assets primarily as a

result of write-downs of deferred preservation costs, inventory, and in-process research and development; accruals for tissue processing and product liability claims; and operating losses.

As of September 30, 2010 the Company had a net deferred tax asset of $14.6 million, including a total of $1.8 million in valuation allowances against deferred tax assets. As of December 31, 2009 the Company had a net deferred tax asset of $13.8 million, including a total of $1.8 million in valuation allowances against deferred tax assets. Valuation allowances at September 30, 2010 and December 31, 2009 related to state net operating loss carryforwards that are not expected to be fully utilized prior to their expiration. The realizability of the Company's deferred tax assets could be limited in future periods following a change in control as mandated by Section 382 of the Internal Revenue Code of 1986, as amended, which relates to certain specified changes in control of taxpayers. The tax years 2006 through 2009 remain open to examination by the major taxing jurisdictions to which the Company is subject.

The Company's effective income tax rate was a benefit of 34% for the three months ended September 30, 2010 and expense of 52% for the nine months ended September 30, 2010 as compared to expense of 41% for both the three and nine months ended September 30, 2009.

9. Debt

GE Credit Agreement

On March 26, 2008 CryoLife entered into a credit agreement with GE Capital as lender, as amended (the "GE Credit Agreement"). The GE Credit Agreement provides for a revolving credit facility in an aggregate amount not to exceed the initial commitment of $15.0 million (including a letter of credit subfacility). The initial commitment may be reduced or increased from time to time pursuant to the terms of the GE Credit Agreement. In the second quarter of 2009, as requested by the German courts, the Company obtained a letter of credit relating to the Company's patent infringement legal proceeding against Tenaxis, Inc. in Germany, which reduced the aggregate borrowing capacity to $14.8 million. The letter of credit had a one-year initial term and automatically renews for additional one-year periods. While the Company currently expects that its aggregate borrowing capacity under the GE Credit Agreement will remain at $14.8 million, there can be no assurance that the borrowing capacity will remain at this level.

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. Further, since April 15, 2008 as required under the terms of the GE Credit Agreement, the Company has been 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 securities on the Company's Summary Consolidated Balance Sheets, as they are restricted for the term of the GE Credit Agreement. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined, of at least $20.0 million. The GE Credit Agreement includes customary conditions on incurring new indebtedness and prohibits payments of cash dividends on the Company's common stock. There is no restriction on the payment of stock dividends. Commitment fees are paid based on the unused portion of the facility. The GE Credit Agreement expires on March 25, 2011, at which time any outstanding principal balance will be due. Based on the expiration date, the Company will classify any amounts due under the GE Credit Agreement as short-term debt and has classified the related restricted securities as a current asset on the September 30, 2010 Summary Consolidated Balance Sheet. As of September 30, 2010 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 at LIBOR, with a minimum rate of 3%, or GE Capital's base rate, with a minimum rate of 4% each, plus the applicable margin. During the second quarter of 2010, the outstanding principal balance of $315,000 on the GE Credit Agreement was paid from cash on hand. As of September 30, 2010 the outstanding balance of the GE Credit Agreement was zero, the aggregate interest rate would be 5.50%, and the remaining availability was $14.8 million. As of December 31, 2009 the outstanding balance of the GE Credit Agreement was $315,000, the aggregate interest rate was 5.50%, and the remaining availability was $14.5 million.

Other

The Company routinely enters into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In March 2010 the Company entered into an agreement to finance approximately $1.5 million in insurance premiums at a 2.707% annual interest rate, which is payable in equal monthly payments over a nine month period. In April 2009 the Company entered into an agreement to finance approximately $1.3 million in insurance premiums at a 3.695% annual interest

rate, which was payable in equal monthly payments over a nine month period. As of September 30, 2010 and December 31, 2009 the aggregate outstanding balances under these agreements were $395,000 and zero, respectively.

Total interest expense was $29,000 and $58,000 for the three months ended September 30, 2010 and 2009, respectively, and $145,000 and $168,000 for the nine months ended September 30, 2010 and 2009, respectively, which included interest on debt and uncertain tax positions.

10. Comprehensive (Loss) Income

The following is a summary of comprehensive (loss) income (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Net (loss) income	$(3,031)	$ 1,862	$1,829	$6,313
Change in translation adjustment	22	(16)	29	30
Comprehensive (loss) income	$(3,009)	$ 1,846	$1,858	$6,343

The tax effect on the translation adjustment is zero for each period presented. The accumulated other comprehensive loss of $9,000 and $38,000 as of September 30, 2010 and December 31, 2009, respectively, consisted solely of currency translation adjustments.

11. (Loss) Income Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Basic (loss) income per common share:				
Net (loss) income	$ (3,031)	$ 1,862	$ 1,829	$ 6,313
Basic weighted-average common shares outstanding	27,783	28,145	28,086	28,074
Basic (loss) income per common share	$ (0.11)	$ 0.07	$ 0.07	$ 0.22

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Diluted (loss) income per common share:				
Net (loss) income	$ (3,031)	$ 1,862	$ 1,829	$ 6,313
Basic weighted-average common shares outstanding	27,783	28,145	28,086	28,074
Effect of dilutive stock options [a]	—	143	126	108
Effect of dilutive unvested restricted stock awards [b]	—	94	144	79
Diluted weighted-average common shares outstanding	27,783	28,382	28,356	28,261
Diluted (loss) income per common share	$ (0. 11)	$ 0.07	$ 0.06	$ 0.22

[a] Stock options to purchase 1.6 million and 1.2 million common shares for the three months ended September 30, 2010 and 2009, respectively, and 1.5 million and 1.3 million common shares for the nine months ended September 30, 2010 and 2009, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding, as such stock options would be antidilutive to the computation of (loss) income per common share.

[b] Unvested restricted stock awards that would have resulted in 145,000 additional dilutive common shares for the three months ended September 30, 2010, were excluded from the calculation of diluted weighted-average common shares outstanding, as such unvested restricted stock would be antidilutive to the computation of (loss) income per common share.

In future periods, basic and diluted (loss) income per common share are expected to be affected by the fluctuations in the fair value of the Company's common stock, the exercise and issuance of additional stock options, the issuance of additional restricted stock awards, and stock repurchases as discussed in Note 12 below.

12. Stock Repurchase

On June 1, 2010 the Company publicly announced that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. The purchase of shares may be made from time to time in the open market or through privately negotiated transactions on such terms as management deems appropriate, and will be dependent upon various factors, including price, regulatory requirements, and other market conditions. As of September 30, 2010 the Company had purchased 767,000 shares of its common stock for an aggregate purchase price of $4.3 million. These shares were accounted for as treasury stock, carried at cost, and reflected as a reduction of shareholders' equity on the Company's Summary Consolidated Balance Sheet.

13. 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 and options to purchase shares of Company common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the "ESPP") for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period.

Equity Grants

The Compensation Committee of the Company's Board of Directors authorized awards of stock from approved stock incentive plans to non-employee Directors and certain Company officers totaling 215,000 and 160,000 shares of common stock during the nine months ended September 30, 2010 and 2009, respectively, which had an aggregate market value of $1.3 million and $1.1 million, respectively.

The Compensation Committee of the Company's Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers and employees totaling 427,000 and 438,000 shares during the nine months ended September 30, 2010 and 2009, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Employees purchased common stock totaling 43,000 and 58,000 shares in the nine months ended September 30, 2010 and 2009, respectively, through the Company's ESPP.

Stock Compensation Expense

The Company values its stock awards based on the stock price on the date of grant and expenses the related compensation cost using the straight-line method over the vesting period. The Company uses a Black-Scholes model to value its stock option grants and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company's ESPP options is also determined using a Black-Scholes model and is expensed over the vesting period. The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, expected volatility, dividend yield, and the risk-free interest rate. The period expense is then determined based on this valuation and, at that time, an estimated forfeiture rate is used to reduce the expense recorded. The Company's estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company and is adjusted to reflect actual forfeitures at each vesting date.

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

	Three Months Ended September 30, 2010		Nine Months Ended September 30, 2010	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	.50 Years	3.75 Years	.34 Years
Expected stock price volatility	N/A	.467	.650	.472
Risk-free interest rate	N/A	0.22%	1.29%	0.16%

	Three Months Ended September 30, 2009		Nine Months Ended September 30, 2009	
	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	N/A	.25 Years	4.00 Years	.25 Years
Expected stock price volatility	N/A	.790	.650	.800
Risk-free interest rate	N/A	0.17%	1.51%	0.15%

The following table summarizes stock compensation expenses (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Stock grant expense	$ 139	$ 224	$ 691	$ 675
Stock option expense	424	383	1,464	1,307
Total stock compensation expense	$ 563	$ 607	$2,155	$1,982

Included in the total stock compensation expense were expenses related to common stock awards and stock options issued in the current year as well as those issued in prior years that continue to vest during the period and compensation related to the Company's ESPP. These amounts were recorded as compensation expense and were subject to the Company's normal allocation of expenses to deferred preservation costs and inventories. The Company capitalized $80,000 and $66,000 in the three months ended September 30, 2010 and 2009, respectively, and $217,000 and $187,000 in the nine months ended September 30, 2010 and 2009, respectively, of the stock compensation expense into its deferred preservation costs and inventories.

As of September 30, 2010 the Company had a total of $1.4 million in unrecognized compensation costs related to unvested stock awards, before considering the effect of expected forfeitures. As of September 30, 2010 this expense is expected to be recognized over a weighted-average period of 1.5 years. As of September 30, 2010 there was approximately $2.3 million in total unrecognized compensation costs related to unvested stock options, before considering the effect of expected forfeitures. As of September 30, 2010 this expense is expected to be recognized over a weighted-average period of 1.5 years.

14. Segment Information

The Company has two reportable segments organized according to its services and products: Preservation Services and Medical Devices. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues during 2010 and 2009 and from shipments of previously preserved orthopaedic tissues during 2009. The Medical Devices segment includes external revenues from product sales of BioGlue® Surgical Adhesive ("BioGlue"), BioFoam® Surgical Matrix ("BioFoam"), and HemoStase, as well as sales of other medical devices. 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 preservation services and products. 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 preservation services and products, and gross margins for the Company's operating segments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Revenues:				
Preservation services	$15,111	$15,033	$45,699	$42,672
Medical devices	13,175	12,806	41,276	39,669
Other [a]	157	380	448	729
Total revenues	28,443	28,219	87,423	83,070
Cost of preservation services and products:				
Preservation services	8,911	8,903	27,322	24,421
Medical devices	4,310	2,275	9,318	6,478
Total cost of preservation services and products	13,221	11,178	36,640	30,899
Gross margin:				
Preservation services	6,200	6,130	18,377	18,251
Medical devices	8,865	10,531	31,958	33,191
Other [a]	157	380	448	729
Total gross margin	$15,222	$17,041	$50,783	$52,171

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Preservation services:				
Cardiac tissue	$ 7,189	$ 7,315	$20,953	$19,377
Vascular tissue	7,922	7,699	24,746	23,147
Orthopaedic tissue	—	19	—	148
Total preservation services	15,111	15,033	45,699	42,672
Products:				
BioGlue and BioFoam	11,046	11,180	35,219	35,323
HemoStase	2,129	1,562	6,127	4,139
Other medical devices	—	64	(70)	207
Total products	13,175	12,806	41,276	39,669
Other [a]	157	380	448	729
Total revenues	$28,443	$28,219	$87,423	$83,070

[a] For the three and nine months ended September 30, 2010 and 2009, the "Other" designation includes grant revenue.

15. Commitments and Contingencies

Liability Claims

In the normal course of business the Company is made aware of adverse events involving its tissues and products. Any adverse event could ultimately give rise to a lawsuit against the Company. In addition, tissue processing and product liability claims may be asserted against the Company in the future based on events it is not aware of at the present time. The Company maintains claims-made insurance policies to mitigate its financial exposure to tissue processing and product liability claims. Claims-made insurance policies generally cover only those asserted claims and incidents that are reported to the insurance carrier while the policy is in effect. Thus, a claims-made policy does not generally represent a transfer of risk for claims and incidents that have been incurred but not reported to the insurance carrier during the policy period. Any punitive damage components of claims are uninsured.

The Company believes that the assumptions it uses to determine its unreported loss liability provide a reasonable basis for its calculation. However, the accuracy of the estimates is limited by the general uncertainty that exists for any estimate of future activity due to uncertainties surrounding the assumptions used and due to Company specific conditions and the scarcity of industry data directly relevant to the Company's business activities. Due to these factors, actual results may differ significantly from the assumptions used and amounts accrued.

The Company accrues its estimate of unreported tissue processing and product liability claims as components of accrued expenses and other long-term liabilities and records the related recoverable insurance amounts as a component of receivables and other long-term assets. The amounts recorded represent management's estimate of the probable losses and anticipated recoveries for unreported claims related to services performed and products sold prior to the balance sheet date.

At September 30, 2010 and December 31, 2009 the short-term and long-term portions of the unreported loss liability and any related recoverable insurance amounts are as follows (in thousands):

	September 30, 2010	December 31, 2009
Short-term liability	$ 1,545	$ 1,890
Long-term liability	1,535	1,790
Total liability	3,080	3,680
Short-term recoverable	575	660
Long-term recoverable	620	680
Total recoverable	1,195	1,340
Total net unreported loss liability	$ 1,885	$ 2,340

Further analysis indicated that the liability as of September 30, 2010 could be estimated to be as high as $5.2 million, based on a higher estimate of future claims frequency.

On March 31, 2010 the Company bound liability coverage for the 2010/2011 insurance policy year. This policy is an eight-year claims-made insurance policy, i.e. claims incurred during the period April 1, 2003 through March 31, 2011 and reported during the period April 1, 2010 through March 31, 2011 are covered by this policy. Claims incurred prior to April 1, 2003 that have not been reported are uninsured.

As of November 4, 2010 there were no pending tissue processing or product liability lawsuits filed against the Company.

Lawsuit with Medafor

See Note 5 above for discussion of CryoLife's ongoing business litigation arising from a contract dispute with Medafor.

PART I – FINANCIAL INFORMATION

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

Overview

CryoLife, Inc. ("CryoLife", the "Company", "we", or "us"), incorporated January 19, 1984 in Florida, preserves and distributes human tissues and develops, manufactures, and commercializes medical devices for cardiac and vascular transplant applications. The human tissue distributed by CryoLife includes the CryoValve® SG pulmonary heart valve ("CryoValve SGPV") and the CryoPatch® SG pulmonary cardiac patch tissue ("CryoPatch SG"), both processed using CryoLife's proprietary SynerGraft® technology. CryoLife's medical devices consist primarily of surgical adhesives, sealants, and hemostats including BioGlue® Surgical Adhesive ("BioGlue"), BioFoam® Surgical Matrix ("BioFoam"), PerClot® , which the Company began distributing for Starch Medical Inc. ("SMI") in October of 2010, and HemoStase® ("HemoStase"), which the Company currently distributes for Medafor, Inc. ("Medafor"), although CryoLife has received notice from Medafor that it has terminated its HemoStase distribution agreement with CryoLife.

In the third quarter of 2010 CryoLife announced that it had entered into an agreement to sell PerClot®, a novel polysaccharide hemostatic agent used in surgery, currently manufactured by SMI. This announcement helped to address the anticipated absence of HemoStase from CryoLife's product portfolio, due to Medafor's most recent termination of the exclusive distribution agreement (the "EDA") between the parties. See further discussion of SMI and Medafor below. In early October 2010, CryoLife also announced that BioGlue has been approved in Japan for use in the repair of aortic dissections. CryoLife expects to begin selling BioGlue in Japan through its distribution partner Century Medical, Inc. in the first half of 2011.

CryoLife generated significant cash from operations of $13.8 million during the first nine months of 2010. This cash flow performance was largely due to the Company's strong sales coupled with careful management of its operating cash requirements, including a $4.2 million reduction in the Company's deferred preservation cost balances since December 31, 2009. See the "Results of Operations" section below for additional analysis of the three and nine months ended September 30, 2010.

Recent Events

Starch Medical

On September 28, 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI of San Jose, California for PerClot®, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powder hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, spinal, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. CryoLife plans to file an Investigational Device Exemption with the U.S. Food and Drug Administration ("FDA") to begin clinical trials for the purpose of obtaining Premarket Approval to distribute PerClot in the U.S.

Medafor

As previously reported, on March 18, 2010 Medafor announced that it was treating the EDA as terminated and ceased shipments of HemoStase to CryoLife. CryoLife thereafter moved the U.S. District Court for the Northern District of Georgia, Atlanta Division (the "Court") to preliminarily enjoin Medafor from proceeding with its termination. Shortly thereafter, Medafor informed CryoLife that, although Medafor had terminated the EDA, it would continue to act as if the EDA were in effect for a short period of time. Medafor resumed shipments of HemoStase in late March of 2010. On September 20, 2010 the Court issued an order denying CryoLife's request for the preliminary injunction. On September 27, 2010 Medafor sent CryoLife a letter stating that it was fully and finally terminating the EDA based upon CryoLife's alleged repudiation, although it had never rescinded its prior termination. This was the sixth time that Medafor notified CryoLife that it either had terminated the EDA or was going to terminate the EDA.

Based on this communication and subsequent communications CryoLife has received from Medafor, CryoLife does not believe that Medafor will make any further inventory shipments to CryoLife. CryoLife was Medafor's largest distributor in 2009 and 2008, accounting for 19% and 15% of Medafor's total revenues, respectively. As of September 30, 2010 CryoLife owned approximately 2.4 million shares of Medafor common stock. See also Part I, Item 2, "Risks and Uncertainties" and Part II, Item 1, "Legal Proceedings."

Stock Repurchase Program

The Company announced on June 1, 2010 that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. As of September 30, 2010 the Company had repurchased approximately 767,000 shares or $4.3 million of its common stock in accordance with this plan.

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, 2009. 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 consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., which require the Company to make estimates and assumptions. The Company did not experience any significant changes during the quarter ended September 30, 2010 in its Critical Accounting Policies from those contained in the Company's Form 10-K for the year ended December 31, 2009.

New Accounting Pronouncements

There were no new accounting pronouncements relevant to the Company that management anticipates adopting during the year ending December 31, 2010.

Results of Operations
(Tables in thousands)

Revenues

	Revenues for the Three Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Three Months Ended September 30,	
	2010	2009	2010	2009
Preservation services:				
Cardiac tissue	$ 7,189	$ 7,315	25%	26%
Vascular tissue	7,922	7,699	28%	27%
Orthopaedic tissue	—	19	—%	—%
Total preservation services	15,111	15,033	53%	53%
Products:				
BioGlue and BioFoam	11,046	11,180	39%	40%
HemoStase	2,129	1,562	7%	6%
Other medical devices	—	64	—%	—%
Total products	13,175	12,806	46%	46%
Other	157	380	1%	1%
Total	$28,443	$28,219	100%	100%

	Revenues for the Nine Months Ended September 30,		Revenues as a Percentage of Total Revenues for the Nine Months Ended September 30,	
	2010	2009	2010	2009
Preservation services:				
Cardiac tissue	$20,953	$19,377	24%	23%
Vascular tissue	24,746	23,147	28%	28%
Orthopaedic tissue	—	148	—%	—%
Total preservation services	45,699	42,672	52%	51%
Products:				
BioGlue and BioFoam	35,219	35,323	40%	43%
HemoStase	6,127	4,139	7%	5%
Other medical devices	(70)	207	—%	—%
Total products	41,276	39,669	47%	48%
Other	448	729	1%	1%
Total	$87,423	$83,070	100%	100%

Revenues increased 1% for the three months and 5% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, respectively. A detailed discussion of the changes in preservation services revenues, product revenues, and other revenues for the three and nine months ended September 30, 2010 is presented below.

Preservation Services

Revenues from preservation services increased 1% for the three months and 7% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, respectively. The increase for the three months ended September 30, 2010 was primarily due to an increase in vascular preservation service revenues. The increase for the nine months ended September 30, 2010 was due to an increase in both cardiac and vascular preservation services revenues. See further discussion of cardiac and vascular preservation services revenues below.

Cardiac Preservation Services

Revenues from cardiac preservation services (consisting of revenues from the distribution of heart valves, cardiac patch tissues, and minimally processed tissues that are distributed to a third party tissue processor) decreased 2% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009, primarily due to the impact of a 7% decrease in shipments of heart valves and cardiac patch tissues, partially offset by favorable tissue mix.

Revenues from cardiac preservation services increased 8% for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009, primarily due to the aggregate impact of favorable tissue mix and a 4% increase in shipments of heart valves and cardiac patch tissues.

The favorable tissue mix in the three and nine months ended September 30, 2010 was primarily due to the favorable impact of SynerGraft tissues including the CryoValve SGPV and CryoPatch SG, which command a premium fee over standard processed tissues.

The decrease in cardiac tissue shipments for the three months ended September 30, 2010 was primarily in traditionally processed pulmonary valves and cardiac patch tissues, partially offset by an increase in CryoValve SGPV. The increase in cardiac tissue shipments for the nine months ended September 30, 2010 was primarily in CryoValve SGPV and CryoPatch SG, partially offset by a decrease in traditionally processed cardiac patch tissues and pulmonary valves.

In both the three and nine months ended September 30, 2010, the decrease in revenues from traditionally processed pulmonary valves was more than offset by an increase in revenues related to the CryoValve SGPV, as hospitals continue to transition to the SynerGraft processed product, particularly after the shelf-life extension discussed further below. In the three months ended, and to a lesser extent in the nine months ended, September 30, 2010 the decrease in revenues from traditionally processed cardiac patch tissues was not fully offset by increases in revenues from the CryoPatch SG. The Company believes that these revenues were unfavorably impacted by increasing competitive pressures and by a reduced supply of standard processed patch tissues available for shipment during the period as the Company works to achieve an optimal balance among its offered tissues. These lost revenues were not replaced by the CryoPatch SG, which has not yet received the market penetration and acceptance of the CryoValve SGPV.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 37% and 33% of total cardiac preservation services revenues for the three and nine months ended September 30, 2010, respectively, and 26% and 24% of total cardiac preservation services revenues for the three and nine months ended September 30, 2009, respectively. Domestic revenues accounted for 93% of total cardiac preservation services revenues for both the three and nine months ended September 30, 2010 and 93% and 95% of total cardiac preservation services revenues for the three and nine months ended September 30, 2009, respectively.

In the second quarter of 2010 the Company received FDA clearance to extend the shelf-life of the CryoValve SGPV to five years. Following the announcement of the shelf-life extension, in June 2010 the Company shipped significantly more CryoValve SGPVs than in any other month since the initial FDA clearance of this valve in March 2008. The Company continued to ship higher numbers of CryoValve SGPVs in the three months ended September 30, 2010 than before the shelf-life extension, although the number of shipments did decrease during the course of the quarter. As a result, the Company believes that it may experience additional favorable tissue mix during the remainder of 2010 if the Company continues shipping a higher percentage of CryoValve SGPVs than in the corresponding prior year periods, however, this trend may not continue or may slow in future months.

Vascular Preservation Services

Revenues from vascular preservation services increased 3% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009, primarily due to an increase in average service fees, which increased revenues by 2%.

Revenues from vascular preservation services increased 7% for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009, primarily due to a 4% increase in unit shipments of vascular tissues, which increased revenues by 5% and an increase in average service fees, which increased revenues by 2%.

The increase in vascular volume for the nine months ended September 30, 2010 was primarily due to increases in shipments of saphenous veins, resulting from the strong demand for these tissues in domestic markets, primarily for use in peripheral vascular reconstruction surgeries to avoid limb amputations.

Products

Revenues from products increased 3% for the three months and 4% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, respectively. These increases were primarily due to an increase in HemoStase revenues. See further discussions of BioGlue, BioFoam, and HemoStase revenues below.

BioGlue and BioFoam

Revenues from the sale of BioGlue and BioFoam decreased 1% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009. This decrease was primarily due to a 9% decrease in the volume of milliliters sold, which decreased revenues by 5% and the unfavorable impact of foreign exchange, which decreased revenues by 1%, largely offset by an increase in average selling prices, which increased revenues by 5%.

Revenues from the sale of BioGlue and BioFoam were flat for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009. The revenues were impacted by a 6% decrease in the volume of milliliters sold, which decreased revenues by 4% and the unfavorable impact of foreign exchange, which decreased revenues by 1%, offset by an increase in average selling prices, which increased revenues by 5%.

The decrease in sales volume for BioGlue and BioFoam for the three and nine months ended September 30, 2010 was primarily due to a decrease in shipments of BioGlue in domestic markets, particularly in the northeast region of the U.S. Management believes that the decrease in domestic BioGlue shipments is a result of various factors, including: the U.S. market introduction of sealant products with approved indications for use in clinical applications in which BioGlue has been used previously; poor economic conditions and their constraining effect on hospital budgets; the resulting attempts by hospitals to control costs by reducing spending on consumable items such as BioGlue; and the efforts of some large competitors in imposing and enforcing contract purchasing requirements for competing non-CryoLife products.

The impact of foreign exchange for the three months ended September 30, 2010 was due to changes in the exchange rates between the U.S. Dollar and both the British Pound and the Euro in the three and nine months ended September 30, 2010 as compared to the respective periods in 2009. The Company's sales of BioGlue and BioFoam through its direct sales force to United Kingdom hospitals are denominated in British Pounds, and its sales to German hospitals, Austrian hospitals, and certain distributors are denominated in Euros.

The increase in average selling prices for the three and nine months ended September 30, 2010 was primarily due to list price increases on certain BioGlue products that went into effect during 2009 and 2010 and the negotiation of pricing contracts with certain customers.

Sales of BioGlue and BioFoam for the three and nine months ended September 30, 2010 included international sales of BioFoam following receipt of the CE Mark approval during the third quarter of 2009. BioFoam sales accounted for less than 1% of total BioGlue and BioFoam sales for the three and nine months ended September 30, 2010. Domestic revenues accounted for 70% and 69% of total BioGlue revenues for the three and nine months ended September 30, 2010, respectively, and 70% of total BioGlue revenues for both the three and nine months ended September 30, 2009.

BioGlue has reached a level of market maturity in the U.S. and is experiencing increasing competitive pressures while continuing to achieve higher levels of growth and penetration in international markets due to its expanded clinical indications. Management believes that as economic conditions begin to improve, growth of BioGlue revenues in future periods would most likely be due to price increases and smaller volume increases or expansions into new markets. The Company expects a decrease in usage of BioGlue in the U.S. in those clinical applications for which new sealant products have FDA approval, partially offset by volume growth of BioGlue due to increases in cardiac and vascular surgical procedure volumes where BioGlue is used. The Company anticipates that it will begin shipping BioGlue to Japan in the first half of 2011, as BioGlue was recently approved in Japan for use in the repair of aortic dissections.

HemoStase

Revenues from the sale of HemoStase increased 36% for the three months ended September 30, 2010 as compared to the three months ended September 30, 2009. This increase was primarily due to a 32% increase in the volume of grams sold, which increased revenues by 33% and an increase in average selling prices, which increased revenues by 4%, partially offset by the unfavorable impact of foreign exchange, which decreased revenues by 1%.

Revenues from the sale of HemoStase increased 48% for the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009. This increase was primarily due to a 45% increase in the volume of grams sold, which increased revenues by 46% and an increase in average selling prices, which increased revenues by 3%, partially offset by the unfavorable impact of foreign exchange, which decreased revenues by 1%.

The increase in sales volume for the three and nine months ended September 30, 2010 was primarily due to an increase in shipments of HemoStase in domestic markets and to a lesser extent in international markets.

Management believes that the Company lost additional sales of HemoStase during the third quarter due to uncertainty in the market as to whether the Company had authority to market HemoStase and as to whether it would be able to continue to supply the product in the future. Management believes that third quarter HemoStase sales were also adversely impacted by continued sales by Medafor of Medafor's product into the Company's exclusive territory in violation of the EDA.

The increase in average selling prices for the three and nine months ended September 30, 2010 was primarily due to an increase in domestic average selling prices.

Domestic revenues accounted for 77% and 75% of total HemoStase revenues for the three and nine months ended September 30, 2010, respectively, and 76% of total HemoStase revenues for both the three and nine months ended September 30, 2009.

As discussed in "–Recent Events" above, on September 27, 2010 Medafor informed CryoLife that it had fully and finally terminated the EDA based upon CryoLife's alleged repudiation. Based on this communication and subsequent communications CryoLife has received from Medafor, CryoLife does not believe that Medafor will make any further inventory shipments to CryoLife. CryoLife expects to continue to sell HemoStase until March 26, 2011, six months from the date Medafor sent the September 27, 2010 termination notice. Therefore, CryoLife does not expect to record revenues for HemoStase after that date. CryoLife expects HemoStase revenues during the fourth quarter of 2010 and the first quarter of 2011 to be flat or to decline from the level of revenues experienced for the three months ended September 30, 2010. Although it is difficult to determine, CryoLife's HemoStase revenues could be significantly negatively impacted during this period by confusion in the marketplace, continued competition from Medafor and other Medafor distributors selling into the Company's markets, and by discounts that the Company has offered and expects to continue to offer to its existing HemoStase customers during the period. See also "Cost of Products" below, Part I, Item 2, "Risks and Uncertainties," and Part II, Item 1, "Legal Proceedings."

Other Revenues

Other revenues for the three and nine months ended September 30, 2010 and 2009 included revenues related to funding allocated from U.S. Congress Defense Appropriations Conference Reports in 2005 through 2008, collectively the ("DOD Grants"). As of September 30, 2010 CryoLife had been awarded and had received a total of $5.4 million for the development of protein hydrogel technology, which the Company is currently developing for use in organ sealing. At September 30, 2010 CryoLife had $2.2 million of deferred income on the Company's Summary Consolidated Balance Sheet from the DOD Grants, of which $1.8 million remains in unspent cash advances recorded as cash and cash equivalents.

Cost of Preservation Services and Products

Cost of Preservation Services

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of preservation services	$8,911	$8,903	$27,322	$24,421
Cost of preservation services as a percentage of preservation services revenues	59%	59%	60%	57%

Cost of preservation services was flat for the three months and increased 12% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009, respectively.

Cost of preservation services in the three months ended September 30, 2010 was primarily impacted by an increase in the per unit cost of processing tissues, offset by a decrease in cardiac tissues shipped, as discussed above. The increase in cost of preservation services in the nine months ended September 30, 2010 was primarily due to an increase in the per unit cost of processing tissues and an increase in vascular and cardiac tissues shipped, as discussed above.

The increase in cost of preservation services as a percentage of preservation services revenues for the nine months ended September 30, 2010 was primarily due to the increase in the per unit cost of processing tissues. The increase in the per unit cost of processing tissues in 2010, due to differences in the first half of 2010 as compared to the first half of 2009, was largely a result of decreased processing and packaging throughput.

Cost of Products

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cost of products	$4,310	$2,275	$9,318	$6,478
Cost of products as a percentage of product revenues	33%	18%	23%	16%

Cost of products increased 89% for the three months and 44% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009.

The increase in cost of products in the three and nine months ended September 30, 2010 was primarily due to a $1.6 million write-down of HemoStase inventory. To a lesser extent the increase in the three and nine months ended September 30, 2010 was due to the increase in shipments of HemoStase, as discussed above, and a slight increase in the per unit cost of BioGlue, partially offset by a decrease in the per unit cost of HemoStase and a slight decrease in shipments of BioGlue, as discussed above.

The write-down of HemoStase inventory was based on the Company's review of its inventory balances after Medafor's September 27, 2010 notice that it had fully and finally terminated the EDA with CryoLife to distribute HemoStase. Per the Company's review of the EDA, it expects to continue to sell HemoStase through March 26, 2011. Based on this review, the Company determined that the carrying value of the HemoStase inventory was impaired and increased its cost of products by $1.6 million to write-down HemoStase inventory. See also "–Recent Events" and "Revenues" above, Part I, Item 2, "Risks and Uncertainties," and Part II, Item 1, "Legal Proceedings."

The amount of this write-down reflects management's estimate based on information currently available. Management will continue to evaluate the recoverability of its HemoStase inventory as more information becomes available and may record additional write-downs if it becomes clear that additional impairments have occurred. The write-down creates a new cost basis which cannot be written back up if the inventory becomes saleable. The cost of products in future periods may be favorably impacted if the Company is able to sell more HemoStase than the amounts estimated as discussed above.

The increase in cost of products as a percentage of product revenues for the three and nine months ended September 30, 2010 was primarily due to a $1.6 million write-down of HemoStase inventory, and to a lesser extent a slight increase in the per unit cost of BioGlue and increasing revenues from HemoStase, which has a lower profit margin than BioGlue, partially offset by an increase in BioGlue average selling prices, as discussed above.

Although the Company does not expect that an inventory write-down of a similar magnitude will affect cost of products and cost of products as a percentage of product revenues in future quarters, costs could be impacted in the fourth quarter of 2010 by additional write-downs or by discounts on sales of HemoStase that the Company has offered and expects to continue to offer, which would negatively impact cost of products as a percentage of product revenues.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
General, administrative, and marketing expenses	$11,376	$12,386	$36,863	$37,440
General, administrative, and marketing expenses as a percentage of total revenues	40%	44%	42%	45%

General, administrative, and marketing expenses decreased 8% for the three months and decreased 2% for the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009.

The decrease in general, administrative, and marketing expenses for the three and nine months ended September 30, 2010 was primarily due to a decrease in marketing expenses for the Ross Summit, which were incurred in the fourth quarter of 2010, while comparable marketing expenses for the 2009 Ross Summit were included in the third quarter of 2009. Additionally, marketing expenses including personnel costs and spending on marketing materials decreased, partially offset by an increase in spending on legal and professional fees.

Expenses in the three months ended September 30, 2010 included approximately $283,000 in costs associated with litigation with Medafor. Expenses in the nine months ended September 30, 2010 included $729,000 in previously capitalized legal fees associated with BioGlue patent litigation in Germany, approximately $1.1 million in costs associated with litigation with Medafor, and approximately $542,000 in business development costs, primarily associated with the Company's proposal to acquire Medafor.

The Company's general, administrative, and marketing expenses included $398,000 and $468,000 for the three months ended September 30, 2010 and 2009, respectively, and $1.7 million and $1.6 million for the nine months ended September 30, 2010 and 2009, respectively, related to the grant of stock options and restricted stock awards.

General, administrative, and marketing expenses for the fourth quarter of 2010 will be negatively impacted as compared to 2009 as a result of the Ross Summit expenses. The Company believes that expenses associated with lawsuits, including lawsuits with Medafor, and business development opportunities, including costs associated with potential acquisitions, may materially impact the Company's general, administrative, and marketing expenses for the remainder of 2010 and during 2011.

Research and Development Expenses

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Research and development	$1,354	$1,461	$3,886	$3,854
Research and development expenses as a percentage of total revenues	5%	5%	4%	5%

Research and development spending in 2010 and 2009 was primarily focused on the Company's BioGlue family of products, including: BioGlue and BioFoam, and SynerGraft tissues and products, including: CryoValve SGPV, CryoValve SG aortic heart valves, CryoPatch SG, and xenograft SynerGraft tissue products.

Write-Down of Acquired In-Process Research and Development

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Write-down of acquired in-process research and development	$ 3,749	$ —	$ 3,749	$ —
Write-down of acquired in-process research and development as a percentage of total revenues	13%	—%	4%	—%

As part of the consideration paid to SMI, the Company allocated $3.7 million to an intangible asset for PerClot distribution and manufacturing rights in the U.S. and certain other countries which do not have current regulatory approvals. This $3.7 million is considered in-process research and development as it is dependant upon regulatory approvals which have not yet been obtained. Therefore, CryoLife wrote-down the $3.7 million as in-process research and development upon acquisition.

Other Income and Expenses

Interest expense was $29,000 and $58,000 for the three months ended September 30, 2010 and 2009, respectively, and $145,000 and $168,000 for the nine months ended September 30, 2010 and 2009, respectively. Interest expense for the three and nine months ended September 30, 2010 and 2009 included interest incurred related to the Company's debt and interest related to uncertain tax positions.

Interest income was $6,000 and $10,000 for the three months ended September 30, 2010 and 2009, respectively, and $16,000 and $73,000 for the nine months ended September 30, 2010 and 2009, respectively. Interest income for the three and nine months ended September 30, 2010 and 2009 was primarily due to interest earned on the Company's cash, cash equivalents, and restricted

securities. The decrease in interest income in 2010 was primarily due to a decline in interest rates paid on the Company's cash and cash equivalents, partially offset by an increase in the balance in these accounts.

The other than temporary investment impairment was $3.6 million for both the three and nine months ended September 30, 2010, due to the impairment in the value of the Company's investment in Medafor common stock during the third quarter of 2010. The carrying value of the Company's investment in Medafor common stock after this write-down was $2.6 million or $1.09 per share as of September 30, 2010. The Company will continue to evaluate the carrying value of this investment as appropriate. If the Company subsequently determines that the value of its Medafor common stock has been impaired further or if the Company decides to sell its Medafor common stock for less than the carrying value, the resulting impairment charge or realized loss on sale of the investment in Medafor could be material.

The gain on valuation of derivative was $143,000 and $1.3 million for the three and nine months ended September 30, 2010, respectively. During the fourth quarter of 2009 and during 2010, the Company made several purchases of Medafor common stock that contained purchase price make-whole provisions, which the Company accounted for as embedded derivatives. The decrease in the value of the liability for these embedded derivatives, largely resulting from a significant decrease in the likelihood of a triggering event occurring, resulted in a non-cash gain for the three and nine months ended September 30, 2010. CryoLife believes that the likelihood of a triggering event occurring was substantially reduced in the first quarter and was zero as of September 30, 2010.

Earnings

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
(Loss) income before income taxes	$ (4,588)	$ 3,138	$ 3,819	$10,682
Income tax (benefit) expense	(1,557)	1,276	1,990	4,369
Net (loss) income	$ (3,031)	$ 1,862	$ 1,829	$ 6,313
Diluted weighted-average common shares outstanding	27,783	28,382	28,356	28,261
Diluted (loss) income per common share	$ (0.11)	$ 0.07	$ 0.06	$ 0.22

(Loss) income before income taxes decreased for the three months and the nine months ended September 30, 2010 as compared to the three and nine months ended September 30, 2009. (Loss) income before income taxes for the three and nine months ended September 30, 2010 was negatively impacted primarily by the write-down of acquired in-process research and development with no alternative future use, the other than temporary investment impairment, and the write-down of HemoStase inventory, as discussed above. These effects were partially offset by the gain on valuation of derivative for the nine months ended September 30, 2010.

The Company's effective income tax rate was a benefit of 34% for the three months ended September 30, 2010 and expense of 52% for the nine months ended September 30, 2010 as compared to expense of 41% for both the three and nine months ended September 30, 2009. The Company's income tax rate for the three and nine months ended September 30, 2010 was negatively impacted by the write-downs discussed above, which reduced pretax net income. The Company's effective income tax rate in the fourth quarter of 2010 is expected to be closer to the rates experienced in the first half of 2010.

Net (loss) income and diluted (loss) income per common share for the three and nine months ended September 30, 2010 decreased compared to the corresponding periods in 2009 due to the decrease in income before income taxes and income taxes as discussed above. Basic and diluted income per common share will be impacted in future periods unfavorably by the issuance of common stock to SMI and favorably by the Company's repurchase of its common stock. Stock repurchases are impacted by many factors, however, 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 its cardiac preservation services is 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, who drive the demand for a large percentage of cardiac tissues processed by CryoLife.

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

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 fewer surgeries being performed on adult patients in the summer months in the U.S.

Liquidity and Capital Resources

Net Working Capital

At September 30, 2010 net working capital (current assets of $98.6 million less current liabilities of $18.3 million) was $80.3 million, with a current ratio (current assets divided by current liabilities) of 5 to 1, compared to net working capital of $76.3 million and a current ratio of 5 to 1 at December 31, 2009.

Overall Liquidity and Capital Resources

The Company's primary cash requirements for the nine months ended September 30, 2010 arose out of general working capital needs, consideration paid for the transaction with SMI, the acquisition of Medafor common stock, repurchases of the Company's common stock, and the payment of legal and professional fees. Legal and professional fees during the three and nine months ended September 30, 2010 included costs associated with the Company's litigation with Medafor and business development costs. The Company funded its cash requirements primarily through its operating activities, which generated cash during the period.

During 2009 the Company analyzed its deferred preservation cost balances and their recent growth and began a series of initiatives to reduce the growth of deferred preservation costs. As a result of these initiatives, the growth rate of the Company's deferred preservation costs slowed during 2009, and the balance of the Company's deferred preservation costs decreased by $4.1 million during the first nine months of 2010. The Company believes that its deferred preservation cost balances will continue to decrease for the remainder of 2010; however, the rate of decrease may slow in future months. The Company will continue to manage its incoming tissue procurement and other costs in an effort to manage its deferred preservation cost balances. However, the Company cannot predict its specific deferred preservation cost balances in the future with certainty. The Company believes that the current balance of its deferred preservation costs along with its ongoing preservation service activities is sufficient to support its current and projected revenues.

CryoLife entered into a credit facility with GE Capital in March of 2008, as amended (the "GE Credit Agreement") which provides for up to $15.0 million in revolving credit for working capital, acquisitions, and other corporate purposes, of which $14.8 million was available for borrowing as of September 30, 2010. As of September 30, 2010 the outstanding balance under this agreement was zero. As required under the terms of the GE Credit Agreement, the Company is maintaining cash and cash equivalents of at least $5.0 million in accounts in which GE Capital has a first priority perfected lien. As a result, these funds will not be available to meet the Company's liquidity needs during the term of the GE Credit Agreement, and as such, have been recorded in restricted securities on the Company's Summary Consolidated Balance Sheet. Also, the GE Credit Agreement requires that after giving effect to a stock repurchase the Company maintain liquidity, as defined, of at least $20.0 million.

The Company's cash equivalents include advance funding received under the DOD Grants for the continued development of protein hydrogel technology. As of September 30, 2010 $1.8 million of the Company's cash equivalents were related to these DOD Grants, which must be used for the specified purposes.

The Company believes that its anticipated cash from operations and existing cash and cash equivalents will enable the Company to meet its operational liquidity needs for at least the next twelve months. The Company's future cash requirements may include cash for general working capital needs, to fund business development activities, including acquisitions and attempted acquisitions, to purchase license agreements, future repurchases of the Company's common stock, to fund the Medafor litigation, and for other corporate purposes. The Company has net operating loss carryforwards that will reduce otherwise required cash payments for federal and state income taxes for the 2010 tax year. Cash payments for taxes will increase in 2011 as the Company's federal net operating loss carryforwards are expected to be fully utilized in 2010.

Liability Claims

As of September 30, 2010 the Company had accrued a total $3.1 million for the estimated costs of unreported tissue processing and product liability claims related to services performed and products sold prior to September 30, 2010 and had recorded a receivable of $1.2 million representing estimated amounts to be recoverable from the Company's insurance carriers with respect to such accrued liability. Further analysis indicated that the liability could be estimated to be as high as $5.2 million, based on a higher estimate of future claims frequency. The $3.1 million accrual does not represent cash set aside. The timing of future payments related to the accrual is dependent on when and if claims are asserted, judgments are rendered, and/or settlements are reached. Should payments related to the accrual be required, these monies would have to be paid from insurance proceeds and liquid assets. Since the amount accrued is based on actuarial estimates, actual amounts required could vary significantly from this estimate.

Net Cash from Operating Activities

Net cash provided by operating activities was $13.8 million for the nine months ended September 30, 2010 as compared to $10.2 million for the nine months ended September 30, 2009.

The Company uses the indirect method to prepare its cash flow statement, and accordingly, the operating cash flows are based on the Company's net income, which is then adjusted to remove non-cash items and for changes in operating assets and liabilities from the prior year end. For the nine months ended September 30, 2010 these non-cash items included a favorable $3.7 million for the write-down of acquired in-process research and development as a result of the transaction with SMI, $2.9 million in depreciation and amortization expense, $3.6 million in other than temporary investment impairment, $2.0 million in write-downs of deferred preservation costs and inventory, primarily HemoStase, and $1.9 million in non-cash stock based compensation, partially offset by a $1.3 million non-cash gain on valuation of derivative.

The Company's working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the nine months ended September 30, 2010 these changes included a favorable $4.2 million due to decreases in deferred preservation costs, largely offset by an unfavorable $1.7 million increase in inventory balances, primarily HemoStase purchases prior to the non-cash write-down discussed above, and $2.1 million due to the timing difference between making cash payments and the expensing of assets, primarily prepaid royalties from the transaction with SMI.

The Company expects that the favorable impact of deferred preservation costs on its net cash from operating activities, as discussed above, will continue for the remainder of 2010.

Net Cash from Investing Activities

Net cash used in investing activities was $9.9 million for the nine months ended September 30, 2010 as compared to $1.3 million for the nine months ended September 30, 2009. The current year cash used was primarily due to $5.4 million in payments related to the transaction with SMI, $2.7 million in purchases of marketable securities and investments, largely related to the purchase of Medafor common stock, and $1.5 million in capital expenditures.

Net Cash from Financing Activities

Net cash used in financing activities was $3.0 million for the nine months ended September 30, 2010 as compared to net cash provided of $995,000 for the nine months ended September 30, 2009. The current year cash used was primarily due to $4.3 million in purchases of treasury stock, related to the Company's publicly announced stock repurchase plan, and $1.1 million in principal payments on capital leases and short-term notes payable, partially offset by $1.5 million in proceeds from the financing of insurance policies.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of September 30, 2010 are as follows (in thousands):

	Total	Remainder of 2010	2011	2012	2013	2014	Thereafter
Operating leases	$29,232	$ 427	$2,601	$2,542	$2,472	$2,487	$18,703
Purchase commitments	8,523	1,312	1,128	2,583	3,500	—	—
Compensation payments	3,589	—	1,604	—	992	993	—
Research obligations	3,077	1,060	821	767	429	—	—
SMI contingent payments	2,250	—	750	—	500	1,000	—
Royalty payments	597	—	597	—	—	—	—
Insurance premium obligations	487	355	132	—	—	—	—
Other obligations	366	353	10	3	—	—	—
Total contractual obligations	$48,121	$ 3,507	$7,643	$5,895	$7,893	$4,480	$18,703

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 2013, as that is when the Company expects to receive U.S. FDA approval for PerClot. Upon U.S. FDA approval the Company may terminate its minimum purchase requirements, which it expects to do, but if the Company does not terminate this provision, it will have minimum purchase obligations in 2014 and through the end of the contract term. The Company's purchase commitments also includes obligations from agreements with suppliers to stock certain custom raw materials needed for the Company's processing and production and contractual payments for licensing computer software and telecommunication services.

The Company's compensation payment obligations represent estimated cash payments to be made for its 2010 performance-based bonus plans and 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 2012 expiration date of the CEO's employment agreement. Payment of this benefit may be accelerated by a change in control or by the voluntary retirement of the CEO.

The Company's research obligations represent commitments for ongoing studies and payments to support research and development activities, which will be partially funded by the advances received under the DOD Grants. The timing of these obligations is based on the Company's estimates and will likely change as the related projects progress toward completion. Subsequent to September 30, 2010 the Company entered into a research obligation of $688,000 related to PerClot, which is not included in the scheduled contractual obligations and related payments above.

The obligation for SMI contingent payments represents the contingent milestone payments that the Company will pay if certain FDA regulatory approvals and other commercial milestones are achieved, as discussed in "–Recent Events" above. The schedule excludes one contingent milestone payment of $500,000 as the Company cannot make a reasonably reliable estimate of timing of this future payment.

The Company's royalty payments are related to BioGlue and BioFoam revenues. The Company's insurance premium obligations represent the 2010 renewal of certain of the Company's insurance policies. The Company's other obligations contain various items including estimated real and personal property tax payments, advertising commitments, and other items as appropriate.

The schedule of contractual obligations above excludes (i) obligations for estimated tissue processing and product liability claims unless they are due as a result of a pending settlement agreement or other contractual obligation and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $869,000, because the Company can not make a reasonably reliable estimate of the amount and period of related future payments as no specific assessments have been made for specific litigation or by any taxing authorities.

Capital Expenditures

Capital expenditures for the nine months ended September 30, 2010 were $1.5 million compared to $1.3 million for the nine months ended September 30, 2009. Capital expenditures in the nine months ended September 30, 2010 were primarily related to routine purchases of tissue processing, manufacturing, computer, and office equipment, computer software, and renovations to the Company's corporate headquarters needed to support the Company's business.

Forward-Looking Statements

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

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

- The timing of the anticipated start of manufacturing of PerClot from plant starch modified by SMI;
- The expected timing of contingent payments in the SMI transaction;
- Expectations regarding the costs and timing related to the development and product launch of PerClot, the securing of Premarket Approval and U.S. FDA approval for PerClot, and the termination of the Distribution Agreement for PerClot;
- The Company's belief that Medafor will not make any further HemoStase shipments to CryoLife;
- The Company's expectations about usage and expiration of its income tax net operating loss carryforwards;
- The Company's expectations regarding its borrowing capacity under the GE Credit Agreement;
- Estimated liability for uncertain tax positions and interest and penalties;
- Expectations regarding the factors that will affect basic and diluted income per common share in future periods, including stock repurchases and the SMI transaction;
- The Company's estimate of probable losses and anticipated recoveries for unreported liability claims;
- Anticipated future demand for cardiac and vascular tissues;
- The Company's belief that it may experience additional favorable tissue mix during the remainder of 2010 if the Company continues shipping a higher percentage CryoValve SGPVs than in the corresponding year periods;
- Expectations regarding growth of BioGlue volume and revenues in future periods;
- The Company's expectations regarding BioGlue usage in the U.S. in clinical applications for which new sealant products have FDA approval;
- The Company's expectation that it will begin selling BioGlue in Japan in the first half of 2011;
- Expectations that the Company will continue to distribute HemoStase for a six-month period following the most recent termination of the EDA and that the Company will not record HemoStase revenues after the expiration of the six-month period;
- The Company's expectations for HemoStase revenues during the fourth quarter of 2010 and the first quarter of 2011;
- The Company's belief that the remaining value of the HemoStase inventory after write-down is recoverable over the six-month period following the most recent termination of the EDA;
- Expectations related to discounted sales of HemoStase inventory and any future write-down of HemoStase inventory, and any resultant impact on cost of products and cost of products as a percentage of product revenues;
- Expectations regarding any future impairment charges or realized losses related to the Company's investment in Medafor, or the likelihood of the occurrence of a Triggering Event with respect to the Company's investment in Medafor;
- Expectations that the Company's general, administrative, and marketing expenses for the remainder of 2010 and during 2011 may be materially impacted by expenses associated with lawsuits and business development opportunities, and that such expenses will be negatively impacted for the fourth quarter of 2010 as compared to 2009 as a result of the Ross Summit expenses;
- Expectations regarding the Company's effective income tax rate in the fourth quarter of 2010;
- The Company's belief that its deferred preservation cost balances will continue to decrease for the remainder of 2010, and that the rate of decrease may slow in future months;

- The Company's belief that the current balance of its deferred preservation costs along with its ongoing preservation service activities is sufficient to support its current and projected revenues;
- The Company's expectations that the favorable impacts of deferred preservation costs and deferred income taxes on its net cash from operating activities will continue for the remainder of 2010;
- The Company's belief that it will have sufficient cash to meet its operational liquidity needs for at least the next twelve months;
- Expectations that the Company's future cash requirements may include cash for general working capital needs, to fund business development activities, including acquisitions and attempted acquisitions, to purchase license agreements, future repurchases of the Company's common stock, to fund the Medafor litigation, and for other corporate purposes;
- Anticipated impact of changes in interest rates and foreign currency exchange rates;
- The Company's expectations regarding the timing of court rulings in its legal proceedings, actions the Company may take during the course of litigation, and any loss that may occur as a result of litigation; 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 risks set forth under Part II, Item 1A of this Form 10-Q, the risks set forth under Part II, Item 1A of the Company's Form 10-Q for the quarter ended March 31, 2010, the risk factors set forth under Part I, Item 1A of the Company's Form 10-K for the year ended December 31, 2009, 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

The risks and uncertainties which might impact the forward-looking statements and the Company, its ability to continue as a going concern, and the trading value of its common stock include the risk factors described under Part II, Item 1A of this Form 10-Q and concerns that:

- We are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product;
- We are subject to stringent domestic and foreign regulation which may impede the approval process of our tissues and products, hinder our development activities and manufacturing processes and, in some cases, result in the recall or seizure of previously cleared or approved tissues and products;
- Our investment in Medafor has been diluted as a result of Medafor's issuance of 1.8 million shares to Magle Life Sciences, and in the future Medafor could issue additional shares to dilute which could result in an additional impairments in the value of our investment in Medafor common stock, which could have a material adverse effect on our financial condition and profitability;
- Our investment in Medafor may be impacted by Medafor's decision to terminate our EDA with Medafor, as CryoLife was Medafor's largest distributor in 2009 and 2008. As a result, we could in the future determine that further impairment in the value of our investment in Medafor common stock has occurred, which could have a material adverse effect on our financial condition and profitability;
- We may not be able to readily liquidate our investment in Medafor, and if we are able to liquidate our investment, we may receive less cash than our original investment and we may receive less than the carrying value of our investment;
- Medafor has terminated the EDA and ceased shipments of HemoStase to us, and our remaining sales of HemoStase, may be at a discount, which may have a material adverse effect on our revenues and profitability;
- We have made a substantial investment in our distribution and license and manufacturing agreements with SMI and will commit additional funds in order to attempt to obtain FDA approval for PerClot in the U.S., and our short-term liquidity and earnings in 2010 and 2011 will be impacted by these expenditures and we will not fully realize the benefit of our investment in future years unless we are able to obtain FDA approval for PerClot in the U.S.;
- We may be unsuccessful in our attempts to sell PerClot in the U.S., we may be prevented by Medafor from selling PerClot in both international and domestic markets, and our ability to successfully market and sell PerClot may take longer than expected;
- Medafor has filed counter-claims against us with respect to our lawsuit against Medafor, and if Medafor is successful in its claims, our revenues, profitability, and cash flows may be materially, adversely affected;
- Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us;
- Uncertainties related to patents and protection of proprietary technology may adversely affect the value of our intellectual property;
- Uncertainties related to patents and protection of proprietary technology for products distributed by CryoLife may adversely affect the ability of CryoLife to distribute those products;
- The tissues we process and our products allegedly have caused, and may in the future cause, injury to patients, and we have been and may be exposed to tissue processing and product liability claims and additional regulatory scrutiny as a result;
- We are dependent on the availability of sufficient quantities of tissue from human donors;
- Our CryoValve SGPV post-clearance study may not provide expected results;
- Demand for our tissues and products could decrease in the future, which could have a material adverse effect on our business;
- The success of many of our tissues and products depends upon strong relationships with physicians;
- Consolidation in the healthcare industry could lead to demands for price concessions or limits or eliminate our ability to sell to certain of our significant market segments;
- Our existing insurance policies may not be sufficient to cover our actual claims liability;
- We may be unable to obtain adequate insurance at a reasonable cost, if at all;
- The loss of any of our sole-source suppliers could have an adverse effect on our revenues, financial condition, profitability, and cash flows;
- Intense competition may affect our ability to operate profitably;

- Regulatory action outside of the U.S. has affected our business in the past and may affect our business in the future;
- Rapid technological change could cause our services and products to become obsolete;
- Continued fluctuation of foreign currencies relative to the U.S. Dollar could materially and adversely impact our business;
- Our credit facility limits our ability to pursue significant acquisitions;
- Key growth strategies may not generate the anticipated benefits;
- There are limitations on the use of our net operating loss carryforwards;
- Our ability to borrow under our credit facility may be limited;
- We may not be successful in obtaining necessary clinical results and regulatory approvals for services and products in development, and our new services and products may not achieve market acceptance;
- Extensive government regulation may adversely affect our ability to develop and sell services and products;
- Investments in new technologies and acquisitions of products or distribution rights may not be successful;
- If we are not successful in expanding our business activities in international markets, we may be unable to increase our revenues;
- We are not insured against all potential losses. Natural disasters or other catastrophes could adversely affect our business, financial condition, and profitability;
- We are dependent on our key personnel;
- Trading prices for our common stock, and for the securities of biotechnology companies in general, have been, and may continue to be, volatile;
- Anti-takeover provisions may discourage or make more difficult an attempt to obtain control of us; and
- We have not paid cash dividends on our capital stock and may be unable to do so due to legal or contractual restrictions.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company's interest income and 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 $31.0 million and $5.0 million of the Company's restricted securities as of September 30, 2010, and could impact interest paid on future borrowings under the Company's variable rate line of credit. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the three months ended September 30, 2010, affecting the Company's cash and cash equivalents, restricted securities, and line of credit would not have a material impact 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 majority of the Company's international BioGlue and BioFoam revenues, a portion of the Company's HemoStase revenues, the majority of the Company's future international PerClot revenues, 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.

Changes in exchange rates which occurred during the nine months ended September 30, 2010 as well as any future material adverse fluctuations in exchange rates could have a material and adverse effect on the Company's revenues, profitability, and cash flows for the full year of 2010. An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2010 affecting the Company's balances denominated in foreign currencies would not have had a material impact on the Company's financial position or cash flows. An additional 10% adverse change in exchange rates from the exchange rates in effect on September 30, 2010 as compared to the weighted-average exchange rates experienced by the Company for the nine months ended September 30, 2010 affecting the Company's revenue and expense transactions denominated in foreign currencies, would not have had a material impact 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. Because of 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.

Based upon the most recent Disclosure Controls evaluation, conducted by management with the participation of the CEO and CFO, as of September 30, 2010 the CEO and CFO have concluded that the Company's Disclosure Controls were effective at the

reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms.

During the quarter ended September 30, 2010, 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.

CryoLife's Lawsuit and Claims with Medafor

As previously reported in CryoLife's Annual Report on Form 10-K for the year ended December 31, 2009, and CryoLife's Forms 10-Q for the quarters ended March 31, 2010, and June 30, 2010, CryoLife filed a lawsuit against Medafor, Inc. in 2009 in the U.S. District Court for the Northern District of Georgia (the "Court"), alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia's Racketeer Influenced and Corrupt Organizations Act ("Georgia RICO"). The lawsuit arises out of an exclusive distribution agreement between the parties (the "EDA"), which gave CryoLife the right to distribute a product manufactured by Medafor under the name HemoStase. The Court dismissed CryoLife's Georgia RICO claim on August 9, 2010. On October 20, 2010 CryoLife filed supplemental claims against Medafor for additional breaches of contract, including those related to Medafor's wrongful termination of the EDA.

CryoLife's Potential Damages

The Company seeks to recover its damages from Medafor, accompanied by preliminary and permanent injunctive relief, punitive damages, and reimbursement of its attorneys' fees. In addition, the Company will seek damages related to Medafor's wrongful termination of the EDA, which will be based upon the Company's lost profits for the period of time during which the EDA would have continued in effect but for Medafor's termination of it. The amount of these damages will be determined through discovery in the lawsuit. No trial date has been set.

Medafor's Counter-claims

On September 8, 2010 Medafor answered CryoLife's complaint and filed a counter-complaint against CryoLife, alleging claims for, among other things, breach of contract, breach of the implied duty of good faith and fair dealing, violation of the Georgia trade secrets act, tortious interference with business relationships, libel, violation of the uniform deceptive trade practices act, fraud and negligent misrepresentation. In addition, Medafor requested that the Court grant a declaratory judgment that CryoLife repudiated the EDA pursuant to the provisions of the Uniform Commercial Code.

Background on Current Status of the EDA – Medafor's Decision to Terminate the EDA Due to CryoLife's Alleged Repudiation

As previously reported in CryoLife's Current Report on Form 8-K dated March 19, 2010, and CryoLife's Forms 10-Q for the quarters ended March 31, 2010 and June 30, 2010, Medafor informed CryoLife on March 18, 2010 of its contention that CryoLife had repudiated the EDA, thereby entitling Medafor to terminate the EDA. Medafor asserted that it had made a valid statutory demand, in a February 10, 2010 letter to CryoLife, for "adequate assurances" of CryoLife's future performance under the EDA, and that CryoLife had repudiated the EDA by failing to respond in a timely manner. On March 22, 2010, CryoLife informed Medafor that it disputed Medafor's assertions, and that Medafor had no right to terminate the EDA. CryoLife then filed a motion for preliminary injunction, asking the Court to enjoin Medafor from proceeding with its termination of the EDA.

As previously reported in CryoLife's Current Report on Form 8-K dated September 20, 2010, the Court, on September 20, 2010, issued an order denying CryoLife's request for a preliminary injunction against Medafor. Although the order denied the preliminary injunction, it did not address the merits of the parties' respective positions on the underlying issues, which the Court viewed as more appropriately addressed at summary judgment.

As previously reported in CryoLife's Current Report on Form 8-K dated September 28, 2010, on September 27, 2010, Medafor sent CryoLife a letter stating that it had fully and finally terminated the EDA based upon CryoLife's alleged repudiation. This was Medafor's sixth termination or termination attempt with respect to the EDA.

Medafor's Letters to CryoLife Asserting Additional Claims

On September 29, 2010 Medafor notified CryoLife that it was Medafor's position that CryoLife's interactions with Starch Medical, Inc. had resulted in numerous breaches of the EDA by CryoLife that could not be cured. Medafor additionally informed CryoLife that Medafor believed these alleged breaches were additional bases for termination of the EDA. Finally, Medafor informed CryoLife that Medafor would promptly move to amend its counter-claim to add additional claims for breach of contract and fraud, and for conspiracy and aiding and abetting, and other undefined claims.

On October 1, 2010 Medafor notified CryoLife that it was Medafor's position that CryoLife's continued selling of HemoStase tortiously interferes with Medafor's customer relationships and violates the Lanham Act and Georgia's Deceptive Trade Practices Act. Medafor informed CryoLife that if CryoLife continued to sell HemoStase, Medafor would amend its counter-claim to add claims for violations of the Lanham Act and Georgia's Deceptive Trade Practices Act, and other undefined claims.

As of November 4, 2010 Medafor has not amended its counter-claims, although CryoLife expects Medafor to do so by November 12, 2010.

Summary of Medafor's Potential Damages Claims

Pursuant to its counter-claims to date, Medafor seeks to recover its alleged damages from CryoLife, including rescinding the EDA to restore to Medafor all of the benefits that CryoLife has received under the EDA, compensatory damages, injunctive relief, prejudgment interest, punitive damages, and attorneys' fees and expenses.

Current Status of the Lawsuit

No trial date has been set. Discovery began on October 8, 2010. CryoLife has filed Rule 12(e) and (f) motions, requesting that the Court compel Medafor to make more definitive claims with regards to its counter-claims for libel, violations of the Uniform Deceptive Trade Practices Act, and rescission and to strike several of Medafor's affirmative defenses to CryoLife's claims. Medafor filed a motion in response to CryoLife's Rule 12(e) and (f) motions generally opposing CryoLife's requests. CryoLife may also file a Rule 12(c) motion for judgment on the pleadings in order to have the Court dismiss certain claims made by Medafor. CryoLife intends to vigorously prosecute the case and defend itself and contest the matter.

Item 1A. Risk Factors.

Other than the risk factors included below, 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, 2009, as updated by Part II, Item 1A, "Risk Factors" in our Forms 10-Q for the quarters ended March 31, 2010 and June 30, 2010.

Medafor Has Terminated The EDA And Ceased Shipments Of HemoStase To Us, Competition From Medafor May Negatively Impact HemoStase Sales And Our Remaining Sales Of HemoStase May Be At A Discount Which May Have A Material Adverse Effect On Our Revenues And Profitability.

On March 18, 2010 Medafor announced that it was treating the EDA as terminated. Medafor alleged that it was entitled under Georgia law to demand adequate assurances from us that we would perform under the EDA, and that we had repudiated the EDA by not timely providing adequate assurances. We, thereafter, moved the Court to preliminarily enjoin Medafor from proceeding with its termination. On September 20, 2010 the Court issued an order denying our request for the preliminary injunction. On September 27, 2010 Medafor informed us that it had fully and finally terminated the EDA based upon our alleged repudiation.

Because Medafor has terminated the EDA and ceased shipments of HemoStase to us, we are no longer able to distribute HemoStase as contemplated by the EDA. As such, we may not be able to sell our remaining inventory of HemoStase. We have begun selling HemoStase at a discount and a portion of our remaining HemoStase inventory will likely continue to be sold at a discount, which may have a material adverse effect on our revenues and profitability in 2010 and into 2011. Also, while we believe that we are entitled, pursuant to the terms of the EDA, to distribute our remaining inventory through March 26, 2011, Medafor may file a claim in court to challenge our ability to continue to distribute the remaining inventory or otherwise attempt to prevent further sales of HemoStase. If we are not able to sell our remaining inventory of HemoStase, our revenues and profitability may be materially, adversely impacted in the remainder of 2010 and into 2011. If we are able to sell our remaining HemoStase inventory, we will not be able to obtain additional product from Medafor and once our current inventory is depleted, we will have no further HemoStase sales. Additionally, competition from Medafor may diminish the sale of our current inventory.

Revenues from HemoStase were approximately $2.1 million, $6.1 million, and $6.0 million for the three months ended September 30, 2010, the nine months ended September 30, 2010, and the year ended December 31, 2009, respectively.

See Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations," for further information regarding the EDA with Medafor and see Part II, Item 1, "Legal Proceedings," for further information regarding our litigation with Medafor.

We Have Made A Substantial Investment In Our Distribution And License And Manufacturing Agreements With SMI And Will Commit Additional Funds In Order To Attempt To Obtain FDA Approval For PerClot In The U.S., And Our Short-Term Liquidity And Earnings In 2010 And 2011 Will Be Materially Impacted By These Expenditures And We Will Not Fully Realize The Benefit Of Our Investment In Future Years Unless We Are Able To Obtain FDA Approval For PerClot In The U.S.

On September 28, 2010 we entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI, pursuant to which we will distribute and ultimately manufacture PerClot. We are also authorized, pursuant to the license and manufacturing agreement, to pursue, obtain, and maintain regulatory approval for PerClot in the U.S., as such regulatory approvals do not yet exist in the U.S. If this approval is not obtained prior to October 1, 2017, SMI may terminate our rights with respect to U.S. regulatory approval and require us to negotiate a reasonable revision to the agreement.

As part of the transaction, we paid SMI $6.75 million in cash which includes $1.5 million in prepaid royalties and $1.25 million in restricted CryoLife common stock. We will pay up to an additional $2.75 million to SMI if certain U.S. regulatory and other commercial milestones are achieved, and will also pay royalties on sales of PerClot manufactured by CryoLife. We anticipate that we will spend between $5.0 million and $6.0 million to gain U.S. regulatory approval in the next several years, most of which will be incurred in 2011 and 2012. Our costs may be greater than anticipated, as the costs to begin manufacturing PerClot from plant starch modified by SMI and the costs involved in the rollout of our new product are estimates and may ultimately be greater than anticipated.

Our investment in our agreements with SMI will impact our short-term liquidity and earnings in 2010 and 2011 and we will not be able to fully realize the benefit of our investment in future years unless we are able to obtain the necessary regulatory approvals in the U.S. to distribute PerClot.

We May Be Unsuccessful In Our Attempts To Sell PerClot In The U.S., Medafor May Attempt To File A Lawsuit, Including A Patent Infringement Case, Against Us Which May Prevent Us From Selling PerClot In Both International And Domestic Markets, And Our Ability To Successfully Market And Sell PerClot May Take Longer Than Expected.

Even if we are able to obtain FDA approval to distribute PerClot in the U.S. according to our estimated timeline, we may be unsuccessful in our attempts to sell PerClot in the U.S. as other competing products may have penetrated the market by that time. Also, while we do not believe Medafor would have a valid reason to do so, based on our past history with Medafor, it is possible that Medafor may attempt to challenge the legality of our distribution of PerClot in both the U.S. and international markets or file a patent infringement action against us. If we are ultimately unable to distribute PerClot in the U.S., we would not be able to fully realize the benefit of our investment in PerClot.

Also, some level of confusion in the marketplace may exist in the short-term as we transition to selling both HemoStase and PerClot, and then to selling only PerClot. Any such confusion among our customers may lead to lower than anticipated sales of PerClot in 2010 and 2011. Further, Medafor may attempt to compete directly with us with respect to our current HemoStase customers and convince them to purchase its hemostatic agent instead of purchasing PerClot from us.

Medafor Has Filed Counter-Claims Against Us With Respect To Our Lawsuit Against Medafor, And If Medafor Is Successful In Its Claims, Our Revenues And Profitability May Be Materially, Adversely Affected.

CryoLife filed a lawsuit against Medafor in 2009 in the Court, alleging claims for, among other things, breach of contract, fraud, negligent misrepresentation, and violations of Georgia's Racketeer Influenced and Corrupt Organizations Act ("Georgia RICO"). The lawsuit arises out of the EDA that has recently been terminated by Medafor.

Medafor has filed counter-claims against CryoLife. We have disputed the validity of Medafor's counter-claims and intend to continue to vigorously defend our rights. If Medafor is successful and the Court rules in their favor, then we could be required to make substantial payments to Medafor as part of the judgment. While the details of any judgment that may be rendered against CryoLife in such a scenario are uncertain, the possibility exists that a judgment against CryoLife could have a material adverse effect on our profitability and cash flows.

See Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations," for further information regarding the EDA with Medafor and see Part II, Item 1, "Legal Proceedings," for further information regarding our litigation with Medafor.

Our Investment In Medafor May Be Impacted By Medafor's Decision To Terminate Our EDA With Medafor, As CryoLife Was Medafor's Largest Distributor In 2009 And 2008. As A Result, We Could In The Future Determine That Further Impairment In The Value Of Our Investment In Medafor Common Stock Has Occurred, Which Could Have A Material Adverse Effect On Our Financial Condition And Profitability.

In November 2009 and in 2010, CryoLife purchased approximately 2.4 million shares of Medafor common stock. The carrying value of that investment on our books was reduced in the third quarter of 2010 to $2.6 million primarily because Medafor terminated our EDA with Medafor. CryoLife was Medafor's largest distributor in 2009 and 2008, accounting for 19% and 15%, respectively of Medafor's total revenues.

Medafor's decision to terminate the EDA may negatively impact its revenues and profitability. In accordance with accounting principles generally accepted in the U.S. ("GAAP") we reviewed available information and determined that as of September 30, 2010, factors were present indicating that we should evaluate our investment in Medafor common stock for impairment and we then determined that an impairment in our investment in Medafor had occurred. We could subsequently determine that, in accordance with GAAP, a further impairment in the value of our investment in Medafor common stock has occurred if, among other things, Medafor's revenues decline further than anticipated due to its loss of its largest distributor. If further impairment occurs in the future, we would be required to take a non-cash charge to earnings, which could have a material adverse effect on our financial condition and profitability. Also, Medafor could take future actions beyond our control that could further impair the value of our investment.

See Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations," for further information regarding the EDA with Medafor and see Part II, Item 1, "Legal Proceedings," for further information regarding our litigation with Medafor.

We May Not Be Able To Readily Liquidate Our Investment In Medafor, And If We Are Able To Liquidate Our Investment, We May Receive Less Cash Than Our Original Investment And We May Receive Less Than The Carrying Value Of Our Investment.

In November 2009 and in 2010, CryoLife purchased approximately 2.4 million shares of Medafor common stock. The carrying value of that investment on our books was reduced in the third quarter of 2010 to $2.6 million. We are a minority Medafor shareholder and may not be able to readily liquidate our investment in Medafor because Medafor is privately held, and there is not a public market for Medafor shares. In addition, the value of the Medafor common stock may further decline in value in the future for reasons including those disclosed in the three immediately preceding risk factors. If we wish to liquidate our investment in Medafor to raise cash, we might not be able to do so in a timely fashion or at all and we may not receive a value that we believe is appropriate at that time. In addition, the cash we receive from such as sale could be less than the $4.9 million initially paid for the Medafor common stock. In the event that we chose to sell our Medafor stock for less than $2.6 million, the recorded value of our investment in Medafor, the difference would be recorded as a charge against earnings, which could have a material adverse effect on our financial condition and profitability.

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

(a) On September 28, 2010 CryoLife agreed to issue $1.25 million in restricted CryoLife common stock to Starch Medical, Inc. ("SMI") as determined by the average closing CryoLife stock price for the trailing ten trading days pursuant to the terms of the distribution agreement and the license and manufacturing agreement between CryoLife and SMI, both dated September 28, 2010, as more fully described in CryoLife's Current Report on Form 8-K filed with the SEC on October 4, 2010. Accordingly, on October 13, 2010, CryoLife issued 209,240 shares of restricted CryoLife common stock to SMI.

The shares have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or applicable state securities laws upon the basis that the transaction involving their sale is exempt from such registration requirements as a transaction by an issuer not involving any public offering in reliance on Rule 506 of Regulation D, as promulgated by the SEC pursuant to the Securities Act. SMI is an accredited investor, as that term is defined in Regulation D.

(c) The following table provides information about purchases by the Company during the quarter ended September 30, 2010 of equity securities that are registered by the Company pursuant to Section 12 of the Exchange Act:

Issuer Purchases of Equity Securities

Common Stock

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
07/01/10 – 07/31/10	238,901	$ 5.49	237,279	$ 12,186,892
08/01/10 – 08/31/10	145,051	5.51	145,051	11,387,468
09/01/10 – 09/30/10	110,878	5.76	110,878	10,748,898
Total	494,830	5.55	493,208	10,748,898

On June 1, 2010 the Company publicly announced that its Board of Directors authorized the purchase of up to $15.0 million of its common stock over the course of the following two years. 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 dependant upon various factors, including price, regulatory requirements, and other market conditions. As of September 30, 2010 the Company had purchased 767,000 shares of its common stock for an aggregate purchase price of $4.3 million.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. (Removed and Reserved).

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 10-K for the year ended December 31, 2007.)
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 January 6, 2010.)
4.1	Form of Certificate for the Company's Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
4.2	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant's Current Report on Form 8-K filed November 3, 2005.)
10.1*+	Distribution Agreement between the Company and Starch Medical, Inc., dated September 28, 2010.
10.2*+	License Agreement between the Company and Starch Medical, Inc., dated September 28, 2010.
31.1*	Certification by Steven G. Anderson pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.
\+ The Registrant has requested confidential treatment for certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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

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

November 5, 2010
DATE

Exhibit 10.1

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.

DISTRIBUTION AGREEMENT

This **DISTRIBUTION AGREEMENT** (this "Agreement") is entered into as of September 28 2010, (the "Effective Date"), by and between (i) STARCH MEDICAL, INC., a Delaware corporation having a principal place of business at 2150 Ringwood Avenue, San Jose, California 95131("SMI"), and (ii) CRYOLIFE, INC., a Florida corporation, having a principal place of business at 1655 Roberts Blvd. NW, Kennesaw, Georgia 30144 ("CryoLife"). SMI and CryoLife are herein sometimes referred to together as the "Parties" and individually each as a "Party".

Background

WHEREAS, SMI has exclusive rights to a proprietary engineering process that modifies plant starch into ultra-hydrophilic, adhesive forming hemostatic polymers (SMI's "Absorbable Modified Polymer" or "AMP™ technology") to create biocompatible, absorbable hemostats containing no animal or human components;

WHEREAS, using the AMP™ technology, SMI produces its proprietary PerClot® and OrthoClot™ products (the "Products," for which more details are provided in Schedule W-1, each a "Product") that rapidly absorb water from blood, increasing the concentration of platelets, coagulation proteins and red blood cells at bleeding sites, and accelerates the physiologic clotting cascade;

WHEREAS, CryoLife desires to market, distribute, and sell the Products for use in all approved clinical applications (the "Permitted Clinical Applications" described in Schedule W-2) in all countries other than China, Hong Kong, Macau, Taiwan, North Korea, Iran and Syria (included countries, the "Territory" all as further set forth herein);

WHEREAS, SMI desires to appoint CryoLife as its exclusive distributor of Products for Permitted Clinical Applications within the Territory;

WHEREAS, while the United States is included in the Territory, the Parties acknowledge that no regulatory approvals exist for the use of the Products in the United States and that, therefore, the Products cannot be sold in the United States at this time;

WHEREAS, SMI and CryoLife are entering into a limited license and technology transfer agreement (the "License Agreement") contemporaneously with this Agreement to supply CryoLife with SMI's proprietary modified starch (the "Modified Starch"), license CryoLife to manufacture the Products using the Modified Starch, and authorize CryoLife to pursue, obtain and maintain regulatory approval in the United States to sell the Products;

WHEREAS, SMI and CryoLife are entering into a trademark assignment and license agreement (the "Trademark Assignment and License Agreement") contemporaneously with this Agreement to assign to CryoLife the PerClot mark and to license back to SMI the right to use the PerClot mark outside of the Territory all as further set forth therein; and

WHEREAS, SMI and CryoLife are entering into a product development agreement (the "Development Agreement") contemporaneously with this Agreement to address development of new products and product applications based on the AMP™ technology.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by each of the Parties, SMI and CryoLife, agree as follows (with a glossary of defined terms in this Agreement set forth in Annex A to this Agreement):

1. **Appointment**

1.1 Appointment. SMI hereby appoints CryoLife as the exclusive distributor of the Products for Permitted Clinical Applications within the Territory. CryoLife hereby accepts such appointment, which includes the right to appoint sub-distributors and sales representatives within the Territory.

1.2 License Grants. In support of the appointment in Section 1.1, SMI hereby grants to CryoLife the exclusive license to market, offer for sale, sell, have sold, distribute, have distributed, import and have imported (collectively, "Distribute" or "Distribution") the Products for Permitted Clinical Applications within the Territory. The rights granted within the United States include the right to Distribute Products to support CryoLife's efforts under the License Agreement to obtain Regulatory Approval in the United States. This license does not authorize CryoLife to manufacture Products nor prohibit SMI from selling Products to CryoLife for resale within the Territory. CryoLife shall be entitled to sublicense its rights under this Agreement to affiliates, sub-distributors and sales representatives involved in the Distribution of Products in the Territory. The Parties acknowledge that provisions of this license overlap provisions of the separate license granted to CryoLife in the License Agreement. The Parties agree that neither license shall be deemed a violation of the other license and that each license will stand on its own and survive any termination of the other license.

1.3 New Clinical Applications. Each Party agrees to notify the other Party in writing as and when it develops or obtains Regulatory Approval in the Territory for clinical applications for the Products that are not included within the Permitted Clinical Applications (each a "New Application," collectively the "New Applications"). Each New Application shall be included within the Permitted Clinical Applications at the Transfer Prices applicable to the Product subtype. For each New Application obtained principally through the efforts of SMI, but not for other New Applications, the Parties agree to negotiate in good faith to adjust the Products Minimum Annual Purchase Requirements taking into consideration reasonable expectations of market increase for such New Application and any reasonable expectation of market decrease for existing Permitted Clinical Applications of Products. Each Party agrees to refrain from developing or from initiating efforts to obtain Regulatory Approval for New Applications until after January 1, 2012 without first obtaining the written consent of the other Party. For the avoidance of doubt, nothing in this Section 1.3 shall be deemed to limit or prohibit any Party's right to seek or obtain Regulatory Approval for the Permitted Clinical Applications in the Territory.

1.4 New Products. With the exception of products listed on Schedule 2.1, SMI agrees that prior to January 1, 2015, it is restricted from selling, marketing, distributing or licensing or permitting

others to do so for any new products that incorporate any powdered absorbable hemostat all as further set forth in Section 2.1 within the Territory. After January 1, 2015, SMI agrees to notify CryoLife in writing as and when it develops or obtains regulatory approval for any new products (with the exception of products listed on Schedule 2.1) that incorporate any powdered absorbable surgical hemostat, including the AMP™ technology, and that are more efficacious or commercially advantageous when compared to the Products (each a "New Product"). At CryoLife's written request, SMI agrees to negotiate exclusively with CryoLife to grant CryoLife exclusive Distribution rights to the New Product within the Territory. If the Parties negotiate diligently and in good faith and are unable to reach agreement within six (6) months after CryoLife notifies SMI, this right of first negotiation shall be suspended as to the notified New Product for a period of six (6) months (the "Open Negotiation Period") during which time SMI may negotiate with others to Distribute the notified New Product within the Territory upon terms and conditions more favorable to SMI than those last offered by CryoLife. As part of such negotiation the Parties must exchange written proposals about the terms proposed for such transaction. If, during the Open Negotiation Period, SMI receives a bona fide offer of terms with a Third Party that are acceptable to SMI for an agreement that includes Distribution of the New Product (a "Bona Fide Offer"), SMI shall notify and warrant to CryoLife in writing (an "Offer Notice") of the receipt of a Bona Fide Offer prior to the termination of the Open Negotiation Period, which notice shall include the specific terms of such Bona Fide Offer. The Offer Notice shall constitute an offer to CryoLife for the Distribution of the New Product on the terms set forth in the Offer Notice. CryoLife shall have sixty (60) days from the date of receipt of the Offer Notice to accept the terms of the Offer Notice and notify SMI in writing of CryoLife's acceptance of such offer. If the Bona Fide Offer includes payment to SMI of any equity securities or any other non-cash assets, CryoLife may substitute for such cash or other non-cash assets, shares of CryoLife's capital stock or other assets of CryoLife with an equal fair market value. If CryoLife fails to deliver notice of its acceptance of the offer set forth in the Offer Notice, SMI shall be free to consummate the Bona Fide Offer with the Third Party who proposed the Bona Fide Offer within sixty (60) days after the expiration of CryoLife's sixty (60) day first refusal right contained in this section. If SMI fails to consummate the Bona Fide Offer within such sixty (60) day period, SMI shall be prohibited from consummating such transaction and shall be required to negotiate with CryoLife as to the Distribution rights related to such New Product. The limitations contained in this section are in addition to the limitations contained in Section 2.1(iv) and the last two sentences of Section 2.1.

1.5 Product Applicators, Etc. SMI agrees to promptly notify CryoLife of all improvements to applicators, tips and other accessories included within or used in connection with the Products, including all new applicators, tips and other accessories. All such improvements and any such new applicators, tips or accessories to the Products shall be included within the Products and the Parties shall adjust the catalog of Products to reflect these new products, with any transfer price to be negotiated in good faith, but based solely on costs to SMI for such improvements and/or new applicators, tips and accessories. The Parties agree that the Endoscopic applicator system used for powder delivery via gastrointestinal endoscope, as further described on Schedule 2.1 is not an improvement or new applicator and is not included in this Agreement.

2. **Distribution**

2.1 Limitations on SMI Activities. During the term of this Agreement SMI agrees (i) to sell the Products exclusively to CryoLife for use in Permitted Clinical Applications within the Territory, (ii) to refrain from selling or licensing any Products to any Existing Distributor or Third Party for sale or distribution in Permitted Clinical Applications within the Territory, (iii) to refrain from directly or indirectly marketing, promoting, or encouraging any Third Party to market, promote or Distribute the Products for any of the Permitted Clinical Applications within the Territory, (iv) to refrain from licensing or transferring any AMP™ Technology to any Third Party within the Territory for the purpose of

manufacturing any Products upon terms or conditions that would enable or allow such Third Party to sell any Products for Permitted Clinical Applications within the Territory. In addition, SMI agrees that it shall refrain until January 1, 2015 from (A) directly, or indirectly selling, permitting to sell, market, promote or encouraging third parties to sell, permit to sell, market or promote any Competitive Product (defined below) for any Permitted Clinical Application within the Territory or (B) licensing or transferring to any Third Party technology that would enable or allow any Third Party to manufacture any Competitive Product within the Territory. The provisions of the foregoing sentence shall be deemed further modified so that SMI may only take the actions described therein if SMI complies with Section 1.4 (and therefore CryoLife does not match the right of first refusal set forth therein). As used herein, "Competitive Product" means any powdered absorbable surgical hemostat that is intended for or could be used for a Permitted Clinical Application. The foregoing limitations do not apply to sales by SMI of those products described on Schedule 2.1.

2.2 CryoLife Limitations. During the term of this Agreement and provided SMI timely fulfills CryoLife's orders for Products, CryoLife will not manufacture or Distribute for Permitted Clinical Applications within the Territory any Competitive Product except for products currently manufactured or Distributed by CryoLife, new and successor products related to products currently manufactured or Distributed by Cryolife and new and successor products that incorporate CryoLife's protein hydrogel technology with any powdered product. In addition, once CryoLife receives final approval from the United States Regulatory Authority (as defined in the License Agreement) to Commercially Distribute Products (as defined in the License Agreement), it shall commence an orderly process to withdraw its HemoStase from distribution in the United States by the earlier of December 31, 2014 or when CryoLife can complete an orderly withdrawal from the market. An orderly withdrawal process will permit CryoLife to complete the sale of its entire inventory of HemoStase and honor existing requirements under contracts CryoLife has with various third parties.

2.3 Current Distributors.

2.3.1 SMI represents and warrants that only the Persons described on Schedule 2.3 (collectively, the "Existing Distributors") have any rights or agreements that entitle them to Distribute any Products for Permitted Clinical Applications within the Territory or represent SMI, or any other Person including Clot Plus Limited (collectively, "Other Parties"), in the Distribution of any Products for Permitted Clinical Applications within the Territory. SMI represents and warrants that it has delivered to CryoLife the most current and complete copies of each and every agreement any of the Existing Distributors has respecting the Products or the right to Distribute any Products for Permitted Clinical Applications within the Territory. SMI represents and warrants that Schedule 2.3 contains a complete list of all such agreements with Existing Distributors (or if such agreement is oral, that it has accurately summarized all terms of such oral arrangement).

2.3.2 SMI agrees to terminate or obtain all rights to distribute or sell Products for Permitted Clinical Applications within the Territory from all of the Existing Distributors within thirty (30) days after the Effective Date (with the exception of those distributors set forth on Schedule 2.3.2, which SMI shall give notice of termination upon the execution of this Agreement by both Parties, and shall terminate in ninety (90) days of the Effective Date and to refrain and cause all Other Parties to refrain from granting to any Third Party any rights to distribute Products or represent SMI or any Other Parties in the sale or distribution of Products for Permitted Clinical Applications within the Territory. Notwithstanding and, with respect to particular Existing Distributors identified by CryoLife in writing, in lieu of the preceding sentence, SMI will assist CryoLife by assigning, or causing the appropriate Other Party to assign to CryoLife any agreements for the distribution or sale of Products by the Existing

Distributors as CryoLife may request in writing. At CryoLife's option with respect to Existing Distributors whose distributorships are otherwise terminated, SMI shall permit and cause all Other Parties to (i) permit such distributor to continue fulfilling orders for existing Tenders and (ii) assign to CryoLife the exclusive right to sell Products to such distributors. SMI warrants that it will take the actions identified above without breaching or causing the breach of any of the agreements referenced therein. SMI agrees to deliver to CryoLife within five (5) Business Days of the execution thereof, copies of any and all agreements (or a summary of any and all oral arrangements) between or among SMI, the Existing Distributors or any Other Parties related to SMI's obligations under this Section 2.3. SMI agrees it shall bear all costs associated with fulfilling its obligations under this Section 2.3 and shall indemnify CryoLife for any Losses resulting therefrom, except for any defamation, libel or other claim regarding damage to CryoLife's reputation.

2.3.3 SMI represents and warrants that other than the Existing Distributors, neither SMI nor any Other Parties currently has any other agents, representatives, or distributors entitled to Distribute Products (except for those products set forth in Schedule 2.1 or any hemostatic powder for Permitted Clinical Applications within the Territory, and that there is no restriction, covenant, or agreement to which it or any Other Party is a party or by which it or any Other Party is bound that would prevent or delay CryoLife from exercising and obtaining the full benefit of the exclusive Distribution rights granted in this Agreement. SMI agrees that it will not, directly or indirectly, undertake, permit, or omit to take any action, or enter into, or permit any Other Party to enter into, any agreement that will prevent or delay the enjoyment by CryoLife of the full benefits of the exclusive relationship provided in this Agreement. SMI agrees to promptly direct and cause all Other Parties to direct all sales inquiries respecting the Product for Permitted Clinical Applications within the Territory to CryoLife during the Term of this Agreement. SMI represents and warrants that the termination of agreements with the Existing Distributors shall not cause CryoLife any Losses. SMI represents and warrants that the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby do not and will not constitute or cause a default or effect an acceleration of the terms under any of the agreements with Existing Distributors.

2.3.4 SMI represents and warrants that (i) its order fulfillment for Products to Existing Distributors during the last ninety (90) days has been consistent insofar as quantity and product mix with its order fulfillment during the preceding one hundred eighty (180) day period and (ii) it has fully advised CryoLife in writing of (A) all shipments of Products into or for resale into the Territory for Permitted Clinical Applications and (B) all outstanding purchase orders for Products into or for resale in the Territory for Permitted Clinical Applications that have not been fulfilled prior to the Effective Date are set forth on Schedule 2.3. SMI shall direct all purchase orders it receives for Products to be shipped into or for resale in the Territory for Permitted Clinical Applications to CryoLife from and after the Effective Date.

2.4 Marketing and Sales. Subject to the terms and conditions of this Agreement, all business decisions concerning the sales and marketing of Product in the Territory, including the price, other sale and promotional terms thereof, will be within the sole discretion of CryoLife. Upon SMI's reasonable request, but no more frequently than twice per calendar year, CryoLife will discuss with SMI CryoLife's marketing plans for Product in the Territory.

2.5 Promotion Limitations. CryoLife will restrict its promotion and marketing of Products to activities reasonably calculated to sell the Products for Permitted Clinical Applications within the Territory and will not sell or distribute Products outside the Territory or sell or distribute Products knowingly to persons for the purpose of sale or distribution outside the Territory. CryoLife agrees that all sales inquiries or leads for sales of Products outside the Territory that it or its Affiliates receive shall be immediately directed to SMI for follow-up. SMI agrees that all sales inquiries or leads for sales of

Products inside the Territory that it or its Affiliates receive shall be immediately directed to CryoLife for follow-up.

3. **Payment and Product Purchases**

3.1 Initial Payment. CryoLife will pay SMI of the sum of Eight Million U.S. dollars ($8,000,000.00) (the "Initial Payment") within five (5) Business Days after both this Agreement and the License Agreement are executed by the Parties. Of the Initial Payment, Six Million and Seven Hundred and Fifty Thousand U.S. dollars ($6,750,000.00) shall be paid in cash or by wire transfer to an account designated by SMI in writing with the remaining One Million and Two Hundred and Fifty Thousand U.S. dollars ($1,250,000.00) to be paid by the issuance to SMI of shares of common stock of CryoLife (the "Shares") equal in number to One Million and Two Hundred and Fifty Thousand U.S. dollars ($1,250,000.00) divided by the average closing price on the New York Stock Exchange of CryoLife's common stock for the ten (10) trading days preceding and ending on the Business Day immediately preceding ("Trailing Average Price") the date both Parties execute and deliver both this Agreement and the License Agreement. The Shares shall be issued in the name of SMI promptly following the Effective Date, but shall be held by CryoLife until March 31, 2012, subject to possible cancellation in accordance with Section 3.3. While the Shares are held by CryoLife, SMI shall have all ownership rights pertaining to the Shares, including without limitation, all voting rights and rights to receive dividends or other distributions thereon; provided, however, that the Shares may not be sold, encumbered, assigned or otherwise transferred by SMI prior to March 31, 2012, or pursuant to the terms of Section 3.3.

3.2 Prepaid Royalties Under the License Agreement. The Parties acknowledge and agree that CryoLife may apply One Million Five Hundred Thousand U.S. dollars ($1,500,000.00) from the Initial Payment as a prepaid royalty payment under the License Agreement (the "Prepaid Royalty Payment"), upon the terms and conditions set forth therein.

3.3 Limited Right to Cancel Shares. The Initial Payment will be non-refundable; provided, however, that: (i) in the event SMI fails to timely supply Product that meets all Product Specifications in the manner required by this Agreement, (ii) if CryoLife determines in good faith that it is prevented from distributing any Products (or is advised by counsel to refrain from distributing to reduce damages) in the manner contemplated by this Agreement by reason of any legitimate claim from a Third Party that distribution of the Product violates any Third Party intellectual property rights, (iii) if CryoLife's exclusive rights to Distribute Products for Permitted Clinical Applications within the Territory is lost or diminished (and such loss or diminishment is not due to any negligent act or omission by CryoLife), or (iv) SMI breaches any covenant contained in Sections 2.1 or 2.3, SMI takes any action described in Section 11.2.4, or any Field Action is taken in a manner that CryoLife believes materially adversely impacts its ability to enjoy the full benefits of this Agreement (any of these, a "Refund Event"), CryoLife shall notify SMI in writing of such Refund Event (a "Refund Notice"). If SMI is unable to cure any Refund Event within sixty (60) days after receipt of the applicable Refund Notice, CryoLife shall have the right (but not the obligation) to satisfy all or any portion of any Losses incurred by the CryoLife Indemnitees as a result of such Refund Event (the "Refund Losses") by promptly cancelling a number of Shares with an aggregate value up to the aggregate amount of such Refund Losses. For purposes of this Section 3.3, the value of each Share shall be the average closing price on the New York Stock Exchange of CryoLife's common stock for the ten (10) trading days preceding and ending on the Business Day immediately preceding the date on which SMI receives the Refund Notice. The Parties agree that CryoLife's right to cancel any Shares pursuant to this Section 3.3 shall be in addition to any other rights or remedies available to CryoLife pursuant to this Agreement or in law or equity.

3.4 Share Representations. SMI hereby acknowledges, represents, warrants, covenants and agrees that: (i) SMI is the sole party in interest with respect to the Shares and is acquiring the Shares for SMI's own account, for investment only and not with a view toward the resale or distribution thereof, (ii) SMI is an "accredited investor," as that term is defined by Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act"), (iii) the Shares were offered to SMI by CryoLife solely by private contacts and not by means of any form of general solicitation, advertisement or sales literature, (iv) SMI must bear the economic risk of its investment in the Shares for an indefinite period of time because none of the Shares are registered under the Securities Act or the securities laws of any state or other jurisdiction, and except as set forth in Section 3.3, the Shares cannot be sold or otherwise transferred by SMI prior to March 31, 2012, (v) SMI is able to bear the economic risk of losing SMI's entire investment in the Shares, and SMI has adequate means of providing for SMI's current and future needs without regard to the investment in the Shares, (vi) SMI has been advised that the Shares are not being registered under the Securities Act or applicable state securities laws upon the basis that the transaction involving their sale is exempt from such registration requirements as a transaction by an issuer not involving any public offering in reliance on Rule 506 of Regulation D, as promulgated by the United States Securities and Exchange Commission pursuant to the Securities Act, and reliance by CryoLife on such exemption is predicated in part on SMI's representations set forth in this Agreement, (vii) SMI is familiar with the business in which CryoLife is engaged and, based upon SMI's knowledge and experience in financial and business matters, SMI is familiar with investments of the sort that SMI is undertaking by investing in the Shares, SMI is fully aware of the merits and risks involved in making its investment in the Shares, and SMI is capable of evaluating the merits and risks of its investment in the Shares, (viii) SMI and SMI's advisors have had an opportunity to ask questions of and to receive answers from representatives of CryoLife and to obtain additional information from CryoLife regarding CryoLife and its business, and SMI and SMI's advisors have obtained all such information that they deem necessary or appropriate to enable SMI to make its decision to invest in the Shares, (ix) SMI will not directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the Shares except in compliance with Section 3.3, the Securities Act, applicable state securities laws and the respective rules and regulations promulgated thereunder, (x) SMI has, in connection with its decision to purchase the Shares, reviewed information contained in documents filed or furnished by CryoLife with the U.S. Securities and Exchange Commission, including without limitation, CryoLife's Form 10-K for the year ended December 31, 2009, all subsequently filed reports on Form 10-Q, and all subsequently filed or furnished reports on Form 8-K (the "SEC Reports"), and (xi) no person other than CryoLife is authorized by CryoLife to provide any representation that is inconsistent or in addition to those contained herein or in the SEC Reports, and SMI acknowledges that it has not received or relied on any such representations.

3.5 Registration Rights and Lockup Requirements. CryoLife and SMI acknowledge and agree that SMI shall have such registration rights with respect to the Shares, and the Shares shall be subject to such lockup requirements, as are set forth in the Registration Rights Agreement attached as Exhibit "A" hereto and to which the Parties are parties. In addition, the Shares shall contain a restrictive legend set forth on Schedule 3.5.

3.6 Initial Orders. Concurrent with the execution of this Agreement, CryoLife has submitted to SMI a purchase order as more particularly set forth on Schedule 3.6. SMI agrees that to the extent that any Product noted on that order cannot be sold because of an expiration date, that SMI will assist CryoLife in shipping substitutes for such Product to CryoLife. Additionally, CryoLife agrees to purchase SMI's current inventory of OrthoClot Product, up to 7,500 units, at a purchase price of [***] U.S. dollars ($[***]) for one gram product and [***] U.S. dollars ($[***]) for three gram product all as further set forth on Schedule 3.6.

3.7 Purchase Minimums

3.7.1 CryoLife agrees to the Minimum Annual Purchase Requirements set forth on Schedule 3.7, as same may be adjusted pursuant to this Agreement.

3.7.2 The Parties acknowledge and agree that the Minimum Purchase Amounts are based on SMI's current sales potential of the Products in the Territory and therefore, SMI represents and warrants that it has delivered to CryoLife, prior to the execution of this Agreement, SMI's current sales information for the 2009 calendar year and the first two calendar quarters of 2010 for Products in the Territory and that such information is true, correct and complete.

3.7.3 The Minimum Annual Purchase Requirements may be reduced by CryoLife in any given period to the extent of any prior purchase by CryoLife in excess of the Minimum Annual Purchase Requirements for any and all preceding periods. The failure of CryoLife to meet any Minimum Annual Purchase Requirements because of any of the following reasons shall not cause CryoLife to be in default of this Agreement: Product returns in accordance with the terms of this Agreement, breach of this Agreement by SMI, failure to timely deliver Products by SMI, delay in obtaining Regulatory Approval based on the timelines set forth on Schedule 5.1 which assumes full cooperation of the CryoLife designated distributor when such distributor is the regulatory applicant, supply interruption by SMI, force majeure, or any Field Action that is not the result of CryoLife's negligent acts or omissions.

3.8 Inventory and Supply Interruption.

3.8.1 SMI represents and warrants that SMI's Products Inventory and components inventory, broken down by product number, was on August 15, 2010 and estimates will be as of September 15, 2010 as set forth on Schedule 3.8. SMI agrees to maintain Product Inventory equal to at least two times CryoLife's trailing three month order volume. SMI shall at all times ensure that sufficient manufacturing capacity (including appropriate manufacturing, storage and distribution facilities and qualified personnel) is maintained to meet CryoLife's forecasted demand plus 50%.

3.8.2 SMI will notify CryoLife immediately in writing upon becoming aware of any supply shortage, or other interruption or potential interruption in the supply of any material, component, or sub-assembly, in each case as it relates to Products, which notice shall include the quantity of such material or component ordered by SMI, name of the distributor and any additional information SMI may have concerning the reasons for the supply interruption and the steps being taken to cure such interruption. In addition, if reasonably requested in writing by CryoLife, SMI agrees to confirm within ten (10) days that it is not aware of any supply shortage, or other interruption or potential interruption in

the supply of any material, component, or sub-assembly. If at any time SMI does not have enough component material to fulfill, or other supply or manufacturing problems prevent SMI from fulfilling on a timely basis, its supply obligations to CryoLife for purchase of Products, SMI shall promptly notify CryoLife of the nature and extent of the impairment to SMI's ability to supply and shall allocate 100% of its full resources to rectifying the impairment until such impairment is overcome.

3.8.3 In the event SMI is unable to fulfill CryoLife's purchase orders for Products, the Minimum Annual Purchase Requirements for the year and subsequent years shall be suspended until SMI is able to fulfill all of CryoLife's purchase orders. Upon SMI's fulfilment of all of CryoLife's purchase orders pursuant to the previous sentence, (i) the Expiration Date (as set forth on Schedule 3.7) of the applicable Minimum Annual Purchase Requirement for such year (and the Expiration Date of each subsequent Minimum Annual Purchase Requirement) shall be expanded by the time of the delay in fulfilment to the date of such fulfilment, unless such date is later than the 20th of the month, in which case it shall be the end of the month (the "Adjusted Expiration Dates") and (ii) the Commencement Date (as set forth on Schedule 3.7) of the following Minimum Annual Purchase Requirement (and the Commencement Date of each subsequent Minimum Annual Purchase Requirement) shall be adjusted to be the beginning of the calendar month following the Adjusted Expiration Date. For example, if SMI fails to fulfill all of CryoLife's purchase orders for a month and 21 days in 2012, (i) the Expiration Date of the Minimum Annual Purchase Requirement for the period currently reflected on Schedule 3.7 as January 1, 2012 to December 31, 2012, shall be February 28, 2013, (ii) the Commencement Date and Expiration Date of the Minimum Annual Purchase Requirement for the period currently reflected on Schedule 3.7 as January 1, 2013 to December 31, 2013, shall be March 1, 2013 to February 28, 2014, respectively; and (iv) the Commencement Date and the Expiration Date of each subsequent Minimum Annual Purchase Requirement shall be March 1st of such year and the end of February of the following year, respectively (each subject to adjustment pursuant to this Section 3.8.3 for any additional failures by SMI to fulfill all of CryoLife's purchase orders in any calendar quarter).

3.9 Transfer Price. CryoLife shall pay SMI the Transfer Prices for any Products ordered, delivered to, and not rejected by CryoLife. For Products with a single product number for which separate transfer prices exist for (1) direct distribution and (2) indirect distribution, CryoLife will make reasonable efforts, but shall not be required, to include on its Forecasts and Purchase Orders product at the appropriate transfer price based on its estimation of final distribution of the Products.

3.9.1 The Parties acknowledge that CryoLife may, due to necessary inventory management practices, distribute Product directly for which it has paid the indirect price or distribute Product indirectly for which it has paid the direct price (a discussion of direct and indirect distribution is set forth on Schedule 3.9). In such event CryoLife will note such inconsistency on its next Purchase Order and will include in such Purchase Order (i) if Product purchased at the indirect Transfer Price is distributed directly, an amount of Product that will be purchased at the direct distribution Transfer Price that will be indirect distributed to address the previous inconsistency or (ii) if Product purchased at the direct Transfer Price is distributed indirectly, an amount of Product that will be purchased at the indirect distribution Transfer Price for direct distribution to address the previous inconsistency. SMI shall have the option each quarter to review CryoLife's internal reports showing PerClot unit distribution and appropriate supporting documentation in order to confirm that CryoLife is following the provisions of this Section 3.9.1 for such quarter.

3.9.2 From and after January 1, 2014, the Transfer Prices may, at the written request of either Party, increase or decrease by an amount negotiated in good faith by the Parties if the currency rate between the Chinese RMB and the U.S. dollar has increased or decreased by more than 10% since the last Adjustment Date. As used herein, the first "Adjustment Date" shall be January 1, 2014 and all

subsequent Adjustment Dates shall be the last date upon which the Transfer Prices were actually changed by the Parties. After the first adjustment, adjustments to Transfer Prices shall be made no more frequently than once every twelve (12) months and, to be effective, shall be memorialized in writing. Among the factors the Parties agree to consider in any negotiations to adjust Transfer Prices will be the practical ability of CryoLife to increase the average selling price of the Products without adversely affecting the demand for such Products.

3.10 Purchase Orders. CryoLife shall issue to SMI purchase orders, which shall specify: (i) the Product, including item or product number; (ii) the Transfer Price; (iii) requested delivery schedule; and (iv) "ship to" and "invoice to" place of business. SMI must accept a purchase order if (i) the purchase order does not establish new or conflicting terms from those set forth in this Agreement and (ii) the Transfer Price and other provisions of the purchase order are in accordance with this Agreement. CryoLife shall place purchase orders so that they have been received by SMI no less than ten (10) days prior to the requested ship date. If SMI rejects a purchase order, SMI must notify CryoLife within seven (7) calendar days of receipt of such purchase order. If a purchase order is rejected, CryoLife will be advised of the reason for rejection and be provided with an opportunity to bring the purchase order into compliance. The terms contained in this Agreement shall govern the sale of Products to CryoLife and shall supersede any inconsistent terms in CryoLife's purchase orders, unless SMI expressly agrees to such terms in writing. Orders placed by telephone, or in person are to be confirmed by facsimile or email to SMI by CryoLife within three (3) business days.

3.11 Forecasts. On a quarterly basis, thirty (30) days before the end of each quarter, CryoLife shall provide to SMI twelve (12) month rolling forecasts of the anticipated quarterly quantities and mix of the Products that CryoLife expects to order (each, a "Forecast"). Such Forecasts shall not be binding except to the following extent: the first three months of each Forecast shall constitute a firm commitment to order the total dollar volume of Products forecast for such period during such period with CryoLife having the ability to vary from the Products mix forecasted provided CryoLife orders at least 80% of the volume forecast for each Product number. On a quarterly basis, thirty (30) days before the end of each quarter, SMI will provide CryoLife with twelve month rolling forecasts of Product inventory and production and a report of inventory on hand. Failure of either Party to provide the forecasts or reports required by this Section 3.11 shall relieve the other Party of its obligations under this Section 3.11. SMI agrees to timely supply CryoLife with the quantities forecasted for the first three months of each Forecast against purchase orders from CryoLife. SMI also agrees, at a minimum, to fulfill all firm additional orders for the Product submitted by CryoLife that are not more than 50% above the amounts forecasted.

3.12 Shipments. CryoLife may provide SMI with a designated shipper. SMI will coordinate the collection of goods with the designated shipper from SMI's warehouse. If CryoLife does not designate a shipper, SMI will designate a shipper of its own choosing. Title to Products and all risk of loss shall pass from SMI to CryoLife at the time and place of SMI's delivery of Products to CryoLife, F.O.B. Shipping Point. CryoLife shall be responsible for costs of shipping. CryoLife shall be solely responsible for insuring Products against damage in shipping after delivery to CryoLife Ex-work or F.O.B. Shipping Point. SMI shall ship Products to CryoLife on the shipping date designated in CryoLife's purchase order provided the purchase order is received at least thirty (30) days before the requested shipping date, subject to the limitations of the prevailing laws and regulations and to forces outside the control of SMI.

3.13 Returns. SMI shall accept returns of any Product that does not meet the Product Specifications, or is otherwise clearly rendered unsalable, provided CryoLife notifies SMI in writing of any alleged failure to meet Product Specifications not later than twenty (20) Business Days from the date of arrival of such Product at the point of delivery or twenty (20) Business Days after discovery of such

Product's failure to meet any Product Specification, such as shelf life, that may not be readily determined upon Product receipt. Any defects of Products resulting from CryoLife's mishandling of Products after collection of the Product from point of shipment to CryoLife is expressly excluded. At SMI's request, CryoLife will return the allegedly defective Product to SMI or provide such other evidence of the deficiency of the Product to SMI. Credit for any such defective Product for which timely notice is provided as set forth above shall be issued if SMI's examination confirms that the Product is defective and that such defect is not the result of any mishandling of the Product after collection of the Product from SMI's warehouse. Credit shall include Transfer Price and shipping charges. CryoLife agrees to advise SMI of any information in its possession regarding mishandling, damage, deterioration, alteration, or modification of any Product or its packaging. CryoLife will follow SMI's reasonable instructions to return Products or to otherwise dispose of them, and will not take any action in relation to Products until it receives such instructions from SMI.

3.14 Payment. SMI shall invoice CryoLife for Products delivered to CryoLife in accordance with this Agreement and relevant purchase orders. CryoLife shall pay for Products within thirty (30) days after the date of SMI's invoice (provided that the invoice date is no earlier than the date that shipment is received and if it is earlier, within thirty (30) days after the date of the shipment). All payments by CryoLife under this Agreement shall be made in United States dollars free of any exchange or collection charges and of any taxes imposed under the laws of any country. If CryoLife fails to pay to SMI any amount when due, SMI shall notify CryoLife of such failure in writing and if CryoLife fails to dispute, contest or pay any portion of such past due amount within five (5) Business Days of receipt of such notice, CryoLife agrees to pay interest on the undisputed and unpaid overdue amounts at the rate of ten percent (10%) per annum or, if lower, the maximum rate permitted by applicable law. Payments shall only be required after full shipments of Products ordered in a single purchase order unless a partial shipment has been approved in advance by CryoLife.

3.15 Samples. SMI shall provide, at no cost to CryoLife, reasonable quantities of sterile and non-sterile Products that CryoLife may use at its sole discretion for samples and demonstrations. These sample units shall be provided within ten (10) days after the Effective Date. Thereafter, and from time to time as the Parties may mutually agree is reasonable for the purpose of supporting CryoLife's promotional and sales efforts, SMI shall provide additional sample units to CryoLife at no cost to CryoLife. Pursuant to the preceding sentence, CryoLife may reasonably request quantities of samples, which request shall not be unreasonably denied. CryoLife shall certify that all orders for additional sample units are for sample units that were actually used for demonstrations and not sold or otherwise provided as part of the sale of Products. The Parties agree that the Products samples mix and quantities set forth on Schedule 3.15 are reasonable.

4. **Product Specifications and Changes**

4.1 Product Specifications. Except for the Product notated on Schedule 3.8, SMI warrants to CryoLife that all Products delivered to CryoLife (i) conform to the Product Specifications, (ii) are contained in packaging that accurately reflect the Products as manufactured and sterilized, (iii) have been manufactured, tested, stored, packaged, labelled and shipped in compliance with Applicable Laws and in accordance with applicable Regulatory Authorities, including CE/MDD Regulatory Approvals, (iv) be free of defects in design, material, engineering, fabrication and workmanship in accordance with the Product Specifications, and (v) have a shelf life of at least thirty-six (36) months with at least twenty-five (25) months shelf life remaining when received by CryoLife. The foregoing warranty shall be in effect with respect to each Product for the labelled shelf life of the Product. SMI further warrants to CryoLife that the Product, when delivered, shall be free and clear of any liens, security interests or encumbrances of any nature whatsoever.

4.2 Product Changes. SMI shall not make any changes to Products (including materials, packaging, and directions for use), Product Specifications, the raw materials, component suppliers, or manufacturing process for the Products (collectively, "Product Changes") unless approved by CryoLife in writing in advance, which approval may not be unreasonably denied (with the Parties understanding that any such changes that would require new or changes to regulatory approval may be denied by CryoLife due to the cost or time involved in that change).

4.2.1 Without limiting the foregoing, all Product Changes (including changes required by law) shall be submitted to CryoLife in writing no later than one hundred eighty (180) days prior to SMI's proposed date of implementation for such change. Unless CryoLife notifies SMI in writing that it disapproves of such change during the thirty (30) calendar day period following the notification of such change or if such a proposed change is otherwise required by law, regulation, or directive, SMI shall be authorized to implement such change and shall be responsible for properly communicating and implementing such change, including with respect to any of SMI's vendors.

4.2.2 Without limiting the foregoing, the following changes shall be deemed governed by this Section 4.2: (i) use of any nonconforming material in the manufacture of any of the Products in variance with the Product Specifications; (ii) implementation of any deviation that could affect the handling, sterility, safety, or efficacy of any of the Products and be at variance with the Product Specifications; or (iii) implementation of any corrective action that could affect the safety or efficacy of the Products. Notwithstanding the foregoing, SMI shall not make any Product Changes that disqualify Products for sale under any regulatory or other approval governing the sale or distribution of Products within any portion of the Territory.

4.2.3 SMI shall be responsible for all costs and expenses associated with developing and implementing any Product Changes including, without limitation, any and all costs associated with obtaining regulatory approval to incorporate Product Changes into Products or to manufacture or Distribute Products that incorporate Product Changes throughout the Territory.

4.2.4 SMI shall maintain sufficient Product Inventory for any discontinued Products to satisfy all Tenders for the discontinued Products in effect on the date such Products are discontinued by reason of a Product Change made pursuant to this Section 4.2 or otherwise.

4.3 Clot Plus, Limited. SMI shall cause Clot Plus Limited and any Other Party who has access to or capability to manufacture and distribute the Products known under the tradename Orthoclot™ to cease all manufacture and distribution of such Products after the transfer of inventory contemplated in Section 3.6. SMI represents and warrants that the Intellectual Property relating to such Products will not be assigned or licensed to any Third Party or used by any Other Party or SMI to manufacture or distribute such Products or Competitive Products.

5. **Approvals and Compliance**

5.1 Regulatory Approvals. SMI represents and warrants to CryoLife that it has applied for and received Regulatory Approvals for the Products in the Permitted Clinical Applications within the Territory jurisdictions as indicated on Schedule 5.1. SMI represents and warrants that each Regulatory Approval identified on Schedule 5.1 as obtained is in good standing. and has never been revoked or suspended for any reason. SMI has no reason to believe that such Regulatory Approvals will be revoked or suspended for any reason. SMI hereby grants to CryoLife the fully paid-up right to use any and all Regulatory Approvals related to the Products within the Territory that are owned by or licensed to SMI

and as of the date hereof and throughout the Term. The Parties acknowledge that to obtain Regulatory Approvals in certain countries in the Territory, CryoLife or its Affiliates may need to be listed as the manufacturer of the Product and that in such case SMI shall be an OEM manufacturer for CryoLife or its Affiliates and the Parties shall enter into appropriate agreements to show that CryoLife or its Affiliates is the manufacturer and SMI is the OEM Manufacturer (provided however that the costs for obtaining, maintaining and communicating with Regulatory Authority and the costs for submissions shall still be borne by SMI and the appropriate agreements shall reflect that fact).

5.1.1 SMI represents, warrants and covenants that it has applied for and will allocate sufficient resources and use reasonable efforts to obtain in a timely fashion additional Regulatory Approvals in additional jurisdictions within the Territory for Permitted Clinical Applications according to the schedule in the Regulatory Approval Development Plan set forth on Schedule 5.1. SMI agrees that its obligations under this subsection include the hiring of a qualified professional or professional firm to supplement or replace its internal efforts to secure and maintain Regulatory Approvals in a timely fashion.

5.1.2 All costs and expenses for obtaining and maintaining Regulatory Approvals throughout the Territory shall be SMI's, except for the costs and expenses of obtaining Regulatory Approval in Canada, the United States and Japan, which CryoLife has responsibility to apply for under this Agreement and the License Agreement. SMI shall have the primary responsibility for all communications, submissions and interactions with the Regulatory Authorities for the purpose of obtaining and maintaining Regulatory Approvals except for Canada, the United States and Japan.

5.1.3 At least once each month, SMI shall report in reasonable detail to CryoLife on the status of SMI's efforts to obtain Regulatory Approvals according to the Regulatory Approval Development Plan. SMI agrees to provide to CryoLife such documentation or analyses as CryoLife may reasonably request in connection with any submission for Regulatory Approval. At CryoLife's reasonable request from time to time, SMI shall also permit CryoLife to contact Regulatory Authorities involved in any Regulatory Approval requests of SMI.

5.1.4 If at any time SMI falls behind schedule for obtaining Regulatory Approval for Products in any jurisdiction in accordance with the Regulatory Approval Development Plan or if the Parties agree, CryoLife may either require SMI to engage at SMI's cost a Third Party professional firm qualified in obtaining Regulatory Approvals that is acceptable to CryoLife or CryoLife may take over responsibility for obtaining Regulatory Approval in a jurisdiction by so notifying SMI in writing. SMI agrees to cooperate fully with CryoLife's efforts and to promptly reimburse CryoLife for all its costs and expenses associated with such effort plus overhead for such endeavour equal to 20% of such amount. In such event and as to the Regulatory Approval application process taken over, CryoLife shall thereafter have primary responsibility for all communications, submissions and interactions with the Regulatory Authorities for the purpose of obtaining and maintaining such Regulatory Approval and SMI shall provide reasonable assistance and cooperate fully with CryoLife with respect to such Regulatory Approvals. If SMI fails to promptly reimburse CryoLife as required herein in Section 5.1.4, CryoLife may notify SMI and offset any such unreimbursed costs and expenses against amounts otherwise due or coming due to SMI under this Agreement, the License Agreement or any other Agreement.

5.1.5 The Parties acknowledge that the Minimum Annual Purchase Requirements are predicated upon SMI meeting or exceeding the goal of obtaining Regulatory Approvals for the Products in the jurisdictions indicated no later than when provided on Schedule 5.1. To the extent any such Regulatory Approvals are not obtained by the date indicated on Schedule 5.1, the Parties agree, at CryoLife's request, to reduce the Minimum Annual Purchase Requirements by the amount set forth on Schedule 5.1 and to amend Schedule 5.1 to reflect such adjustments.

5.1.6 CryoLife agrees to use commercially reasonable efforts to apply for Regulatory Approval, in CryoLife's name, to distribute and sell Products in Permitted Clinical Application in Canada. SMI shall provide reasonable personnel assistance to SMI with respect to such Regulatory Approval. SMI's assistance in this effort will include providing information about SMI and Products as needed for such application, such as clinical trial information relating to the Products. CryoLife's obligations related to obtaining Canadian Regulatory Approval does not include or require CryoLife to conduct any clinical trials involving Products, nor is SMI required to conduct such clinical trials for Canada. If SMI's reasonable failure to cooperate causes, in CryoLife's reasonable estimation, Regulatory Approval in Canada to be delayed past January 1, 2012 the Parties agree to reduce the Minimum Annual Purchase Requirements by [***] US Dollars ($[***]) starting with calendar year 2012, with a pro-rata adjustment made for any approval that occurs during a calendar year.

5.2 Manufacturing Requirements. SMI has and will manufacture Products in accordance with the (i) Product Specifications, (ii) applicable Regulatory Laws, including master device and lot history records, and ISO 13485 requirements (including appropriate certification), MDD Requirements, CMDCAS Requirements (when such CMDCAS Requirements are necessary for CryoLife to obtain Canadian registration), and (iii) other pertinent rules and regulations of Regulatory Authorities that have granted Regulatory Approval for the Products. Upon the request of CryoLife, SMI shall provide CryoLife with written evidence of compliance with the criteria set forth in the preceding sentence. Upon CryoLife's request, SMI shall provide CryoLife with written evidence of compliance with the criteria set forth herein. During the Term, SMI will maintain, or cause to be maintained, the Products manufacturing facility's registration as a certified medical device manufacturing facility with all applicable Regulatory Authorities and cause such facility to be maintained such that the facility would pass an audit for compliance with ISO 13485 (including appropriate certification), MDD Requirements, and CMDCAS Requirements (when such CMDCAS Requirements are necessary for CryoLife to obtain Canadian registration). SMI shall maintain ongoing quality assurance and testing policies sufficient to satisfy its obligations under this Agreement, CryoLife's standard requirements for approval as a vendor as described in CryoLife's quality system review policy, and SMI's standard quality assurance policies, copies of which are attached hereto.

5.3 Manufacturing Sources. SMI represents that, as of the Effective Date, it has a fully CE Marking certified and functioning manufacturing source for the Products capable of producing sufficient Product to meet CryoLife's needs under this Agreement. SMI agrees to maintain such manufacturing source or procure other sources, facilities and/or equipment in order to replace such manufacturing source that are reasonably acceptable to CryoLife and CE Marking certified in the event that SMI's then-active manufacturing facility becomes unable or unwilling to supply Products in a timely manner. SMI further agrees to establish a second CE Marking certified and fully functioning manufacturing facility for Products that is reasonably acceptable to CryoLife on or before December 31, 2012.

5.4 Regulatory and Products Communications. SMI shall be responsible to Regulatory Authorities throughout the Territory as the manufacturer of the Products.

5.4.1 Each Party shall promptly notify the other and provide to the other a copy or transcription, if available, of any communication from any Regulatory Authority relating to the Products, the marketing thereof, or any related matter (including copies of all product approvals) and shall keep the other Party reasonably apprised of regulatory interactions and similar activities with governmental authorities and international bodies in connection with the Products anywhere in the Territory.

5.4.2 Each Party shall notify the other immediately by fax or email, with confirming notice via overnight delivery, as soon as it becomes aware of any issue with the Products or their testing, manufacture, labelling, or packaging, including any issue relating to regulatory compliance, safety or efficacy of the Products or breach by such Party of the terms of this Agreement. Without limiting the generality of the foregoing, each Party will notify the other immediately if it becomes aware of any death or bodily injury caused by a Product unit (or suspected to be caused by a Product unit) or any malfunction of any of the Products.

5.4.3 If either Party receives notice of an actual or threatened inspection, investigation, inquiry, recall, import or export ban, product seizure, enforcement proceeding or similar action by a Regulatory Authority with respect to the Product or a Party's activities in connection with the Product, it will notify the other Party within forty-eight (48) hours after its receipt of notice of the action and will promptly deliver to the other Party copies of all relevant documents received from the Regulatory Authority. Any notice respecting a recall or action that in any way restricts the ability of either Party to Distribute Products shall be delivered to the other Party promptly upon receipt.

5.4.4 The Parties shall cooperate in response to the action, including providing information and documentation as requested by the Regulatory Authority. If the action primarily concerns CryoLife's activities or if the action involves the Regulatory Authority in Canada and Japan, then CryoLife shall have primary responsibility to respond to the Regulatory Authority; otherwise, SMI shall have primary responsibility to respond. In either case, upon request of the responding Party, the other Party shall provide consulting advice and assistance with the response. In addition, each Party shall promptly notify the other and provide to the other a copy or transcription, if available, of any communication from any Regulatory Authority relating to the products, the marketing thereof, or any related matter and shall keep the other Party reasonably apprised of regulatory interactions and similar activities with Regulatory Authorities in connection with the Products.

5.4.5 If either Party in good faith determines that a removal, correction, recall or other Field Action involving the product or its labelling is warranted (whether or not required by a Regulatory Authority), such Party shall immediately notify the other Party and shall advise such other Party of the reasons underlying its determination that a removal, correction, recall or other Field Action is warranted. The Parties shall consult with each other as to any action to be taken in regard to such removal, correction, recall or other Field Action. If, after consultations, either Party in good faith believes that such a removal, correction, recall or Field Action should be undertaken with respect to the Products or its labelling, the Parties shall cooperate in carrying out the same. SMI shall be responsible for all of CryoLife's reasonable out-of-pocket costs and expenses, including the cost of the Products and the replacement cost of the Products, quality control testing and notification in the event of removals, correction, recall or other Field Action involving the Product or its labelling, provided it copies CryoLife. In the event of a Field Action of any Products, SMI shall promptly correct noted deficiencies relating to its manufacturing, packaging, labelling, testing and SMI's storage or handling of Products, if applicable,

or cause the vendor of any material, component, or sub-assembly incorporated into such Products to do likewise with respect to such material, component, or sub-assembly and CryoLife shall correct noted deficiencies related to matters for which it is responsible. If SMI fails to promptly reimburse CryoLife as required herein in Section 5.4.5, CryoLife may notify SMI and offset any such unreimbursed costs and expenses against amounts otherwise due or coming due to SMI under this Agreement, the License Agreement or any other Agreement.

5.4.6 In the event of any action by a Regulatory Authority or Field Action that impedes CryoLife's ability to sell Products, the Minimum Annual Purchase Requirements shall be adjusted equitably downward to reflect such impediment.

5.4.7 The provisions of this Section 5.4 do not apply to the Regulatory Authority in the United States.

5.5 Compliance with Laws. Each Party will comply with all Applicable Laws in the Territory that pertain to the testing, manufacture, labelling, marketing, distribution, sale, or packaging of the Products and in any other manner pertaining to the performance of its obligations under this Agreement, including the maintenance of ongoing quality assurance and testing procedures to comply with applicable regulatory requirements. Each Party will also comply with Applicable Laws in the Territory pertaining to the import, export, distribution, sales, and marketing of the Products. Without limiting the generality of the foregoing, each Party will, as required by law, (i) report to every applicable Regulatory Authority within any relevant time periods all events that are required to be reported (including any death or serious bodily injury caused by a Product); and (ii) deliver, within the permitted time periods, all annual or other periodic reports required to be delivered to every applicable Regulatory Authority.

5.6 SMI Inspection Rights. SMI shall have the right, upon thirty (30) days advance notice, to inspect during regular business hours any or all premises used by CryoLife in the distribution and storage of the Products and all records of CryoLife reasonably necessary to verify the accuracy of any Forecasts or reports provided by CryoLife. Any such inspections will be subject to the confidentiality agreements set forth in Section 7.

5.7 CryoLife Inspection Rights. CryoLife shall have the right to have its representatives present at the plant or plants at which Products or Products components are manufactured during normal business hours to conduct an initial and periodic inspections of such facilities and manufacturing procedures for compliance with ISO 13485 (including appropriate certification), MDD Requirements, and when necessary, CMDCAS Requirements, applicable Regulatory Laws, the Product Specifications and CryoLife's quality assurance requirements and to inspect SMI's inventory of Products, work-in-process, raw materials to be used for Products, production records, design history file, quality manuals, regulatory dossiers, and such other matters as may be pertinent to proper quality assurance of Products to be delivered hereunder. CryoLife agrees to give SMI a minimum of thirty (30) days prior notice of any such inspection and each CryoLife representative may be required by SMI to sign a confidentiality agreement. SMI shall promptly use its best efforts to take such action as is required to correct any deficiencies identified by CryoLife relating to the production of Products. SMI further agrees to use its best efforts to provide such documentation or conduct such analyses as CryoLife may reasonably request in connection with any regulatory submission or audit. Unless required by law, or if necessary to apply for Regulatory Approval in Canada, or after an event identified in Sections 5.4.3 or 5.4.5, CryoLife will limit its inspections for each plant to no more often than once in any twelve (12) month period, without SMI's consent, which shall not be unreasonably withheld. Any such inspections will be subject to the confidentiality agreements set forth in Section 7.

5.8 Regulatory Audits and QA Assessments. SMI will permit authorized representatives of any applicable Regulatory Authority to inspect SMI's plant and production facilities (and will secure the same rights with respect to any Third Party plant and production facilities) relating to or used in connection with the manufacture of Products or component materials used in Products and will promptly notify CryoLife when SMI receives notice of any such inspection. At CryoLife's request SMI will perform a quality system assessment of the vendors who provide SMI with raw components and/or materials, sub-assemblies or contract services for any Products. SMI will advise CryoLife of the findings of any regulatory inspection or quality system assessment and will promptly take the necessary steps to correct any deficiencies found by the Regulatory Authority or the quality system assessment relating to the production of Products or component materials. SMI further agrees to use its reasonable best efforts to provide to CryoLife such documentation or conduct such analyses as CryoLife may reasonably request in connection with any regulatory submission or audit or quality system assessment concerning Products. CryoLife will permit authorized representatives of any Regulatory Authority to inspect CryoLife's facilities relating to distribution of Products and will promptly notify SMI when CryoLife receives notice of any such inspection. CryoLife will advise SMI of the findings of any regulatory inspection and will promptly take the necessary steps to correct any compliance deficiencies found by the Regulatory Authority relating to CryoLife's activities with Products.

5.9 Traceability. SMI shall maintain manufacturing and traceability records with respect to the Products, including records by lot number. For seven years after delivery to CryoLife of each Product unit, or such longer period as may be required by applicable Regulatory Laws, SMI shall (i) maintain traceability for each SMI Product unit including the manufacturing date and lot number of each SMI Product unit and each component and material comprising each SMI Product and (ii) provide CryoLife a copy of such records upon CryoLife's written request.

5.10 Product Complaints and Reports. The Parties shall each collect and record Product Complaints (and any other events required to be recorded under Applicable Laws) in accordance with Applicable Laws and their standard procedures and policies in effect from time to time. Each Party shall provide to the other Party reports of such complaints or events within seventy-two (72) hours after receipt. SMI shall be responsible for investigating all Product Complaints, shall promptly respond to such complaints and shall copy CryoLife on any response made by SMI. SMI shall be responsible for submitting to the Regulatory Authorities all required reports and other materials, including annual reports, distribution reports and safety reports. SMI's obligations shall apply to Product Complaints within and outside the Territory.

5.11 Post-Market Clinical Studies. Each Party shall inform the other Party in the event that such Party becomes aware of post-market clinical studies being conducted with the Product. Each Party shall inform the other Party in the event that they become aware of published literature or unpublished reports of data from any clinical or non-clinical laboratory studies involving the Product.

6. **Indemnification and Liability**

6.1 Indemnification by CryoLife. CryoLife assumes responsibility and shall indemnify SMI, its subsidiaries, parent corporations, affiliates, officers, directors, independent contractors, partners, shareholders, employees, agents, and their respective successors and assigns (collectively, the "SMI Indemnitees") and hold the SMI Indemnitees harmless from and against any and all Losses resulting from any Third Party claims made or legal proceedings instituted against any of the SMI Indemnitees which arise out of or result from the marketing, shipping, storage, distribution, or any handling by CryoLife of the Products, including any Losses resulting from any claim by a Third Party that SMI has tortiously

interfered with any contract that CryoLife may have with such Third Party, unless such Losses also result from or arise out of the negligence of any SMI Indemnitee, any manufacturing, design or defects in the Products, or any claim respecting intellectual property rights. SMI shall promptly notify CryoLife in writing of any such claim or proceeding and shall permit CryoLife to control the defense of such claim or proceeding; provided, however, that SMI may in its discretion participate at its own expense in such defense; and provided further, that CryoLife shall not settle any such claim or proceeding that may adversely impact any SMI Indemnitee without SMI's prior written consent.

6.2 Indemnification by SMI. SMI assumes responsibility and shall indemnify CryoLife its subsidiaries, parent corporations, affiliates, officers, directors, independent contractors, partners, shareholders, employees, agents, and their respective successors and assigns (collectively, the "CryoLife Indemnitees") and hold the CryoLife Indemnitees harmless from and against any and all Losses resulting from any Third Party claims made or legal proceedings instituted against any of the CryoLife Indemnitees which arise out of or result from (i) any product defect, or any product description or claim made by or on behalf of SMI and upon which CryoLife or any Third Party has relied, including, but not limited to claims for personal injury, including death, or property damage; (ii) the manufacture, processing, design, testing, packaging, labelling, storage, handling, or distribution by or for SMI (other than by CryoLife) of any of the Products, including but not limited to claims for personal injury, including death, or property damage; or (iii) any allegation or claim of infringement by the Products, their manufacture, processing, distribution or sale, of the patent or other intellectual property rights of a Third Party, except to the extent such Losses also result from or arise out of the negligence of a CryoLife Indemnitee. CryoLife shall promptly notify SMI in writing of any such claim or proceeding and shall permit SMI to control the defense of such claim or proceeding; provided, however, that CryoLife may in its discretion participate at its own expense in such defense; and provided further, that SMI shall not settle any such claim or proceeding that may adversely impact a CryoLife Indemnitee without CryoLife's prior written consent. If any Product is held to constitute an infringement or misappropriation of any Third Party's intellectual property right or if CryoLife and SMI concur that any Product constitutes an infringement or misappropriation, SMI will at its expense either: (i) procure the right for CryoLife to continue distributing the Product in accordance with this Agreement at no additional cost to CryoLife, (ii) replace the Product with a non-infringing and non-misappropriating equivalent product conforming to the Product Specifications at no additional cost to CryoLife, or (iii) modify the Product to make it non-infringing and non-misappropriating while conforming to the Product Specifications at no additional cost to CryoLife.

6.3 Other Claims. Each of SMI and CryoLife (each, in such capacity, an "Indemnifying Party") will defend, indemnify, and hold harmless the other Party, its subsidiaries, parent corporations, affiliates, officers, directors, independent contractors, partners, shareholders, employees, agents, and their respective successors and assigns (collectively, in such capacity, the "Indemnitees") from and against any Losses, including Losses imposed upon or caused to be incurred by the Indemnitee(s) by any Third Party, arising from or related to any (i) breach of such Indemnifying Party's representations and warranties, covenants, or obligations under this Agreement or (ii) an assertion that this Agreement or Indemnified Party's actions pursuant to this Agreement tortuously interfere with any contracts to which the Indemnifying Party is a Party.

6.4 Contribution. To the extent that CryoLife and SMI have indemnification obligations to one another in connection with a single Claim, CryoLife and SMI shall contribute to the aggregate damages arising from such Claim in such proportion as is appropriate to reflect their relative responsibilities for such damages, as well as any other relevant equitable considerations. The amount paid or payable by CryoLife or SMI for purposes of apportioning the aggregate damages shall be deemed to include all reasonable legal fees and expenses incurred by such Party in connection with investigating, preparing for or defending against such Claim. Such finding of contribution shall be as agreed to in writing by the Parties, or as determined by a judicial determination, in final, non-appealable form.

6.5 Procedure. A Party seeking indemnification pursuant to the terms of this Agreement shall promptly notify the other Party in writing of a claim or suit; provided, that a Party's failure to give such notice or delay in giving such notice shall not affect such Party's right to indemnification under this Section 6 except to the extent that the other Party has been prejudiced by such failure or delay. Neither Party has any obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld. The Indemnitee has the right to participate (i) at its own expense in the claim or suit with counsel of its own choosing and (ii) in selecting counsel to be used by the Indemnifying Party in such claim or suit. The Indemnifying Party will consult with the Indemnitee in good faith with respect to all non-privileged aspects of the defense strategy. The Indemnitee shall cooperate with the Indemnifying Party as reasonably requested, at the Indemnifying Party's sole cost and expense. The Indemnifying Party shall not settle any claim or suit without the Indemnitee's prior written consent unless such settlement is limited to the payment of cash by the Indemnifying Party and contains a full release of the Indemnitee.

6.6 Insurance. At all times during which any of the Products are being clinically tested with human subjects or commercially distributed or sold by CryoLife hereunder, as well as for a period of seven years thereafter, each Party shall procure and maintain insurance from a reputable insurer reasonably satisfactory to the other Party, including product liability insurance, adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated. In any event, the amount of insurance obtained and maintained pursuant to this Section 6.6 by each Party shall not be less than [***] U.S. dollars ($[***]). It is understood that such insurance shall not be construed to create a limit of each Party's liability with respect to its indemnification obligations under this Section 6. Each Party shall provide the other Party with written evidence of such insurance (or financial information that describes the amounts available under any self-insurance facility) upon request. SMI shall provide CryoLife with written notice at least fifteen (15) days prior to the cancellation, non-renewal, or material change in such insurance.

6.7 No Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATIONS OR WARRANTIES AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

7. **Confidentiality**

7.1 Confidentiality. Each of SMI and CryoLife acknowledge that in order to satisfy their respective obligations under this Agreement, it will be necessary for the Parties to exchange certain trade secret and confidential information (collectively, the "Confidential Information"). The provisions of this Section 7 shall apply to disclosures furnished to or received by a Party and its employees, agents and representatives (which may include employees, agents and representatives of its Affiliates). Each Party shall advise its employees, agents and representatives of the requirements of this Section 7 and shall be responsible to ensure their compliance with such provisions. In consideration of the mutual benefits to be derived from the exchange of Confidential Information, SMI and CryoLife agree as follows:

7.1.1 For purposes hereof, "Confidential Information" with respect to a disclosing Party includes all information, in any form or media, concerning the disclosing Party that the disclosing Party furnishes to the recipient, whether furnished before or after the Effective Date, and all notes, analyses, compilations, studies and other materials, whether prepared by the recipient or others, that contain or reflect such information; provided, however, that Confidential Information does not include information that (i) is or hereafter becomes generally available to the public other than as a result of a breach of this Agreement by the recipient, (ii) was already known to the recipient prior to receipt from the disclosing Party, as evidenced by prior written documents in its possession not subject to an existing confidentiality obligation to the disclosing Party, (iii) is disclosed to the recipient on a non-confidential basis by a person who is not in default of any confidentiality obligation to the disclosing Party or (iv) is developed by or on behalf of the recipient without reliance on confidential information received hereunder. The contents of this Agreement shall be deemed to be Confidential Information of each Party.

7.1.2 The recipient of Confidential Information shall (i) maintain its confidentiality using efforts and precautions at least as great as those it uses and takes to protect its own confidential information and trade secrets; (ii) use such Confidential Information solely in connection with the discharge of its obligations under this Agreement and (iii) not disclose such Confidential Information to any person other than those of its agents and representatives who need to know such Confidential Information in order to accomplish the objectives for which it was disclosed. Notwithstanding the foregoing, the recipient of Confidential Information may disclose it to the extent necessary to comply with applicable laws, stock exchange rules, or with an order issued by a court or Regulatory Authority with competent jurisdiction; provided that, in connection with such disclosure, the recipient uses commercially reasonable efforts to obtain confidential treatment or an appropriate protective order, to the extent available, with respect to such Confidential Information. The receiving Party may provide access to the Confidential Information to such employees and consultants of the receiving Party who reasonably require such access in connection with the transactions contemplated by this Agreement.

7.1.3 The obligations under this Section 7 shall remain in effect from the Effective Date through the third anniversary of the expiration or termination of this Agreement.

7.1.4 In addition to any other remedies available in law or equity, the disclosing Party shall be entitled to temporary and permanent injunctive relief in the event of a breach (or threatened breach) under this Section 7.

7.2 Prior Confidentiality Agreements. The provisions of this Section 7 shall supersede and replace any prior agreements between the Parties relating to Confidential Information covered hereby; provided that notwithstanding the foregoing the Parties acknowledge and agree that upon execution of this Agreement by the Parties that certain nondisclosure agreement, dated April 20, 2010, between the

Parties hereto (the "Confidentiality Agreement") shall be deemed terminated as of the date hereof but those terms set forth therein shall survive in accordance with their terms.

7.3 Public Announcements. Notwithstanding the provisions of this Section 7 the Parties acknowledge they may desire (or be required) to make a public announcement, issue a press release or provide similar publicity with respect to this Agreement or the transactions contemplated herein, and each Party shall notify the other Party of its intent to make such publicity and deliver a draft of such publicity to the other Party. Neither Party shall make any public announcement, press release or similar public pronouncement with respect to this Agreement or the transactions contemplated herein without the consent of the other Party regarding the content, time and manner of such publicity; provided that neither Party shall unreasonably withhold its consent under this Section 7 and nothing in this Section 7 shall prevent either Party from timely making any disclosure required by law or by the New York Stock Exchange or other applicable public stock exchange.

8. **Other Duties**

8.1 CryoLife Duties. CryoLife shall exert commercially reasonable best efforts to introduce, promote, sell, and distribute the Products for Permitted Clinical Applications within the Territory. CryoLife shall make no false or misleading representations to customers or other persons with regard to the Products or SMI, and shall not make any representations with respect to the specifications, features or capabilities of the Products which are not consistent with the Product Specifications or those described in then-current literature distributed by SMI. CryoLife will conduct post-marketing evaluations for the Product as and when CryoLife deems necessary. When SMI desires to conduct field work in the Territory, CryoLife will assist in planning an effective schedule of appointments for the visit. CryoLife shall use commercially reasonable efforts to hire, train and retain such competent personnel, as may be required to carry out its obligations under this Agreement. CryoLife agrees that its personnel involved with the distribution of Products will receive training consistent with SMI training programs and instructions prior to initiating sales and promotional activities.

8.2 SMI Duties. In addition to its obligations under Section 9, SMI shall provide reasonable marketing support to CryoLife without charge to CryoLife. Such marketing support shall include furnishing CryoLife with any market surveys and related information prepared by or for SMI pertaining to the market for Products in the Territory as well as the functions set forth on Schedule 8.2. SMI will cooperate with CryoLife in the sponsorship and planning of technical seminars on Products in the Territory.

9. **Product Information and Training**

9.1 Product Information. SMI will provide to CryoLife, at no cost to CryoLife, with all product handling manuals, sales literature, promotional materials, training materials, videos, demonstration kits, and other applicable information for Products. The material provided (collectively, the "Product Information") shall include information SMI has that it believes will be helpful and appropriate in assisting CryoLife in formulating any other manuals and promotional materials deemed necessary or appropriate by CryoLife for Products. Product Information shared will also include camera ready artwork and copies of all marketing support material produced by or for SMI. Product Information shared may be used by CryoLife solely for the purpose identified above. SMI shall also provide, at no cost to CryoLife, reasonable information concerning the technical aspects of Products, their use, and the like in writing and/or oral presentations. SMI represents and warrants that the Product Information shall be accurate and complete in all material respects, and undertakes to update any such Product Information when any information included therein becomes outdated, inaccurate, or misleading. CryoLife shall have

the right to produce, at its expense, promotional material, Products handling manuals, instructions for use, and other written information relating to Products that is based in whole or in part on the material supplied by SMI subject to the limitations set forth above and subject to SMI's prior approval, which shall not be unreasonably withheld, delayed or conditioned. SMI shall, at its expense, translate and label all Products and Product Information with the seventeen (17) languages set forth on Schedule 9.1 for all Products manufactured by SMI after January 1, 2011. If after January 1, 2011, SMI fails to do so (i) SMI agrees to indemnify CryoLife Indemnitees for any and all Losses arising out of or related to such failure by SMI and (ii) CryoLife may, at its option and at SMI's cost, translate or engage a Third Party to translate such Product Information to the languages required by any applicable Regulatory Law related to such Product Information. If SMI fails to promptly reimburse CryoLife as required herein in this Section 9.1, CryoLife may notify SMI and offset any such unreimbursed costs and expenses against amounts otherwise due or coming due to SMI under this Agreement, the License Agreement or any other Agreement. If CryoLife desires additional languages other than the seventeen (17) languages set forth on Schedule 9.1, translation and labelling shall be at CryoLife's costs, although SMI shall use its reasonable efforts to include any such new language in its next revision of the Products and Product Information once CryoLife provides translations into such language(s).

9.2 Training. SMI will provide reasonable train-the-trainer technical assistance and training in the field with CryoLife's sales force regarding Products as CryoLife reasonably requests. SMI shall also provide to CryoLife other services or other support information to assist CryoLife in marketing Products as CryoLife reasonably requests. SMI shall be responsible for the costs and expenses of its personnel incurred in connection with providing train-the-trainer technical assistance and training provided pursuant to this Section 9.2.

10. **Intellectual Property Rights**

10.1 Intellectual Property Representations. SMI hereby represents and warrants to, and covenants with, CryoLife as follows:

10.1.1 SMI, and only SMI, owns or holds valid and enforceable rights to exclusively manufacture, Distribute, use or license (to the extent a license is required) any and all Intellectual Property (such Intellectual Property rights collectively, the "SMI IP") that is necessary (i) to manufacture and Distribute the Products or to permit others to manufacture or Distribute the Products, (ii) for CryoLife to Distribute the Products as contemplated by this Agreement and (iii) for SMI to grant to CryoLife the rights to Distribute under this Agreement. No license of Intellectual Property rights from Third Parties is needed for CryoLife to Distribute the Products for Permitted Clinical Applications within the Territory.

10.1.2 SMI owns or licenses all right, title and interest in and to the SMI IP.

10.1.3 SMI has not granted any license, covenant not to sue or other right that would be inconsistent with or conflict with the grant of the exclusive rights to Distribute granted to CryoLife under this Agreement.

10.1.4 No Person has asserted any claim, suit, proceeding, action or demand (a "Claim") with respect to any of the SMI IP, which Claim (i) challenges the validity of SMI's interest in the SMI IP, (ii) alleges that SMI's use or practice of the SMI IP infringes, misappropriates or violates the rights of any Person or (iii) seeks to enjoin or restrain SMI's use or practice of the SMI IP in any manner

that would interfere with the transactions contemplated by this Agreement. Except as disclosed on Schedule 10.1, SMI has no knowledge that any Person intends to assert such a Claim.

10.1.5 No Intellectual Property or contract rights of others will be infringed by (i) the development, manufacture, or Distribution of Products by SMI or Distribution of Products by CryoLife as contemplated by this Agreement, (ii) the entering into of this Agreement, or (iii) the performance of this Agreement by either Party.

10.1.6 Prior to and during the Term, SMI has not granted any Person any license or right of first refusal that conflicts with the rights granted to CryoLife hereunder or the right to purchase all or substantially all of SMI or its business or the assets constituting the Products.

10.1.7 SMI owns or licenses all right, title and interest in and to the SMI IP. A complete list of all patents and patent applications included in the SMI IP, with the status of registrations in all countries in the Territory, is included on Schedule 10.1.

10.2 Intellectual Property/Information and Ideas. CryoLife acknowledges SMI's exclusive right, title and interest in and to the SMI IP. If any claim or action is asserted against SMI or CryoLife alleging that a Product infringes any Third Party intellectual property rights, the Party receiving such information shall immediately notify the other Party in writing of such claim or action.

10.2.1 In such event, SMI shall defend such action and, if necessary to permit CryoLife to continue selling the Products, use commercially reasonable efforts to secure such right, title, interest, or license to the intellectual property necessary for CryoLife to market, distribute and sell the Products.

10.2.2 If SMI is unable to secure sufficient rights to permit CryoLife to market, distribute, and sell the Products in the manner contemplated by this Agreement, SMI may remove the Products from the market if it reasonably determines such action is necessary due to infringement or possible infringement of Third Party intellectual property rights, and in such case CryoLife shall use commercially reasonable efforts to halt sales of Product in the Territory.

10.2.3 In the event of any action contemplated by this Section 10.2 adversely impacts CryoLife's ability to sell Products, the Minimum Annual Purchase Requirements shall be adjusted equitably downward to reflect such impediment.

10.2.4 If SMI or CryoLife recall or remove any Products from the market, SMI shall, at CryoLife's option, promptly repurchase CryoLife's entire Products inventory at the price paid by CryoLife (including shipping) and CryoLife shall be released of its obligation to distribute Products. The Parties agree that CryoLife's rights under this Section 10.2.4 shall be in addition to any other rights or remedies available to CryoLife pursuant to this Agreement or in law or equity.

10.3 Infringement Notification. Each Party shall promptly notify the other Party of any and all infringements of the SMI IP of which such Party becomes aware within the Territory. SMI shall, at its own cost, take any and all actions, legal or equitable, necessary to defend the SMI IP against such infringements and to eliminate or minimize the consequences of any infringement of the SMI IP in the Field in the Territory. At SMI's request and expense, CryoLife will assist SMI in taking action against any such infringements. If SMI fails to take appropriate action against such infringements within sixty (60) days after notice, CryoLife may take such actions as it deems necessary and appropriate, including but not limited to filing a lawsuit against a Third Party (and/or their patents) in SMI's name or its own name and/or requesting that patent offices (or their equivalents) reconsider Third Party patents and SMI

shall reasonably assist CryoLife as directed by CryoLife. In addition to any responsibility of SMI pursuant to Section 10.2, if any Product is held to constitute an infringement or misappropriation of any Third Party's Intellectual Property right, if SMI and CryoLife concur that any Products constitutes an infringement or misappropriation, or if CryoLife is advised by its legal counsel that any Products potentially infringe or misappropriate any Third Party's Intellectual Property right, SMI will at its expense either: (i) procure the right for CryoLife to continue distributing the Products in accordance with this Agreement at no additional cost to CryoLife, (ii) replace the Product with a non-infringing and non-misappropriating equivalent product conforming to the Specifications at no additional cost to CryoLife, or (iii) modify the Product to make it non-infringing and non-misappropriating while conforming to the Specifications at no additional cost to CryoLife. If SMI declines to take the foregoing action after notice from CryoLife within sixty (60) days or if SMI is unable to secure sufficient rights to permit CryoLife to Distribute the Products in the manner contemplated by this Agreement within a reasonable time, SMI shall, at CryoLife's option, promptly repurchase CryoLife's entire Product inventory as provided in Section 10.2.4 at CryoLife's original purchase price (including shipping) set forth herein, and CryoLife shall be released of its obligation to Distribute the Products. CryoLife shall also be authorized in the foregoing event to procure the right for CryoLife to continue distributing Products in accordance with this Agreement and to offset the cost of obtaining such rights from amounts otherwise due or coming due to SMI under this Agreement, the License Agreement or any other agreement.

10.4 Patent Prosecution. At its own cost, SMI shall apply for, prosecute, and maintain all patent applications and patents or rights to license or use the patents and patent applications included in the SMI IP within the Territory in the manner and according to the schedule set forth in the Patents Protection Plan included as Schedule 10.4. SMI shall keep CryoLife reasonably informed as to the status of the prosecution and maintenance of such patents and patent applications in the Territory and with respect to any actions regarding such patents and patent applications in the Territory.

11. **Term and Termination**

11.1 Term. The term of this Agreement shall take effect as of the Effective Date and shall remain in effect for fifteen (15) years (the "Term"). At least six (6) months prior to the expiration of the Term, the Parties shall discuss options for concluding a new agreement to take effect upon the expiration of this Agreement. Nothing in the preceding sentence shall require either Party to enter into or be bound by a new agreement or shall be construed to require a minimum length of time for such discussions.

11.2 Termination. Notwithstanding anything in Section 11.1, this Agreement may be terminated at any time as follows:

11.2.1 By CryoLife for reason of the SMI's material breach of a duty or obligation under this Agreement by giving SMI at least sixty (60) days prior written notice of termination which specifies such default and SMI fails to cure the material default during such sixty (60) day period.

11.2.2 After the fifth anniversary of the Effective Date, by SMI for reason of CryoLife's material breach of a duty or obligation under this Agreement by giving CryoLife at least sixty (60) days prior written notice of termination which specifies such default and CryoLife fails to cure the material default during such sixty (60) day period.

11.2.3 By CryoLife at any time and with or without cause by providing at least one hundred eighty (180) days prior written notice of termination to SMI.

11.2.4 By either Party forthwith on written notice of termination to the other Party for the other Party's Insolvency Event, or winding up of its operations; or in the event of nationalization, in whole or part, of the other Party.

11.2.5 By CryoLife upon sixty (60) days written notice of termination to SMI at any time after CryoLife obtains regulatory approval in the United States that permits commercial distribution of the Product and CryoLife no longer needs to order Product under this Agreement for sale in the Territory.

11.2.6 By CryoLife upon sixty (60) days written notice of termination to SMI at any time SMI fails on any two occasions within any twelve (12) month period to timely deliver Product, or material quantities of Product, ordered by CryoLife in a delivery that conforms to Product Specifications and CryoLife's invoice (a "Failure to Supply").

11.2.7 By SMI upon ninety (90) days written notice if CryoLife fails to achieve the Annual Minimum Quota in any year where there are no events under the provisions herein that grant a reduction in the Annual Minimum Quota; provided that CryoLife may purchase additional Product in order to meet the Annual Minimum Quota if it does so within forty-five (45) days of receipt of such notice by SMI and in such event SMI may not terminate the Agreement pursuant to this Section 11.2.7.

11.3 Effect of Termination. Notwithstanding anything to the contrary contained herein, upon and after any termination or expiration of this Agreement (i) SMI shall continue to fill all CryoLife purchase orders made in accordance with the provisions of this Agreement prior to the date of the initial notice of such termination or expiration; (ii) CryoLife shall continue to have all rights necessary or appropriate to sell Products (including Products delivered pursuant to post-termination orders and any Products ordered by CryoLife prior to termination or expiration) for twelve (12) months following the date of termination or expiration, and SMI shall continue to comply with all of its duties and obligations hereunder necessary or appropriate to facilitate such sales by CryoLife; (iii) SMI shall continue to comply with all of its duties and obligations hereunder necessary or appropriate to permit CryoLife to fulfill its obligations to deliver Products (directly or through subdistributors) pursuant to tenders or sales contracts outstanding at the time of such termination or expiration until such tenders or sales contracts have expired, including SMI's obligation to fill any related CryoLife purchase orders; and (iv) CryoLife shall continue to comply with its obligations under this Agreement. Termination of this Agreement shall not affect rights and obligations of either Party that may have accrued prior to the effective date of termination or any obligation that by its nature or express terms survives termination. Sections 3.2, 3.3, 3.4, 3.13, 3.14, 4, 5, 6, 7, 10, 11, 13, and 14 shall survive the termination or expiration of this Agreement.

11.4 Inventory Repurchases. Upon termination or expiration of this Agreement for any reason other than for CryoLife's material breach of its obligations hereunder, SMI shall, at CryoLife's option, repurchase from CryoLife all Products that are commercially usable at the Transfer Price paid by CryoLife for such Products, and CryoLife shall return to SMI any advertising or sales materials previously provided by SMI, if any. Within thirty (30) days after any such termination of this Agreement, CryoLife shall provide SMI an inventory of Products in its possession, including samples of Products, and information relating to the Transfer Prices CryoLife paid for such Products. If SMI disputes any information provided by CryoLife, it shall deliver a written notice thereof to CryoLife within fifteen (15) days after receiving such information, in which case, the Parties shall negotiate in good faith to resolve such dispute. CryoLife shall deliver to SMI all remaining Products, including samples, promptly after the expiration of the fifteen (15) day period if no dispute is raised by SMI, or after the resolution of such dispute.

12. **Other Product Agreements**

12.1 New Product Developments. The Parties agree to negotiate in good faith to come to agreement on terms of the Development Agreement, a joint development agreement relating to new intellectual property generated directly from the Product, the modified starch particles used in the production of the Products and the AMP™ technology. The Development Agreement will include provisions that detail how a new hemostatic powder might be developed, the rights of SMI and CryoLife to such powder, the allocation of costs and duties in such development, and the fees to CryoLife for exclusive rights to distribute such powder.

13. **Representations and Warranties**

13.1 Representations and Warranties

13.1.1 SMI hereby represents and warrants that:

(i) it is a duly and validly organized and existing corporation in good standing under the laws of the state of Delaware, and that it or its affiliates that may be performing its obligations under this Agreement are legally qualified to do business in each jurisdiction in which this Agreement may be performed and where its activities hereunder require such qualification,

(ii) the performance of this Agreement and the consummation of the transactions contemplated herein will not result in any breach, conflict, or violation of any terms or provisions of, or constitute a default under, its Certificate of Incorporation or By-Laws, or other organizational documents, or any material agreement or instrument to which it is a Party, by which it is bound, or to which any of its property is subject,

(iii) all requisite corporate action has been taken for the due authorization, execution, delivery, and performance of this Agreement by it, and this Agreement constitutes a legally binding obligation, enforceable against such Party, in accordance with its terms, except insofar as enforceability may be limited by bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally,

(iv) it is not a Party to any litigation relating to, or that could reasonably be expected to affect, its ability to perform its obligations under this Agreement, or

(v) Schedule W-2 lists all approved clinical applications for products based on the AMP technology within the Territory.

13.1.2 CryoLife hereby represents and warrants that:

(i) it is a duly and validly organized and existing corporation in good standing under the laws of the state of Florida, and that it or its affiliates that may be performing its obligations under this Agreement are legally qualified to do business in each jurisdiction in which this Agreement may be performed and where its activities hereunder require such qualification,

(ii) the performance of this Agreement and the consummation of the transactions contemplated herein will not result in any breach or violation of any terms or provisions of, or constitute a default under, its Certificate of Incorporation or By-Laws, or other organizational documents, or any material agreement or instrument to which it is a Party, by which it is bound, or to which any of its property is subject,

(iii) all requisite corporate action has been taken for the due authorization, execution, delivery, and performance of this Agreement by it, and this Agreement constitutes a legally binding obligation, enforceable against such Party, in accordance with its terms, except insofar as enforceability may be limited by bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally, and

(iv) it is not a Party to any litigation relating to, or that could reasonably be expected to affect, its ability to perform its obligations under this Agreement.

14. **General**

14.1 Notice. Any notice or other communication required or permitted by this Agreement must be given in writing and must be delivered by personal delivery (including personal delivery by overnight courier such as Federal Express, DHL, or similar overnight courier), first class mail (registered or certified), telecopy (with a copy sent by personal delivery or first class mail), or email (with a copy sent by personal delivery or first class mail) at the address of the Party as set forth herein or such other changed address of the Party as to which notice has been given, and will be deemed as having been given when received or delivered.

14.2 Binding; Assignment. This Agreement shall be binding on CryoLife, SMI, and their respective successors and assigns. Neither Party may assign its obligations under this Agreement or in any way transfer its rights or obligations under this Agreement, directly or indirectly, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that either Party may, without such consent, assign this Agreement in connection with any sale of substantially all of its assets or stock or pursuant to any merger, reclassification, or reorganization.

14.3 Entire Agreement; Modification; Waiver. This Agreement contains the entire agreement between the Parties with respect to the subject matter of the Agreement and shall supersede and terminate all prior agreements, commitments, or understandings, whether oral or written, related to the Products, except for the Confidentiality Agreement as modified by Section 7.2. No waiver or modification of any of the provisions of this Agreement shall be binding unless it is in writing and signed by the Parties. Any waiver of any condition on any one occasion shall not constitute a waiver on any subsequent occasion. A failure to exercise or a delay in exercising a right or remedy provided by this Agreement or by law shall not constitute a waiver of that right or remedy.

14.4 Arbitration; Governing Law; Jurisdiction. The Parties agree that any dispute concerning, relating to, or arising out of this Agreement shall be resolved by final and binding arbitration in accordance with the procedures set forth herein. Provided, however that, notwithstanding any other provision herein, either Party, in its sole and exclusive discretion, may apply to any court with jurisdiction over the Parties for a temporary restraining order, preliminary or permanent injunction, without submission of such claim for equitable relief to arbitration.

14.4.1 In the event a dispute is not resolved informally, the Parties agree that such dispute will be resolved exclusively through arbitration to be conducted in Chicago, Illinois, U.S.A., or any other place selected by mutual agreement of the Parties. The arbitration shall be conducted through the American Arbitration Association ("AAA"), unless the Parties mutually agree to use a different arbitral body or individual arbitrator. In any case, the arbitration shall be administered in accordance with the AAA's commercial arbitration rules (the "Rules"), except as the Rules are modified herein. The Parties consent to the jurisdiction and venue of the state and federal courts located in Chicago, Illinois,

U.S.A., and further consent that any process, or notice, or applications to the court, including applications for judgment upon an award, may be served outside of the State of Illinois by overnight mail or by personal service.

14.4.2 Unless otherwise mutually agreed by the Parties, the dispute will be decided by three arbitrators with at least ten (10) years experience in distributorship arrangements. Each Party shall select one of the arbitrators. The third arbitrator shall be mutually selected by the two Party-selected arbitrators, or, absent agreement, in accordance with the then-effective Rules, with such third arbitrator having in addition to the distribution arrangement experience described above, at least ten (10) years experience with medical device distributorship arrangements.

14.4.3 The Parties shall cooperate to the fullest extent practicable in the voluntary exchange of documents and information to expedite the arbitration. The Parties agree that the discovery provisions of the Federal Rules of Civil Procedure shall apply to discovery by the Parties. Any disputes concerning discovery shall be submitted to the arbitrator for resolution.

14.4.4 The arbitrator shall have the same authority to award remedies and damages as provided to a judge and/or jury under applicable law. The arbitrator shall not have the power to alter, amend, or modify any provision of this Agreement. The arbitrator shall have the power to decide only the dispute(s) submitted to the arbitrator. The substantive law of the State of New York, without regard to its conflict of laws principles, shall apply to the interpretation, application and legality of this Agreement.

14.4.5 The arbitrator shall issue a reasoned opinion and award, in writing, within thirty (30) days of closing arguments or the receipt of post-hearing briefs, whichever is later. The opinion and award must be signed and dated and decide all disputes submitted by the Parties. The opinion and award shall set forth the legal principles supporting each part of the opinion. The decision of a majority of the arbitrators shall be binding on the Parties. Judgment on the award rendered pursuant to such arbitration may be entered in any court having jurisdiction thereof, and such judgment may be entered and enforced in any state and any country. The losing party shall pay the fees associated with the costs of the arbitrators and any costs associated with the arbitration proceedings. Each Party shall bear its own legal expenses and costs. The Parties agree that any judgment shall be considered “Confidential Information” under this Agreement and subject to the provisions of this Agreement related to Confidential Information.

14.5 Controlling Language. This Agreement has been written, and all discussions leading up to this Agreement have been conducted, in the English language which the Parties thoroughly understand. Each Party represents that it has read and fully understands this Agreement.

14.6 Independent Contractor. CryoLife shall operate as an independent contractor and nothing contained in this Agreement shall be deemed or construed to recreate an employer/employee, principal/agent, joint venture, partnership, or fiduciary relationship between the Parties.

14.7 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, such provision will be severed from this Agreement without affecting the validity or enforceability of any of the remaining provisions.

14.8 Heading and Captions. Headings and captions used herein are for convenience only and are not to be deemed part of this Agreement.

14.9 Inapplicability of UCC. The Parties agree that neither the Uniform Commercial Code of Georgia nor any other State of the United States shall apply to this Agreement or the activities contemplated by this Agreement. The Parties intend that the provisions of this Agreement, including those relating to purchase of Products and termination, govern their activities exclusively under this Agreement where provisions of the Uniform Commercial Code might otherwise provide.

14.10 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be an original, and all of which together shall constitute one and the same instrument.

14.11 Assignment. Neither Party may assign its rights or obligations hereunder without the prior written consent of the other, which consent may not be unreasonably withheld.

14.12 Successors and Assigns. This Agreement shall bind and inure to the benefit of the Parties and their respective successors and permitted assigns.

14.13 Further Assurances; Force Majeure. Each Party covenants and agrees that, subsequent to the execution and delivery of this Agreement and without any additional consideration, it will execute and deliver any further legal instruments and perform any acts that are or may become reasonably necessary to effectuate the purposes of this Agreement. Neither SMI nor CryoLife will have any liability for any failure or delay in performing any obligation under this Agreement (except the obligation to make payments promptly when and as due) if the failure or delay results from force majeure, understood as a cause which is beyond the control of either Party and one which could not have been avoided even with the exercise of due care. The Party claiming force majeure will give the other Party written notice of the cause within fifteen (15) days after occurrence thereof, and will exercise reasonable diligence to remove the cause and resume performance.

14.14 Specific Performance. Each Party acknowledges that it will be impossible to measure in money the damage to the other Party if a Party fails to comply with the confidentiality obligations imposed by Section 7, and that, in the event of any such failure, the other Party will not have an adequate remedy at law or in damages. Accordingly, each Party agrees that injunctive relief or other equitable remedy, in addition to remedies at law or damages, is an appropriate remedy for any such failure and will not oppose the granting of such relief on the basis that the other Party has an adequate remedy at law. Each Party agrees that it will not seek, and agrees to waive any requirement for, the securing or posting of a bond in connection with any other Party's seeking or obtaining such equitable relief.

[Signatures on the following page(s)]

IN WITNESS WHEREOF, the Parties have caused this Distribution Agreement to be executed by their respective duly authorized officers, and have duly delivered and executed this Agreement under seal as of the Effective Date.

CRYOLIFE, INC.

By: _____
Name:
Title:

STARCH MEDICAL, INC.

By: _____
Name:
Title:

ANNEX A

Defined Terms

The following terms shall have the following meanings:

"AAA" – as defined in Section 14.4.1.

"Absorbable Modified Polymer" – as defined in the first Whereas clause.

"Adjusted Expiration Dates" – as defined in Section 3.8.3.

"Adjustment Date" – as defined in Section 3.9.2.

"Agreement" – as defined in the first paragraph.

"AMP™ technology" – as defined in the first Whereas clause.

"Affiliates" as it relates to a Party, shall mean any Person controlling, controlled by or under common control with such Party.

"Applicable Laws" means all applicable common law, statutes, ordinances, rules, regulations or orders of any Governmental Authority, including Regulatory Laws, within the Territory.

"Bona Fide Offer" – as defined in Section 1.4.

"Business Day" means any day other than a Saturday, a Sunday or a day on which banks in New York are authorized or obligated by law or executive order to remain closed.

"CMDCAS Requirements" means Canadian Medical Devices Conformity Assessment System.

"Claim" – as defined in Section 10.1.4.

"Commencement Date" – as defined in Section 3.8.3.

"Competitive Products" – as defined in Section 2.1.

"Confidential Information" – as defined in Section 7.1.

"Confidentiality Agreement"– as defined in Section 7.2.

"CryoLife" means CryoLife, Inc., a Florida corporation, as defined in the first paragraph.

"CryoLife Indemnitees" – as defined in Section 6.2.

"Development Agreement" – as defined in the eighth Whereas clause.

"Distribute" and "Distribution" – as defined in Section 1.2.

"Effective Date" means September 29, 2010.

"Existing Distributors" – as defined in Section 2.3.1.

"Expiration Date" – as defined in Section 3.8.3.

"Failure to Supply" – as defined in Section 11.2.6.

"FDA" means the United States Food and Drug Administration or any successor agency having the administrative authority to grant Regulatory Approval in the United States.

"Field Action" means any correction or removal action due to safety, efficacy, quality or regulatory compliance concerns, including actions to recover title to or possession of, or to halt distribution of, Products that previously have been shipped to customers.

"Forecast" – as defined in Section 3.11.

"Governmental Authority" means any country in which the Products are manufactured, marketed, sold, tested, investigated or otherwise regulated, and all states or other political subdivisions thereof and supranational bodies applicable thereto, including the European Union, and all agencies, commissions, officials, courts or other instrumentalities of the foregoing.

"Indemnifying Party" – as defined in Section 6.3.

"Indemnitees" – as defined in Section 6.3.

"Insolvency Event" means that the Party (a) has commenced a voluntary proceeding under any insolvency law, (b) had an involuntary proceeding commenced against it under any insolvency law which has continued undismissed or unstayed for sixty (60) consecutive days, (c) had a receiver, trustee or similar official appointed for it or for any substantial part of its property, (d) made an assignment for the benefit of creditors or (e) had an order for relief entered with respect to it by a court of competent jurisdiction under any insolvency law. For purposes hereof, the term "insolvency law" means any applicable bankruptcy, insolvency or other similar law now or hereafter in effect.

"Initial Payment" – as defined in Section 3.1.

"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 and (e) all proprietary rights relating thereto, including all applications, registrations and renewals in connection therewith.

"Kitted Product" means the PerClot™ endoscopic hemostatic system when sold in a kit that includes one endoscope of at least 100 cm length for each application of powdered absorbable hemostat.

"License Agreement" – as defined in the sixth Whereas clause.

"Losses" means and includes any and all liability, damage, loss, expense, including reasonable attorney's fees.

"MDD Requirements" means medical device directive,

"Minimum Annual Purchase Requirements" – as defined in Section 3.7.1.

"Modified Starch" – as defined in the sixth Whereas clause.

"New Application" – as defined in Section 1.3.

"New Product" – as defined in Section 1.4.

"Offer Notice" – as defined in Section 1.4.

"Open Negotiation Period" – as defined in Section 1.4.

"Other Parties" – as defined in Section 2.3.

"Party" and "Parties" – as defined in the first paragraph.

"Patents Protection Plan" means the plan for obtaining and maintaining patent protection on the SMI IP within the Territory that is set forth on Schedule 10.4.

"Permitted Clinical Applications" – as defined in the third Whereas clause.

"Person" means any individual, group or entity, including Governmental Authorities.

"Prepaid Royalty Payment" – as defined in Section 3.2.

"Product Changes" – as defined in Section 4.2.

"Product Complaint" means any expression by a Third Party of dissatisfaction relating to the identity, durability, reliability, safety, efficacy or performance of any Product, including actual or suspected product tampering, contamination, mislabeling or misformulation.

"Product Information" – as defined in Section 9.1.

"Product Specifications" means, collectively, (i) SMI's design and functionality specifications relating to the Products and (ii) any specifications for manufacturing, testing, storing, packaging, shipping or labeling the Products set forth in any approved application for Regulatory Approval and any supplements and amendments thereto. Current Product Specifications for each product category identified in the Schedules has been delivered to CryoLife under separate cover contemporaneously with the execution of this Agreement. Product Specifications may only be amended in the manner provided in this Agreement.

"Products" – as defined in the second Whereas clause.

"Products in Inventory" shall mean and include only Products with approved shelf lives of at least three (3) years and remaining shelf lives of at least two (2) years at time of computation.

"Refund Event" – as defined in Section 3.3.

"Refund Losses" – as defined in Section 3.3.

"Refund Notice" – as defined in Section 3.3.

"Regulatory Approval" means, with respect to any country or jurisdiction, the act of the applicable Regulatory Authority that is necessary under applicable Regulatory Laws for the manufacture, marketing, distribution and sale of the Product in that country or jurisdiction, and satisfaction of all applicable regulatory and notification requirements and, to the extent applicable, the grant of pricing Approval.

"Regulatory Approval Development Plan" means the dates for obtaining Regulatory Approval for Products within the Territory as detailed in Schedule 5.1.

"Regulatory Authority" means, with respect to any country or jurisdiction, any Governmental Authority involved in granting Regulatory Approval or Pricing Approval or in administering Regulatory Laws in that country or jurisdiction, including the FDA in the United States.

"Regulatory Laws" means all Applicable Laws governing (i) the import, export, testing, investigation, manufacture, marketing or sale of the Product, (ii) establishing recordkeeping or reporting obligations, (iii) any Field Action or (iv) similar regulatory matters.

"Rules" – as defined in Section 14.4.1.

"Securities Act" – as defined in Section 3.4.

"SEC Reports" – as defined in Section 3.4.

"Shares" – as defined in Section 3.1.

"SMI" means Starch Medical, Inc. a Delaware corporation, as defined in the first paragraph.

"SMI Indemnitees" – as defined in Section 6.1.

"SMI IP" – as defined in Section 10.1.1.

"Tenders" means multiple month supply contracts with hospitals, government agencies or group purchasing authorities.

"Term" – as defined in Section 11.1.

"Territory" – as defined in the third Whereas clause.

"Third Party" means any Person other than a Party or its Affiliates.

"Trademarks" means all trademarks, service marks, trade dress, logos and trade names, together with all translations, adaptations, derivations and combinations thereof (including all goodwill associated therewith), and all applications, registrations and renewals in connection therewith.

"Trademark Assignment and License Agreement" – as defined in the seventh Whereas clause.

"Trailing Average Price" – as defined in Section 3.1.

"Transfer Prices" means the prices charged to CryoLife by SMI for each of the Products, as such prices may be amended from time to time pursuant Section 3.9. Current Transfer Prices are set forth in Schedule 3.9.

"United States" means the United States of America, including its territories, commonwealths and possessions.

SCHEDULE W-1

Products

Products include all products currently identified by SMI catalog numbers: STA0001, STA0003, STA2001, STA2003, Lap3801, Lap 3803, along with rights to 5 gram products and other sizes as may be agreed to by the Parties with the same applicators and any improvements to the foregoing. Products also include the OrthoClot™ products in all configurations, with the exception of OrthoClot Endoscopic and OrthoClot Express.

SCHEDULE W-2

Permitted Clinical Applications

All permitted indications for use of the Products obtained by SMI that are for class III medical devices as of the Effective Date of this Agreement (whether such indications could be downgraded or modified in the future to be for class I or class II medical devices). Such permitted indications include use in surgical procedures or injuries as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

Contra-indications specified in the PerClot IFU are not Permitted Clinical Applications.

Notwithstanding the foregoing, Permitted Clinical Applications do not include topical hemostasis, first aid, woundcare, all non-absorbable hemostatic applications (defined as class I or class II medical device) and anti-adhesion applications.

SCHEDULE 2.1

Exclusions from Competitive Products and New Products

1. SMI's Perclot® endoscopic hemostatic system designed for applications in minimally invasive surgical procedures so long as SMI distributes and sells such product exclusively as a Kitted Product.

2. Products packaged and sold exclusively for topical uses so long as such products (i) do not use the PerClot name or any name or trade dress that is confusingly similar to the PerClot name or any trade dress associated with the Products, (ii) are distributed in packaging that clearly states the product is "NOT FOR INTERNAL USE," (iii) are packaged in single use pouches, (iv) are not usable in a sterile field within a healthcare facility, and (v) are not in quantities of or about 1, 3 grams.

3. Non-powdered format absorbable hemostats, including configurations in freeze-dried foam, sponge, glue, gel, film, and microfibrillar fibers.

4. Topical hemostasis, first aid, woundcare, all non-absorbable hemostatic applications (defined as class I or class II medical device), anti-adhesion film, anti- infection composited and wound healing promotion agents.

[***] – 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.

Schedule 2.3

Existing Distributors, Agreements with Existing Distributors, Outstanding Purchase Orders

(as of August 31, 2010)

No.	Country	Distributor Name	Distributed Product	Distribution Agreement	Signed With	Outstanding Purchase Orders	
						Products	Volumes (Units)
1	[***]	[***]	PerClot	Yes	SMI	—	—
2	[***]	[***]	PerClot	Yes	SMI	—	—
3	[***]	[***]	PerClot	Yes	SMI	—	—
4	[***]	[***]	PerClot	Yes	SMI	—	—
5	[***]	[***]	PerClot	Yes	SMI	—	—
6	[***]	[***]	PerClot	Yes	SMI	—	—
7	[***]	[***]	PerClot	Yes	SMI	—	—
8	[***]	[***]	PerClot	Yes	SMI	—	—
9	[***]	[***]	PerClot	Yes	SMI	—	—
10	[***]	[***]	PerClot	Yes	SMI	[***]	[***]
11	[***]	[***]	PerClot	Yes	SMI	—	—
12	[***]	[***]	PerClot	Yes	SMI	—	—
13	[***]	[***]	PerClot	Yes	SMI	—	—
14	[***]	[***]	PerClot	Yes	SMI	—	—
15	[***]	[***]	PerClot	Yes	SMI	[***]	[***]

No.	Country	Distributor Name	Distributed Product	Distribution Agreement	Signed With	Outstanding Purchase Orders	
						Products	Volumes (Units)
16	[***]	[***]	PerClot	No	—	—	—
17	[***]	[***]	PerClot	No	—	[***]	[***]
18	[***]	[***]	PerClot	No	—	—	—
19	[***]	[***]	PerClot	No	—	—	—
20	[***]	[***]	PerClot	Expired	—	—	—
21	[***]	[***]	PerClot	No	—	—	—
22	[***]	[***]	PerClot	No	—	—	—
1	[***]	[***]	[***]	Yes	[***]	—	—
2	[***]	[***]	[***]	Yes	[***]	—	—
3	[***]	[***]	[***]	No	—	—	—
4	[***]	[***]	[***]	No	—	—	—
5	[***]	[***]	[***]	No	—	—	—
6	[***]	[***]	[***]	No	—	—	—

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SCHEDULE 2.3.2

Distributors That Will Not Be Terminated for 90 Days

Country	Distributor	Products
France	[***]	[***]
Greece	[***]	[***]
New Zealand	[***]	[***]
UK	[***]	[***]

SCHEDULE 3.5

Restrictive Legend on Shares

The securities described herein have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or under the provisions of any state securities laws, and have been acquired by the holder thereof for purposes of investment and in reliance on statutory exemptions under the Securities Act and applicable state securities laws. The securities may not be sold, pledged, transferred or assigned except pursuant to section 3.4 of that certain Distribution Agreement dated September 28, 2010, as may be amended from time to time, an effective registration statement under the Securities Act and applicable state securities laws, or in a transaction which is exempt from registration under the provisions of the Securities Act and applicable state securities laws; and in the case of an exemption, only if the issuer has received an opinion of counsel that such transaction does not require registration of the Securities, which opinion and which counsel shall be satisfactory to the issuer in its sole discretion.

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SCHEDULE 3.6

Initial Stocking Order

The breakdown of indirect vs. direct at the bottom of this schedule.

	Initial Order	Product Exp. Date	Pricing Direct	Pricing Indirect	Extended Cost
1 gram Standard - STA0001 INT - Boxes	[***]	[***]	$[***]	$[***]	$[***]
3 gram Standard - STA0003 INT - Boxes	[***]	[***]	$[***]	$[***]	$[***]
1 gram Standard - 20cm - STA2001 INT - Boxes	[***]	[***]	$[***]	$[***]	$[***]
3 gram Standard - 20cm - STA2003 INT - Boxes	[***]	[***]	$[***]	$[***]	$[***]
1 gram Lap - 38cm - LAP3801 INT - Units	[***]	[***]	$[***]	$[***]	$[***]
3 gram Lap - 38cm - LAP3803 INT - Units	[***]	[***]	$[***]	$[***]	$[***]
1 gram OrthoClot - STA0001 INT - Units	[***]	[***]	$[***]	$[***]	$[***]
3 gram OrthoClot - STA0003 INT - Units	[***]	[***]	$[***]	$[***]	$[***]
				Order Total	$[***]

Sterile and Non-Sterile Sample Product

	Qty	Unit of Measure	Costs
Sterile Samples - STA0003-S	[***]	Boxes	$[***]
Sterile Samples - STA2003-S	[***]	Boxes	$[***]
Sterile Samples - LAP3803-S	[***]	Boxes	$[***]
Non-Sterile Samples - STA0003	[***]	Units	$[***]
Non-Sterile Samples - STA2003	[***]	Units	$[***]
Non-Sterile Samples - LAP0003	[***]	Units	$[***]

Direct vs. Indirect Calculations*	Direct	Indirect
1g Product	[***]%	[***]%
3g Product	[***]%	[***]%

[***] – 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.

SCHEDULE 3.7

Minimum Annual Purchase Requirements*

Commencement Date	Expiration Date	Amount
Effective Date	December 31, 2010	$[***]
January 1, 2011	December 31, 2011	$[***]
January 1, 2012	December 31, 2012	$[***]
January 1, 2013	December 31, 2013	$[***]
Each Calendar Year commencing on January 1, 2014	$ [***]	

* Unit credit to be given toward the Minimum Annual Purchase Requirements for Product units shipped by SMI after closing pursuant to unfulfilled purchase orders described in Section 2.3.4(ii)(B).

* The Parties agree that the minimum purchase amounts will be eliminated once CryoLife is able and obtains approval from the U.S. Food and Drug Administration to manufacture Products in the U.S. for commercial distribution, all as more particularly described in the License Agreement. The minimum purchase amount for the year in which the minimum purchase amount is eliminated will be the amount set forth in the chart above for such year multiplied by a fraction. The numerator for the fraction will be the number of full calendar months completed in the year before CryoLife notices SMI that it has met the requirement for elimination and the denominator for the fraction is twelve (12).

* Subject to adjustment as provided in Sections 1.3, 3.7, 3.8, 5.1, 5.4 or 10.2.

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SCHEDULE 3.8

Product Name	Number of Units	Expiry Date
PC: STA0001/ 1 g	[***]	[***]
PC: STA0003/ 3 g	[***]	[***]
PC: STA2001/ 1 g	[***]	[***]
PC: STA2003/ 3 g	[***]	[***]
PC: LAP3801/ 1 g	[***]	[***]
PC: LAP3803/ 3 g	[***]	[***]
OC: STA0001/ 1 g	[***]	[***]
OC: STA0003/ 3 g	[***]	[***]

[***] – 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.

SCHEDULE 3.9

Transfer Prices
FOB Shanghai or Beijing

DIRECT DISTRIBUTION*

STA 0001	US$[***] each, US$[***] box of 5 for direct distribution
STA 0003	US$[***] each; US$[***] box of 5 for direct distribution
STA 0005	US$[***] each, US$[***] box of 5 for direct distribution**
STA 2001	US$[***] each, US$[***] sold only individually for direct distribution
STA 2003	US$[***] each; US$[***] sold only individually for direct distribution
LAP 3801	US$[***] each; sold only individually for direct distribution
LAP 3803	US$[***] each; sold only individually for direct distribution

INDIRECT DISTRIBUTION***

STA 0001	US$[***] each; US$[***] box of 5 for indirect distribution
STA 0003	US$[***] each; US$[***] box of 5 for indirect distribution
STA 0005	US$[***] each, US$[***] box of 5 for indirect distribution**
STA 2001	US$[***] each; US$[***] sold only individually for indirect distribution
STA 2003	US$[***] each; US$[***] sold only individually for indirect distribution
LAP 3801	US$[***] each; sold only individually for indirect distribution
LAP 3803	US$[***] each; sold only individually for indirect distribution

* Direct distribution indicates CryoLife directly sells the PerClot Products to End Users (e.g. hospitals, clinics, etc.) and invoices directly to the End User.
** Standard version only, no Lap and no XL
*** Indirect distribution indicates CryoLife sells the PerClot Products to Distributors/agents and invoices to the distributors/Agents.

SMI agrees to file/submit to its notified body by September 30, 2010, appropriate information to allow it to produce [***] and that it shall begin producing such product by [***].

SCHEDULE 3.15

Products Samples

Non-Sterile Samples

- All samples should be of 3g volume (to allow for multiple demos per unit)
- Initial Request (in units, not boxes) - To be sent with first order
    - [***] ea STA0003
    - [***] ea STA2003
    - [***] ea LAP3803
- Quarterly Sample Provisions (starting the first calendar quarter after product launch)
    - [***] ea STA0003
    - [***] ea STA2003
    - [***] ea LAP3803
- Ordering = CryoLife to list non-sterile samples needs with each order

Sterile Samples

- For first three contract years:
    - Contract Year 1 - [***] units of STA0003 and [***] units of STA2003 and [***] units of LAP3803
    - Contract Year 2 and 3 - [***] units of STA0003 and [***] units of STA2003 and [***] units of LAP3803

[***] – 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.

SCHEDULE 5.1

List of Countries Where Approved:

Australia, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, Hungary, Iceland, Republic of Ireland, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, The Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Sweden, United Kingdom

Regulatory Approval Schedule & Forecast With Amount of Minimums Reduced

Jurisdiction	Approval or Forecast Date	Amount*
[***]	January 1, 2013	$[***]
[***]	January 1, 2012	$[***]
[***]	January 1, 2012	$[***]
[***]	January 1, 2012	$[***]
[***]	July 1, 2014	$[***]
[***]	July 1, 2011	$[***]
[***]	July 1, 2011	$[***]
[***]	January 1, 2012	$[***]
[***]	January 1, 2012	$[***]
[***]	January 1, 2012	$[***]
[***]	January 1, 2011	$[***]
[***]	January 1, 2013	$[***]
[***]	January 1, 2013	$[***]
[***]	January 1, 2012	$[***]
[***]	July 1, 2014	$[***]
[***]	January 1, 2012	$[***]
[***]	January 1, 2012	$[***]
[***]	January 1, 2012	$[***]

[***]	January 1, 2012	$[***]

* The Parties acknowledge that the amount set forth above is not an actual calculation by either party of the amount of sales available in each such country and is not based on any such calculation, but just an agreed upon amount negotiated between the parties.

SCHEDULE 8.2

Marketing Support

The following apply to all Products and will be provided by SMI without charge to CryoLife.

- Supply 5000 printed brochures in English and associated marketing materials as needed to support the sales efforts in all countries where Regulatory Approval has been obtained.
- Supply CryoLife all images, videos, and electronic files of all marketing and training materials.
- Provide CryoLife with all information related to the preclinical and clinical performance of the Products (abstracts, poster, published papers, white papers, videos).
- Provide CryoLife with a written update of all ongoing and planned preclinical/clinical studies on the Products.
- Make changes to marketing materials as necessary to meet the requests and requirements of any Regulatory Authority.
- Prior to making any changes/revisions to any marketing materials, allow CryoLife a chance to review and make recommendations.
- Provide prompt review (within 5 Business Days) of all marketing materials created by CryoLife.
- Provide currently available graphic design updates for trade show displays in sizes and formats requested by CryoLife.
- Supply all images and provide support for CryoLife use of image in all media (web, print, and other media).
- Provide CryoLife with final file of all trade show graphics and artwork. (CryoLife will pay bills for trade show and advertising space.)

SCHEDULE 9.1

Languages

Czech
Danish
Dutch
English
French
German
Greek
Hungarian
Italian
Norwegian
Polish
Portuguese
Russian
Slovak
Spanish
Swedish
Turkish

[***] – 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.

Schedule 10.1

Intellectual Property

No.	Title	Filing Date	Application No.	Internation Filing Date	Priority Date	International Application No.	Applicants	Inventor	Current Status	National Phase
1(1)		[***]	[***]	/	/	/			[***]	
1(2)	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	Submitted to [***], [***] and [***] via [***]**

** **Application No. for [***]: [***], [***]: [***] and [***]: [***]**

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Schedule 10.4

Patent Protect Plan

No.	Title	Filing Date	Application No.	Internation Filing Date	Priority Date	International Application No.	Applicants	Inventor
1	[***]	[***]	[***]**	[***]	[***]	[***]	[***]	[***]

** **Application No. for [***]: [***], [***]: [***] and [***]: [***]**

National Phase and Protect Plan:

As part of its efforts, SMI shall prepare quarterly written reports describing the current status of the patent and patent application listed herein and written notifications describing any amendments made to the claims during the prosecution of any application of patent and any receipt of notice from the [***] of its intent to grant a patent on the [***] patent listed above, no later than 30 days before the deadline for CryoLife to select and SMI to effect the national stage entry (i.e. validation) in the designated [***] states of CryoLife's choosing, which states shall include all those nations in which CryoLife [***] its [***] ([***]) and any new countries added in which a [***] can be [***] since that time. SMI will continue to pursue the patent in [***], [***] and [***].

Exhibit 10.2

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.

LICENSE AGREEMENT

This **LICENSE AGREEMENT** (this "Agreement") is entered into as of September 28, 2010, (the "Effective Date"), by and between (i) STARCH MEDICAL, INC., a Delaware corporation having a principal place of business at 2150 Ringwood Avenue, San Jose, California 95131 ("SMI"), and (ii) CRYOLIFE, INC., a Florida corporation, having a principal place of business at 1655 Roberts Blvd. NW, Kennesaw, Georgia 30144 ("CryoLife"). SMI and CryoLife are herein sometimes referred to together as the "Parties" and individually each as a "Party".

Background

WHEREAS, SMI has the exclusive right to create biocompatible, absorbable polysaccharides using the AMP™ technology;

WHEREAS, using the AMP™ technology, SMI produces Products containing no animal or human components that rapidly absorb water from blood, increasing the concentration of platelets, coagulation proteins and red blood cells at bleeding sites, and accelerating the physiologic clotting cascade;

WHEREAS, CryoLife desires to manufacture Products using Modified Starch for use in Permitted Clinical Applications in the Territory;

WHEREAS, SMI desires to license CryoLife to manufacture Products using Modified Starch upon the terms and conditions set forth herein; and

WHEREAS, SMI and CryoLife are contemporaneously entering into a Distribution Agreement (which Distribution Agreement includes consideration for this Agreement), a Trademark License, and a Development Agreement (as referred to in the License Agreement) relating to the AMP™ technology and Products.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by each of the Parties, SMI and CryoLife, agree as follows (with a glossary of defined terms in this Agreement set forth in Annex A to this Agreement):

1. License

1.1 Grant of License. SMI hereby grants to CryoLife the exclusive license to Manufacture, use and Distribute Products for Permitted Clinical Applications within the Territory (the "License"). All Products must be Manufactured using Modified Starch at a CryoLife Facility in the United States or at any CryoLife Facility outside of the United States approved by SMI in writing. The License includes the right to sublicense to affiliates, sub-distributors and sales representatives the right to use and Distribute

Products (but not to Manufacture). The Parties acknowledge that provisions of the License overlap provisions of a separate license granted to CryoLife in the Distribution Agreement (the "Distribution License"). The Parties agree that neither the License nor the Distribution License shall be deemed a violation of the other and that each of the License and the Distribution License will stand on its own and survive any termination of any other license.

1.2 Manufacturing IP.

1.2.1 Within sixty (60) days following the Effective Date, SMI shall deliver to CryoLife all documents, memoranda, schematics, diagrams and other information (whether in written, electronic or other form) disclosing and describing all methods and processes necessary or useful for Manufacturing the Products using Modified Starch (collectively, and together with any New Intellectual Property described in Section 1.3.1, the "Manufacturing IP"). Manufacturing IP also includes information respecting the suppliers for bellows, tips, applicators, packaging and any other Products features that are not manufactured by SMI but included within the Products (collectively, the "Acquired Components") and any New Intellectual Property incorporated into or used with any Product.

1.2.2 SMI represents and warrants that the Manufacturing IP will be sufficient together with the Modified Starch to readily permit and enable CryoLife, applying reasonable manufacturing experience, to Manufacture Products that meet or exceed all Products Specifications in a manner that is as efficient and cost effective, excluding costs associated with producing Modified Starch (or cost differences in land and insurance), as the processes SMI uses to Manufacture Products.

1.2.3 CryoLife shall have the right to access, copy, duplicate or abstract any and all portions of the Manufacturing IP in the possession or under the control of SMI. Such access and copying shall be in accordance with a reasonable request and schedule to be mutually agreed upon between the Parties. All costs associated with the assembling, copying and delivering of such Manufacturing IP shall be borne by the Party who is producing the documents and other items described above.

1.2.4 CryoLife shall be entitled to purchase any Acquired Components from SMI at SMI's cost.

1.3 New Product Developments. Each Party shall notify the other in writing about any improvement it applies or proposes to apply to either the process for Manufacturing Products or the formulation of Products (such improvements developed or acquired by either Party collectively, the "New Intellectual Property"). Such notification shall fully and accurately describe the New Intellectual Property.

1.3.1 SMI shall own all New Intellectual Property directly related to the formulation of the Products and all New Intellectual Property that SMI develops or acquires relating to the process for Manufacturing Products, subject to the limited license rights granted to CryoLife in Sections 1.2 and 1.3.2.

1.3.2 CryoLife may not modify, change or revise the Specifications for the Products without SMI's prior written approval (however, CryoLife may change labelling, packaging and even amount of Product in each package without SMI's approval provided the Products are made according to the Specifications). All New Intellectual Property that CryoLife develops that directly relates to the formation of the Products will be promptly disclosed to SMI and belong to SMI, subject to same license

grant to CryoLife set forth in Section 1.1 above. Any New Intellectual Property generated by CryoLife directly relating to the process for Manufacturing Products will be promptly disclosed to SMI and subject to a limited, non-exclusive, royalty-free license to SMI to use such New Intellectual Property in the Manufacture of Products or powdered hemostats for Distribution outside the Territory or within the Territory in applications that are not Permitted Clinical Applications.

1.4 New Clinical Applications. Each Party agrees to notify the other Party in writing as and when it develops or obtains Regulatory Approval in the Territory for clinical applications for the Products that are not precluded from the Permitted Clinical Applications (each a "New Application," collectively the "New Applications"). Each New Application shall be included within the Permitted Clinical Applications at the Transfer Prices applicable to the Product subtype. For each New Application obtained principally through the efforts of SMI, but not for other New Applications, the Parties agree to negotiate in good faith to adjust the Products Minimum Annual Purchase Requirements taking into consideration reasonable expectations of market increase for such New Application and any reasonable expectation of market decrease for existing Permitted Clinical Applications of Products. Each Party agrees to refrain from developing or from initiating efforts to obtain Regulatory Approval for New Applications until after January 1, 2012 without first obtaining the written consent of the other Party. For the avoidance of doubt, nothing in this Section 1.4 shall be deemed to limit or prohibit any Party's right to seek or obtain Regulatory Approval for the Permitted Clinical Applications in the Territory.

1.5 New Products. The provisions of Section 1.4 of the Distribution Agreement entitled New Products are hereby incorporated by reference into this Agreement and shall be considered a separate provision of this Agreement as if its provisions were repeated here in their entirety.

1.6 Translations. All written material provided to CryoLife in connection with this Agreement shall be translated into Chinese and English certified to CryoLife's requirements at SMI's cost. If SMI fails or in the future fails to translate or label any such material into either Chinese or English language required by any Regulatory Law applicable to the Products, (i) SMI agrees to indemnify CryoLife Indemnitees for any and all Losses arising out of or related to such failure by SMI and (ii) CryoLife may, at its option and at SMI's cost, translate or engage a Third Party to translate such material into such language(s).

2. Distribution

2.1 SMI Limitations. During the term of this Agreement, SMI agrees (i) to Distribute Modified Starch and Acquired Components to CryoLife for use in Manufacturing Products, (ii) to refrain from selling or licensing any Products to any Existing Distributor or Third Party for sale or distribution in Permitted Clinical Applications within the Territory, (iii) to refrain from directly or indirectly marketing, promoting, or encouraging any Third Party to market, promote or Distribute the Products for any of the Permitted Clinical Applications within the Territory, (iv) to refrain from licensing or transferring any AMP™ Technology to any Third Party within the Territory for the purpose of manufacturing any Products upon terms or conditions that would enable or allow such Third Party to sell any Products for Permitted Clinical Applications within the Territory. In addition, SMI agrees that it shall refrain until January 1, 2015 from (A) directly, or indirectly sell, permit to sell market, promote or encourage Third Parties to sell, permit to sell market or promote any Competitive Product (defined below) for any Permitted Clinical Application within the Territory or (B) licensing or transferring to any Third Party technology that would enable or allow any Third Party to manufacture any Competitive Product within the Territory. The provisions of the foregoing sentence shall be deemed further modified so that SMI may only take the actions described therein if SMI complies with Section 1.5 of this Agreement, which incorporates Section 1.4 of the Distribution Agreement (and therefore CryoLife does

not match the right of first refusal set forth therein). As used herein, "Competitive Product" means any powdered absorbable surgical hemostat that is intended for or could be used for a Permitted Clinical Application. The foregoing limitations do not apply to sales by SMI of those products described on Schedule 2.1.

2.2 Marketing and Sales. Subject to the terms and conditions of this Agreement, all business decisions concerning the sales and marketing of Product in the Territory, including the price, other sale and promotional terms thereof, will be within the sole discretion of CryoLife. Upon SMI's reasonable request, but no more frequently than twice per calendar year, CryoLife will discuss with SMI CryoLife's marketing plans for Product in the Territory. Once CryoLife has obtained United States Regulatory Approval for the Products, CryoLife will be responsible for all marketing support and related costs for Products it Manufactures.

2.3 Promotion Limitations. CryoLife will restrict its promotion and marketing of Products to activities reasonably calculated to sell the Products for Permitted Clinical Applications within the Territory and will not sell or distribute Products outside the Territory, directly or indirectly, or sell or distribute Products knowingly to persons for the purpose of sale or distribution outside the Territory. CryoLife agrees that all sales inquiries or leads for sales of Products outside the Territory that it or its Affiliates receive shall be immediately directed to SMI for follow-up. SMI agrees that all sales inquiries or leads for sales of Products inside the Territory that it or its Affiliates receive shall be immediately directed to CryoLife for follow-up.

3. Modified Starch Purchases and Production

3.1 Royalties. CryoLife shall pay SMI royalties equal to [***] percent ([***]%) of Aggregate Net Sales of any Product Manufactured by CryoLife up to and equal to Fifty Million U.S. dollars ($50,000,000.00); [***] percent ([***]%) of Aggregate Net Sales of any Product Manufactured by CryoLife in excess of Fifty Million U.S. dollars ($50,000,000.00) and less than One Hundred Million U.S. dollars ($100,000,000.00); and [***] percent ([***]%) of Aggregate Net Sales of any Product Manufactured by CryoLife in excess of One Hundred Million U.S. dollars ($100,000,000.00). Payment shall occur within sixty (60) days after the end of each calendar quarter commencing with Commercial Distribution of Products manufactured by CryoLife anywhere in the Territory. The first One Million Five Hundred Thousand U.S. dollars ($1,500,000.00) in royalty payments otherwise due under this Section 3.1 are fully prepaid by application of the Prepaid Royalty Payment.

3.2 Milestone Payments. In addition to the royalties, CryoLife shall pay SMI the following milestone payments within ninety (90) days after the occurrence of the following events:

Milestone	U.S. Dollar Payment Obligation	
CryoLife submission of application for United States IDE designation for the Products with the FDA	$	500,000.00*
CryoLife receipt of IDE designation for the Products from the FDA	$	500,000.00
CryoLife receipt of United States Regulatory Approval	$	500,000.00
CryoLife first Commercial sale of Products in the United States after receipt of United States Regulatory Approval	$	1,000,000.00
Issuance to SMI of a United States patent from patent application number [***] that prevents Third Parties from Manufacturing and Distributing Products within the United States	$	500,000.00

* The amount for this milestone shall be reduced by the Pre-Clinical Trial Cost, but in no event shall this milestone be reduced below $250,000.

3.3 Transfer Price. CryoLife shall pay SMI the Transfer Price of [***] Dollars and [***] Cents U.S. ($[***]) per gram for the Modified Starch ordered, delivered to, and not rejected by CryoLife.

3.4 Transfer Price Adjustments. From and after January 1, 2016, the Transfer Price may, at the written request of either Party, increase or decrease by an amount negotiated in good faith by the Parties if the currency rate between the Chinese RMB and the U.S. dollar has increased or decreased by more than 10% since the last Adjustment Date. As used herein, the first "Adjustment Date" shall be the Effective Date and all subsequent Adjustment Dates shall be the last date upon which the Transfer Prices were actually changed by the Parties. After the first adjustment, adjustments to Transfer Prices shall be made no more frequently than once every twelve (12) months and, to be effective, shall be memorialized in writing. Among the factors the Parties agree to consider in any negotiations to adjust Transfer Prices will be the practical ability of CryoLife to increase the average selling price of the Products without adversely affecting the demand for such Products.

3.5 Purchase Orders. CryoLife shall issue to SMI purchase orders, which shall specify: (i) the amount of Modified Starch being ordered which such amount shall not be less than the Minimum Requirement (as defined below); (ii) the applicable Transfer Price; (iii) requested delivery schedule; and (iv) exact "ship to" and "invoice to" place of business. SMI must accept a purchase order as long as it is consistent with the Minimum Requirement, regardless of quantity, if (i) the purchase order does not establish new or conflicting terms from those set forth in this Agreement and (ii) the Transfer Price and other provisions of the purchase order are in accordance with this Agreement. CryoLife shall place purchase orders so that they have been received by SMI no less than six (6) months prior to the requested ship date. If SMI rejects a purchase order, SMI must notify CryoLife within three (3) Business Days of receipt of such purchase order. If a purchase order is rejected, CryoLife will be advised of the reason for rejection and be provided with an opportunity to bring the purchase order into compliance. The terms contained in this Agreement shall govern the sale of Modified Starch and the Products to CryoLife and shall supersede any inconsistent terms in CryoLife's purchase orders, unless SMI expressly agrees to such terms in writing. Orders placed by telephone, or in person are to be confirmed by facsimile or email

to SMI by CryoLife within a commercially reasonable time thereafter. For purposes of this Agreement the term "Minimum Requirement" shall be [***] ([***]) kilograms of Modified Starch or less with SMI's consent (or [***] ([***]) kilograms provided that at least an additional [***] ([***]) kilograms are ordered within a calendar year from the initial [***] ([***]) kilogram order); provided, however, that the Parties agree to negotiate in good faith a reasonable adjustment in the Minimum Requirement after CryoLife has had sufficient time to evaluate the manufacturing process following the successful transfer of the Manufacturing IP pursuant to Section 1.2 based on CryoLife's projections for Products sales, the necessary and required manufacturing runs required to produce Products, and other relevant factors. The foregoing procedures, other than the Minimum Amount, shall apply to purchases of Acquired Components from SMI by CryoLife with a minimum lead time for orders of three (3) months instead of six (6) months.

3.6 Forecasts and Inventory. Forecasting, inventory requirements, and supply interruption procedures relating to Acquired Components are set forth on Schedule 3.6.

3.7 Shipment. CryoLife may provide SMI with a designated shipper and requested ship date. SMI will coordinate the collection of goods with the designated shipper from SMI's warehouse. If CryoLife does not designate a shipper, SMI will designate a shipper of its own choosing. Title to the Modified Starch and all risk of loss shall pass from SMI to CryoLife at the time and place of SMI's delivery of the Modified Starch to CryoLife, Ex work or F.O.B. Shipping Point. CryoLife shall be responsible for costs of shipping. CryoLife shall be solely responsible for insuring Modified Starch against damage in shipping after delivery to CryoLife F.O.B. Shipping Point. SMI shall ship the Modified Starch to CryoLife on the shipping date designated in CryoLife's purchase order provided the purchase order is received at least six (6) months before the requested shipping date. SMI shall not ship Modified Starch or Acquired Components prior to CryoLife's requested ship date, without CryoLife's prior written consent.

3.8 Returns. SMI shall accept returns of any Modified Starch that does not meet the Modified Starch Specifications, or is otherwise clearly rendered unsaleable, provided CryoLife notifies SMI in writing of any alleged failure to meet the Modified Starch Specifications not later than thirty (30) Business Days from the date of arrival of such Modified Starch at the point of delivery or twenty (20) Business Days after discovery of any of the Modified Starch's failure to continue to meet any Modified Starch Specification, such as shelf life, that may not be readily determined upon Modified Starch receipt. Any defects of Modified Starch resulting from CryoLife's mishandling of such Modified Starch after collection of the Modified Starch from point of shipment to CryoLife is expressly excluded. At SMI's request, CryoLife will return the allegedly defective Modified Starch to SMI or provide such other evidence of the deficiency of the Modified Starch to SMI. Credit for any such defective Product for which timely notice is provided as set forth above shall be issued if SMI's examination confirms that the Modified Starch is defective and that such defect is not the result of any mishandling of the Modified Starch by CryoLife after collection from the point of shipment. Credit shall include Transfer Price and shipping charges. CryoLife agrees to advise SMI of any information in its possession regarding mishandling, damage, deterioration, alteration, or modification of any Modified Starch or its packaging. CryoLife will follow SMI's reasonable instructions to return Modified Starch or to otherwise dispose of

it, and will not take any action in relation to any such Modified Starch until it receives such instructions from SMI.

3.9 Payment. SMI shall invoice CryoLife for Modified Starch delivered to CryoLife in accordance with this Agreement and relevant purchase orders. CryoLife shall pay for Modified Starch within thirty (30) days after the date of SMI's invoice (provided that the invoice date is no earlier than the date that shipment is received and if it is earlier, within thirty (30) days after the date of the shipment). All payments by CryoLife under this Agreement shall be made in United States dollars free of any exchange or collection charges and of any taxes imposed under the laws of any country. If CryoLife fails to pay to SMI any amount when due, SMI shall notify CryoLife of such failure in writing and if CryoLife fails to dispute, contest or pay any portion of such past due amount within five (5) Business Days of receipt of such notice, CryoLife agrees to pay interest on the undisputed and unpaid overdue amounts at the rate of ten percent (10%) per annum or, if lower, the maximum rate permitted by applicable law. Payments shall only be required after full shipments of Modified Starch ordered in a single purchase order unless a partial shipment has been approved in advance by CryoLife.

4. Specifications and Changes

4.1 Modified Starch Specifications. SMI warrants to CryoLife that all Modified Starch delivered to CryoLife will (i) conform to the Modified Starch Specifications, (ii) be contained in sealed packaging (iii) have been manufactured, tested, stored, packaged, labelled and shipped in compliance with Applicable Laws and in accordance with applicable Regulatory Authorities, including all Regulatory Approvals, (iv) be free of defects in design, material, engineering, fabrication and workmanship in accordance with the Modified Starch Specifications, (v) have been manufactured no longer than [***] ([***]) months prior to the date received by CryoLife, (vi) have at least [***] ([***]) months remaining when received at the CryoLife Facility, provided CryoLife's shipper takes no longer than six (6) months from receipt of Modified Starch to complete delivery and (vii) be free and clear of any liens, security interests or encumbrances of any nature whatsoever.

4.2 Specification Changes. SMI shall not make any change to the Modified Starch (including materials, packaging, and directions for use), Modified Starch Specifications, the raw materials, suppliers of starch, manufacturing process for the Modified Starch or the Products Specifications (collectively, "Specification Changes"), unless approved by CryoLife in writing in advance, which approval may not be unreasonably denied (with the Parties understanding that any such changes that would require new, or change to any Regulatory Approval may be denied by CryoLife due to the cost or time involved in that change).

4.2.1 Without limiting the foregoing, all Specification Changes (including changes required by law) shall be submitted to CryoLife in writing no later than one hundred eighty (180) days prior to SMI's proposed date of implementation for such change. Unless CryoLife notifies SMI in writing that it disapproves of such change during the thirty (30) calendar day period following the notification of such change or if such a proposed change is otherwise required by law, regulation, or directive, SMI shall be authorized to implement such change and shall be responsible for properly communicating and implementing such change, including with respect to any of SMI's vendors.

4.2.2 Without limiting the foregoing, the following changes shall be deemed governed by this Section: (i) use of any nonconforming material in the Manufacturing of the Modified Starch in variance with the Modified Starch Specifications or the Products Specifications; (ii) implementation of any deviation that could affect the handling, sterility, safety, or efficacy of any of the Modified Starch or the Products or be at variance with the Modified Starch Specifications or the Products Specifications; or (iii) implementation of any corrective action that could affect the safety or efficacy of the Modified Starch or the Products. Notwithstanding the foregoing, SMI shall not make any Specification Changes that disqualify Products for sale under any Regulatory Approval respecting the Products within any portion of the Territory.

4.2.3 SMI shall be responsible for all costs and expenses associated with developing and implementing any Specification Changes including, without limitation, any and all cost associated with obtaining regulatory approval to incorporate Specification Changes into Products or to Manufacture or Distribute Products that incorporate Specification Changes throughout the Territory.

4.3 Manufacturing Sources. SMI represents that, as of the Effective Date, it has a fully certified and functioning ISO 9000 manufacturing source for the Modified Starch. In addition, SMI represents that, as of the Effective Date, its sources of raw materials used in the Modified Starch are ISO certified sources that would allow SMI to manufacture the Modified Starch as required by CryoLife.

4.3.1 SMI agrees to maintain such manufacturing source or procure other sources, facilities and/or equipment in order to replace such manufacturing source that are reasonably acceptable to CryoLife and meet ISO 13485 requirements in the event that SMI's then-active manufacturing facility becomes unable or unwilling to supply Modified Starch in a timely manner.

4.3.2 SMI shall have an approved second source for Modified Starch within thirty-six (36) months from the Effective Date of this License Agreement. Further, SMI will grant CryoLife an option, for a period of thirty-six (36) months from the Effective Date of this License Agreement, to acquire the full Modified Starch production technology for a negotiated sum not to exceed One Million U.S. dollars ($1,000,000.00).

4.4 CryoLife Inspection Rights. CryoLife shall have the right to have its representatives present at the plant or plants at which the Modified Starch or Acquired Components are manufactured during normal business hours to conduct an initial and periodic inspections of such facilities and manufacturing procedures for compliance with ISO 13485 (including appropriate certification), MDD, appropriate FDA GMP compliance, and CMDCAS requirements, applicable Regulatory Laws, the Modified Starch Specifications and CryoLife's quality assurance requirements and to inspect SMI's inventory of Modified Starch and Acquired Components, work-in-process, raw materials to be used for Modified Starch, production records, design history file, quality manuals, regulatory dossiers, and such other matters as may be pertinent to proper quality assurance of the Modified Starch to be delivered hereunder. The Parties agree that as to inspections at any facility of any Third Party permitted by the sentence above, shall be subject to consent of the Third Party (which shall be obtained by SMI if requested by CryoLife) to CryoLife's inspection of such facility, which shall not be unreasonably withheld, conditioned or delayed. SMI may, at its sole cost and expense, attend such inspection. SMI shall promptly use its best efforts to take such action as is required to correct any deficiencies identified by CryoLife relating to the production of the Modified Starch. SMI further agrees to use its best efforts to provide such documentation or conduct such analyses as CryoLife may reasonably request in connection with any regulatory submission or audit. Unless required by law, or if necessary to apply for Regulatory Approval in the United States or Canada, or after an event identified in Sections 5.6.3 or 5.6.5, CryoLife will limit its inspections for each plant to no more often than once in any twelve (12)

month period unless an inspection (i) is required by law or any Regulatory Authority, (ii) is necessary or advisable to support an application for Regulatory Approval in the United States or Canada, (iii) is deemed advisable by CryoLife following an event described in Section 5.6.3 or 5.6.5, or (iv) is consented to by SMI, which consent shall not be unreasonably withheld. Any inspection conducted pursuant to items (i) through (iv) in the immediately preceding sentence shall not count toward the one inspection per twelve (12) months accorded to CryoLife by such sentence. Any such inspections will be subject to the confidentiality agreements set forth in Section 7.1.

5. Approvals and Compliance

5.1 Regulatory Approvals. SMI represents and warrants each of the matters represented or warranted in the first two sentences of the Distribution Agreement and hereby incorporates such representations and warranties into this Agreement. SMI hereby grants to CryoLife the fully paid-up right to use any and all Regulatory Approvals related to the Products within the Territory that are owned by or licensed to SMI as of the date hereof and throughout the Term. As and when requested by CryoLife, after CryoLife has commenced Commercial production of Products, SMI shall cooperate, at CryoLife's expense (to the extent such expense is to reimburse any out-of-pocket expenses to SMI only) to facilitate CryoLife in obtaining transfers or modifications of existing Regulatory Approvals throughout the Territory to CryoLife's name (or if not in CryoLife's name at least to allow CryoLife to manufacture on SMI's behalf) including, but not limited to obtaining a CE Mark, to allow CryoLife to Manufacture Products and Distribute Products throughout the Territory. The Parties acknowledge that due to the timing of obtaining transfers into CryoLife's name that they may need to modify existing Regulatory Approvals to allow CryoLife to Manufacture the Product, without changing the Regulatory Approval into CryoLife's name, and at some point in the future change the Regulatory Approval into CryoLife's name. Such transfer or modification may require that the notified body that currently holds SMI's CE Marking be changed.

5.2 United States Regulatory Approval. CryoLife shall have the exclusive right and license to apply for, pursue and maintain United States Regulatory Approval for Products and SMI and CryoLife shall have the mutually exclusive right and license to pursue obtaining Regulatory Approval for Products outside of the United States and Canada within the Territory. CryoLife will use reasonable efforts to design, fund, and conduct a program intended to gain required United States Regulatory Approval (the "Regulatory Approval Program"). United States Regulatory Approval, once obtained, shall be in the name of and owned by CryoLife.

5.2.1 CryoLife will bear all costs of the Regulatory Approval Program, including the cost of regulatory submissions, clinical trials (other than trials conducted by SMI or trial support or activities in support thereof provided by SMI pursuant to other provisions of this Agreement), and activities to support approval by the applicable Regulatory Authority in the United States except that CryoLife shall not be required to reimburse SMI for any costs or expenses incurred by it or its affiliates, contractors, or agents in connection with the reasonable assistance and cooperation that are provided under Section 5.3.

5.2.2 CryoLife will be responsible for the preparation of regulatory documents and submissions to the FDA in connection with the Regulatory Approval Program. CryoLife shall have exclusive responsibility for all communications, submissions and interactions with FDA and other Regulatory Authorities for the purpose of obtaining and maintaining United States Regulatory Approval.

5.2.3 Until United States Regulatory Approval has been obtained and at SMI's written request, CryoLife will (i) provide SMI with a written report summarizing the progress of the Regulatory

Approval Program no more frequently than once each calendar quarter and (ii) meet with representatives of SMI in person or by phone no more frequently than once per calendar quarter to discuss the status of the Regulatory Approval Program. CryoLife shall review with SMI clinical trial protocols and the selection of clinical sites of any clinical trial to be conducted with respect to SMI Product. CryoLife will own all data generated by it in the Regulatory Approval Program.

5.2.4 Once CryoLife receives final approval from the United States Regulatory Authority to [***], it shall commence an orderly process to withdraw its [***] from distribution in the United States by the earlier of [***] or when CryoLife can complete an orderly withdrawal from the market. An orderly withdrawal process will permit CryoLife to sell its [***] inventory of [***] and honor existing requirements under contracts CryoLife has with various third parties.

5.3 United States Regulatory Approval Assistance. SMI shall provide reasonable assistance to CryoLife in its efforts to obtain United States Regulatory Approval. SMI's assistance in this effort will include providing information about SMI and Products as needed for such application, such as clinical trial information relating to the Products and include, without limitation, the assistance detailed below.

5.3.1 SMI will provide CryoLife with non-financial assistance and cooperation in support of the Regulatory Approval Program, as reasonably requested by CryoLife. Such assistance will include reasonable and timely access to SMI's employees, consultants, and agents for consultation on technical and regulatory matters, including acting as the sponsor of any potential premarket application supplements or other regulatory filings, and providing access to relevant historical research, development, clinical, and regulatory files necessary for implementation of the Regulatory Approval Program and the submission of premarket applications.

5.3.2 SMI shall permit CryoLife to use any relevant data owned or controlled by SMI, including (i) any information or studies conducted by SMI or on its behalf, to support each premarket or regulatory application being made by CryoLife for Products in the Territory and (ii) any information relating to specifications, methods, ingredients, materials, procedures or production methods associated with the Modified Starch or Acquired Components that is required or useful to support any regulatory application being made by CryoLife for Products in the Territory. To the extent any of the foregoing information is not owned or controlled by SMI (such as information related to Acquired Components), SMI shall obtain such information for CryoLife.

5.3.3 SMI shall also permit CryoLife to reference all data it provides in submissions to each Regulatory Authority and permit the Regulatory Authority to use such data in its reviews. SMI shall update the data submissions it makes under Section 5.3.2 and provide CryoLife with all new data promptly after the same is developed, assembled, or comes to the attention of SMI. CryoLife will provide the same rights and privileges to SMI with respect to data owned or generated by or on behalf of CryoLife in connection with SMI Product.

5.3.4 SMI shall provide to CryoLife copies of its existing scientific, medical, clinical, regulatory, technical, marketing, and other data related to the Product to support CryoLife's clinical, regulatory, or marketing activities.

5.3.5 SMI shall, upon request of CryoLife, at the applicable Transfer Price determined pursuant to the Distribution Agreement, supply CryoLife such quantities of Products as CryoLife requests to support CryoLife's Regulatory Approval Program.

5.4 Canadian Regulatory Assistance. SMI will provide assistance to CryoLife in support of its efforts to obtain Regulatory Approval in Canada in the same manner and to the same extent as it provides assistance with respect to United States Regulatory Approval pursuant to Sections 5.2 and 5.3.

5.5 Manufacturing Requirements.

5.5.1 SMI has and will manufacture the Modified Starch in accordance with the (i) Modified Starch Product Specifications, (ii) applicable Regulatory Laws including United States Regulatory Laws, and ISO 13485 requirements (including appropriate certification), MDD requirements, CMDCAS requirements, and (iii) other pertinent rules and regulations of Regulatory Authorities that have granted Regulatory Approval for the Modified Starch. In addition, during the Term, SMI will maintain, or cause to be maintained, the Modified Starch manufacturing facility's (ies') registrations as a certified medical device manufacturing facility with all applicable Regulatory Authorities and cause such facility to be maintained such that the facility would pass an audit for compliance with ISO 13485 (including appropriate certification), MDD, QSR and CMDCAS requirements. SMI shall maintain ongoing quality assurance and testing policies sufficient to satisfy its obligations under this Agreement, CryoLife's standard requirements for approval as a vendor as described in CryoLife's quality system review policy, and SMI's standard quality assurance policies, copies of which have been provided to the other Party contemporaneously with the execution of this Agreement.

5.5.2 Once it obtains United States Regulatory Approval, CryoLife will Manufacture Products in accordance with the (i) Products Specifications, (ii) applicable Regulatory Laws, and ISO 13485 requirements (including appropriate certification), MDD requirements, QSR requirements, CMDCAS requirements, and (iii) other pertinent rules and regulations of Regulatory Authorities that have granted Regulatory Approval for the Products manufactured by CryoLife. Once it commences Commercial Manufacturing of the Products for a country in the Territory for which it can Manufacture pursuant to appropriate Regulatory Approval, CryoLife will maintain, or cause to be maintained, the Products manufacturing facility's (ies') registration as a certified medical device manufacturing facility with all applicable Regulatory Authorities and cause such facility to be maintained such that the facility would pass an audit for compliance with ISO 13485 (including appropriate certification), MDD, FDA GMP compliance, CMDCAS requirements, as applicable for such country. CryoLife shall maintain ongoing quality assurance and testing policies sufficient to satisfy its obligations under this Agreement.

5.5.3 Upon the request of either Party, the other Party shall provide the requesting Party with written evidence of compliance with the criteria set forth in this Section 5.5.

5.6 Regulatory and Products Communications. CryoLife shall be responsible to Regulatory Authorities in the countries throughout the Territory as the manufacturer of any Products it Manufactures that are sold in such country, unless SMI is still listed as the named holder of the Regulatory Approval for such country. SMI's contractual responsibilities relating to communications with Regulatory Authorities for Products Manufactured by or at the direction of SMI (including CryoLife if CryoLife is not the holder of the Regulatory Approval) are as set forth in Section 5.4 of the Distribution Agreement and are incorporated herein by this reference and made a part of this Agreement. As used below, "Party's Product" means the Modified Starch when referring to SMI and Products Manufactured by CryoLife when referring to CryoLife.

5.6.1 Each Party shall promptly notify the other and provide to the other a copy or transcription, if available, of any communication from any Regulatory Authority relating to Party's Product, the marketing thereof, or any related matter (including copies of all product approvals) and shall keep the other Party reasonably apprised of regulatory interactions and similar activities with governmental authorities and international bodies in connection with the Party's Product anywhere in the Territory.

5.6.2 Each Party shall notify the other immediately by fax or email, with confirming notice via overnight delivery, as soon as it becomes aware of any issue with the Party's Product or their testing, manufacture, labelling, or packaging, including any issue relating to compliance with Regulatory Laws, safety or efficacy of the Party's Product or breach by the Party of the terms of this Agreement. Without limiting the generality of the foregoing, each Party will notify the other immediately if it becomes aware of any death or bodily injury caused by the Party's Product.

5.6.3 If either Party receives notice of an actual or threatened inspection, investigation, inquiry, recall, import or export ban, product seizure, enforcement proceeding or similar action by a Regulatory Authority with respect to the Party's Product or a Party's activities in connection with the Party's Product, it will notify the other Party within forty-eight (48) hours after its receipt of notice of the action and will promptly deliver to the other Party copies of all relevant documents received from the Regulatory Authority. Any notice respecting a recall or action that in any way restricts the ability of either Party to Manufacture or Distribute a Party's Product shall be delivered to the other Party promptly upon receipt.

5.6.4 The Parties shall cooperate in response to the action, including providing information and documentation as requested by the Regulatory Authority. If the action primarily concerns CryoLife's activities or if the action involves the Regulatory Authority in the United States or Canada in relation to the Products (or any other Regulatory Authority where CryoLife has accepted primary responsibility and been named by the Regulatory Authority as the holder of the Regulatory Approval), then CryoLife shall have primary responsibility to respond to the Regulatory Authority; otherwise, SMI shall have primary responsibility to respond as set forth in the Distribution Agreement. In either case, upon request of the responding Party, the other Party shall provide consulting advice and assistance with the response. In addition, each Party shall promptly notify the other and provide to the other a copy or transcription, if available, of any communication from any Regulatory Authority relating to Party's Product, the marketing thereof, or any related matter and shall keep the other Party reasonably apprised of regulatory interactions and similar activities with Regulatory Authorities in connection with Party's Product.

5.6.5 If either Party in good faith determines that a removal, correction, recall or other Field Action involving the Product or its labelling is warranted (whether or not required by a Regulatory Authority), such Party shall immediately notify the other Party and shall advise such other Party of the reasons underlying its determination that a removal, correction, recall or other Field Action is warranted. The Parties shall consult with each other as to any action to be taken in regard to such removal, correction, recall or other Field Action. If, after consultations, either Party in good faith believes that such a removal, correction, recall or Field Action should be undertaken with respect to the Product or labelling, the Parties shall cooperate in carrying out the same. SMI shall be responsible for all of CryoLife's reasonable out-of-pocket costs and expenses, including the cost of the Products and the replacement cost of the Products, quality control testing and notification in the event of removals, correction, recall or other Field Action resulting, in whole or in part, in CryoLife's reasonable judgment, from (i) the Modified Starch component of the Products, (ii) Products not Manufactured by CryoLife,

(iii) features of the Products Specifications or the Modified Starch Specifications, or (iv) the negligence or breach by SMI.

5.6.6 In the event of a Field Action related to a deficiency of quality of the Modified Starch or any Acquired Components as provided by SMI, SMI shall promptly correct the deficiencies or cause the vendor thereof to do likewise and CryoLife shall correct noted deficiencies related to matters for which it is responsible.

5.7 Compliance with Laws. Each Party will comply with all Applicable Laws in the Territory that pertain to the testing, manufacture, labelling, marketing, distribution, sale, or packaging of the Party's Product and in any other manner pertaining to the performance of its obligations under this Agreement, including the maintenance of ongoing quality assurance and testing procedures to comply with applicable regulatory requirements. Each Party will also comply with Applicable Laws in the Territory pertaining to the Manufacturing, import, export, distribution, sales, and marketing of the Party's Product. Without limiting the generality of the foregoing, each Party will, as required by law, (i) report to every applicable Regulatory Authority within any relevant time periods all events that are required to be reported (including any death or serious bodily injury caused by the Party's Product); and (ii) deliver, within the permitted time periods, all annual or other periodic reports required to be delivered by such Party to every applicable Regulatory Authority. Inasmuch as the Modified Starch is incorporated into the Products, if there is a disagreement between the Parties as to what is required to comply with this Section 5.7 as it relates to Modified Starch that is used by CryoLife in the Manufacture of Products, CryoLife shall be the final arbiter of what is required to meet the requirements for compliance.

5.8 Regulatory Audits and QA Assessments. Each Party will permit authorized representatives of any applicable Regulatory Authority to inspect their plant and production facilities (and will secure the same rights with respect to any Third Party plant and production facilities) relating to or used in connection with the manufacture of the Party's Product or component materials used in the Party's Product and will promptly notify the other Party when such Party receives notice of any such inspection. Upon request of a Party, the other Party will perform a quality system assessment of the vendors who provide it with raw components and/or materials, sub-assemblies or contract services for any of the requesting Party's Products and will advise the requesting Party of the findings of any regulatory inspection or quality system assessment. Each Party will promptly take the necessary steps to correct any deficiencies found by the Regulatory Authority or the quality system assessment relating to the production of Products or component materials. Each Party further agrees to use its reasonable best efforts to provide the other Party such documentation or conduct such analyses as each Party may reasonably request in connection with any regulatory submission or audit or quality system assessment concerning Products.

5.9 Traceability. Each Party shall maintain manufacturing and traceability records with respect to the Party's Product, including records by lot number. For seven years or such longer period as may be required by applicable Regulatory Laws, each Party shall (i) maintain traceability for each batch of the Party's Product including the manufacturing date and each component and material comprising the Party's Product and (ii) provide the other Party a copy of such records upon the other Party's written request.

5.10 Post-Market Clinical Studies. Each Party shall inform the other Party in the event that such Party becomes aware of post-market clinical studies being conducted with the Product or the Modified Starch. Each Party shall inform the other Party in the event that they become aware of published literature or unpublished reports of data from any clinical or non-clinical laboratory studies involving the Product.

6. Indemnification and Liability

6.1 Indemnification by CryoLife. CryoLife assumes responsibility and shall indemnify SMI, its subsidiaries, parent corporations, affiliates, officers, directors, independent contractors, partners, shareholders, employees, agents, and their respective successors and assigns (collectively, the "SMI Indemnitees") and hold the SMI Indemnitees harmless from and against any and all Losses resulting from any Third Party claims made or legal proceedings instituted against any of the SMI Indemnitees which arise out of or result from (i) the storage or handling by CryoLife of the Modified Starch, unless such Losses result from or arises out of the negligence or intentional acts or omissions of any SMI Indemnitee or any manufacturing, design or defects in the Modified Starch, (ii) any injury, illness, or death resulting from CryoLife's failure to Manufacture Products that meet Products Specifications, (iii) any Products description or claim made by or on behalf of CryoLife which is inconsistent with the Products description or claims made by SMI and upon which any Third Party has relied, or (iv) any claim by a Third Party that SMI has tortiously interfered with any contract that CryoLife may have with such Third Party; except to the extent such liability, loss, damage or expense in (i), (ii) or (iii) above does not result from or arise out of the negligence or intentional acts or omissions of a SMI Indemnitee or by reason of the failure of the Modified Starch to meet Modified Starch Specifications. SMI shall promptly notify CryoLife in writing of any such claim or proceeding and shall permit CryoLife to control the defense of such claim or proceeding; provided, however, that SMI may in its discretion participate at its own expense in such defense; and provided further, that CryoLife shall not settle any such claim or proceeding that may adversely impact any SMI Indemnitee without SMI's prior written consent.

6.2 Indemnification by SMI. SMI assumes responsibility and shall indemnify CryoLife its subsidiaries, parent corporations, affiliates, officers, directors, independent contractors, partners, shareholders, employees, agents, and their respective successors and assigns (collectively, the "CryoLife Indemnitees") and hold the CryoLife Indemnitees harmless from and against any and all Losses resulting from any Third Party claims made or legal proceedings instituted against any of the CryoLife Indemnitees which arise out of or result from (i) any injury, illness, or death involving Products Manufactured by CryoLife that meet or exceed the Products Specifications or from Products Manufactured by SMI; (ii) any injury, illness, or death resulting from the use of Modified Starch in any Products, any defect in the Modified Starch or failure of the Modified Starch to meet Modified Starch Specifications, or any description of the Modified Starch or claim made by or on behalf of SMI relating to the Modified Starch and upon which CryoLife or any Third Party has relied; (iii) the manufacture, processing, design, testing, packaging, labelling, storage, handling, or distribution by or for SMI (other than by CryoLife) of the Modified Starch, including but not limited to claims for personal injury, including death, or property damage; or (iv) any allegation or claim of infringement by the Products or the Modified Starch, their manufacture, processing, distribution or sale, of the patent or other intellectual property rights of a Third Party, except to the extent such liability, loss, damage or expense results from or arises out of the negligence or intentional acts or omissions of a CryoLife Indemnitee. CryoLife shall promptly notify SMI in writing of any such claim or proceeding and shall permit SMI to control the defense of such claim or proceeding; provided, however, that CryoLife may in its discretion participate at its own expense in such defense; and provided further, that SMI shall not settle any such claim or proceeding that may adversely impact a CryoLife Indemnitee without CryoLife's prior written consent. If the Modified Starch or any Product is held to constitute an infringement or misappropriation of any Third Party's intellectual property right or if CryoLife and SMI concur that the Modified Starch or any Product constitutes an infringement or misappropriation, SMI will at its expense either: (i) procure the right for CryoLife to continue Manufacturing and Distributing the Products using Modified Starch in accordance with this Agreement at no additional cost to CryoLife, or (ii) if such infringement or misappropriation is related to the Modified Starch, (a) replace the Modified Starch with a non-infringing and non-misappropriating equivalent product conforming to the Modified Starch Specifications at no additional

cost to CryoLife or (b) modify the Modified Starch to make it non-infringing and non-misappropriating while conforming to the Modified Starch Specifications at no additional cost to CryoLife.

6.3 Other Claims. Each of SMI and CryoLife (each, in such capacity, an "Indemnifying Party") will defend, indemnify, and hold harmless the other Party, its subsidiaries, parent corporations, affiliates, officers, directors, independent contractors, partners, shareholders, employees, agents, and their respective successors and assigns (collectively, in such capacity, the "Indemnitees") from and against any Losses, including Losses imposed upon or caused to be incurred by the Indemnitee(s) by any Third Party, arising from or related to any (i) breach of such Indemnifying Party's representations and warranties, covenants, or obligations under this Agreement or (ii) an assertion that this Agreement or Indemnified Party's actions pursuant to this Agreement tortuously interfere with any contracts to which the Indemnifying Party is a party.

6.4 Contribution. To the extent that CryoLife and SMI have indemnification obligations to one another in connection with a single Claim, CryoLife and SMI shall contribute to the aggregate damages arising from such Claim in such proportion as is appropriate to reflect their relative responsibilities for such damages, as well as any other relevant equitable considerations. The amount paid or payable by CryoLife or SMI for purposes of apportioning the aggregate damages shall be deemed to include all reasonable legal fees and expenses incurred by such Party in connection with investigating, preparing for or defending against such Claim. Such finding of contribution shall be as agreed to in writing by the Parties, or as determined by a judicial determination, in final, non-appealable form.

6.5 Procedure. A Party seeking indemnification pursuant to the terms of this Agreement shall promptly notify the other Party in writing of a claim or suit; provided, that a Party's failure to give such notice or delay in giving such notice shall not affect such Party's right to indemnification under this Section 6 except to the extent that the other Party has been prejudiced by such failure or delay. Neither Party has any obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld. The Indemnitee has the right to participate (i) at its own expense in the claim or suit with counsel of its own choosing and (ii) in selecting counsel to be used by the Indemnifying Party in such claim or suit. The Indemnifying Party will consult with the Indemnitee in good faith with respect to all non-privileged aspects of the defense strategy. The Indemnitee shall cooperate with the Indemnifying Party as reasonably requested, at the Indemnifying Party's sole cost and expense. The Indemnifying Party shall not settle any claim or suit without the Indemnitee's prior written consent unless such settlement is limited to the payment of cash by the Indemnifying Party and contains a full release of the Indemnitee.

6.6 Insurance. At all times during which any of the Products are being clinically tested with human subjects or Commercially Manufactured or Distributed by CryoLife hereunder, as well as for a period of seven years thereafter, each Party shall procure and maintain from a reputable insurer reasonably satisfactory to the other Party insurance, including product liability insurance, adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated. In any event, the amount of insurance obtained and maintained pursuant to this Section 6.6 by each Party shall not be less than Ten Million U.S. dollars ($10,000,000.00). It is understood that such insurance shall not be construed to create a limit of any Party's liability with respect to its indemnification obligations under this Section 6. Each Party shall provide the other Party with written evidence of such insurance (or financial information that describes the amounts available under any self-insurance facility) upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal, or material change in such insurance.

6.7 No Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATIONS OR WARRANTIES AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

7. Protection of Intellectual Property

7.1 Confidentiality. Each of SMI and CryoLife acknowledge that in order to satisfy their respective obligations under this Agreement, it will be necessary for the Parties to exchange certain trade secret and confidential information (collectively, the "Confidential Information"). The provisions of this Section shall apply to disclosures furnished to or received by a Party and its employees, agents and representatives (which may include employees, agents and representatives of its Affiliates). Each Party shall advise its employees, agents and representatives of the requirements of this Section and shall be responsible to ensure their compliance with such provisions. In consideration of the mutual benefits to be derived from the exchange of Confidential Information, SMI and CryoLife agree as follows:

7.1.1 For purposes hereof, "Confidential Information" with respect to a disclosing party includes all information, in any form or media, concerning the disclosing party that the disclosing party furnishes to the recipient, whether furnished before or after the Effective Date, and all notes, analyses, compilations, studies and other materials, whether prepared by the recipient or others, that contain or reflect such information; provided, however, that Confidential Information does not include information that (i) is or hereafter becomes generally available to the public other than as a result of a breach of this Agreement by the recipient, (ii) was already known to the recipient prior to receipt from the disclosing party, as evidenced by prior written documents in its possession not subject to an existing confidentiality obligation to the disclosing party, (iii) is disclosed to the recipient on a non-confidential basis by a person who is not in default of any confidentiality obligation to the disclosing party or (iv) is developed by or on behalf of the recipient without reliance on confidential information received hereunder. The contents of this Agreement shall be deemed to be Confidential Information of each Party.

7.1.2 The recipient of Confidential Information shall (i) maintain its confidentiality using efforts and precautions at least as great as those it uses and takes to protect its own confidential information and trade secrets; (ii) use such Confidential Information solely in connection with the discharge of its obligations under this Agreement; and (iii) not disclose such Confidential Information to any person other than those of its agents and representatives who need to know such Confidential Information in order to accomplish the objectives for which it was disclosed. Notwithstanding the foregoing, the recipient of Confidential Information may disclose it to the extent necessary to comply with applicable laws, stock exchange rules, or with an order issued by a court or Regulatory Authority with competent jurisdiction; provided that, in connection with such disclosure, the recipient uses commercially reasonable efforts to obtain confidential treatment or an appropriate protective order, to the extent available, with respect to such Confidential Information. The receiving party may provide access to the Confidential Information to such employees and consultants of the receiving party who reasonably require such access in connection with the transactions contemplated by this Agreement.

7.1.3 The obligations under this Section shall remain in effect from the Effective Date through the third anniversary of the expiration or termination of this Agreement.

7.1.4 In addition to any other remedies available in law or equity, the disclosing party shall be entitled to temporary and permanent injunctive relief in the event of a breach (or threatened breach) under this Section.

7.2 Prior Confidentiality Agreements. The provisions of this Section shall supersede and replace any prior agreements between the Parties relating to Confidential Information covered hereby; provided that notwithstanding the foregoing the Parties acknowledge and agree that upon execution of this Agreement by the Parties that certain nondisclosure agreement, dated [***], between the Parties shall be deemed terminated as of the date of execution but those terms set forth therein shall survive in accordance with their terms.

7.3 Public Announcements. Notwithstanding the provisions of this Section 7, the Parties acknowledge they may desire (or be required) to make a public announcement, issue a press release or provide similar publicity with respect to this Agreement or the transactions contemplated herein, and each Party shall notify the other Party of its intent to make such publicity and deliver a draft of such publicity to the other Party. Neither Party shall make any public announcement, press release or similar public pronouncement with respect to this Agreement or the transactions contemplated herein without the consent of the other Party regarding the content, time and manner of such publicity; provided that neither Party shall unreasonably withhold its consent under this section and nothing in this Section 7 shall prevent either Party from timely making any disclosure required by law or by the New York Stock Exchange or other applicable public stock exchange.

8. Intellectual Property Rights

8.1 Intellectual Property Representations. SMI hereby represents and warrants to, and covenants with, CryoLife as follows:

8.1.1 SMI, and only SMI, owns or holds valid and enforceable rights to exclusively Manufacture, Distribute, use or license (to the extent a license is required) any and all Intellectual Property that is necessary (i) to Manufacture and Distribute the Products and the Modified Starch or to permit others to Manufacture or Distribute the Products or Modified Starch, (ii) for CryoLife to Manufacture and Distribute the Products or to use Modified Starch in the Manufacturing of Products as contemplated by this Agreement and (iii) for SMI to grant to CryoLife the rights to Manufacture and Distribute under this Agreement (such Intellectual Property rights collectively, the "SMI IP"). No license of Intellectual Property rights from Third Parties is needed for CryoLife to Manufacture or Distribute the Products for Permitted Clinical Applications within the Territory or to use Modified Starch in the Manufacture of Products.

8.1.2 SMI owns or licenses all right, title and interest in and to the SMI IP.

8.1.3 SMI has not granted any license, covenant not to sue or other right that would be inconsistent with or conflict with the grant of the exclusive rights to Manufacture and Distribute the Products granted to CryoLife under this Agreement.

8.1.4 No Person has asserted any Claim with respect to any of the SMI IP, which Claim (i) challenges the validity of SMI's interest in the SMI IP, (ii) alleges that SMI's use or practice of the SMI IP infringes, misappropriates or violates the rights of any Person or (iii) seeks to enjoin or restrain SMI's use or practice of the SMI IP in any manner that would interfere with the transactions

contemplated by this Agreement. Except as disclosed on Schedule 8.1, SMI has no knowledge that any Person intends to assert such a Claim.

8.1.5 No Intellectual Property or contract rights of others will be infringed by (i) the development, Manufacturing or Distribution of Modified Starch or the Manufacture or Distribution of Products by CryoLife as contemplated by this Agreement, (ii) the entering into of this Agreement, or (iii) the performance of this Agreement by either Party.

8.1.6 Prior to and during the Term, SMI has not granted any Person any license or right of first refusal that conflicts with the rights granted to CryoLife hereunder or the right to purchase all or substantially all of SMI or its business or the assets constituting the Products.

8.1.7 SMI owns or licenses all right, title and interest in and to the SMI IP. A complete list of all patents and patent applications included in the SMI IP, with the status of registrations in all countries in the Territory, is included on Schedule 8.1.

8.2 Intellectual Property/Information and Ideas. CryoLife acknowledges SMI's exclusive right, title and interest in and to the SMI IP. If any claim or action is asserted against SMI or CryoLife alleging that a Product infringes any Third Party intellectual property rights, the Party receiving such information shall immediately notify the other Party in writing of such claim or action.

8.2.1 In such event, SMI shall defend such action and, if necessary to permit CryoLife to continue to use, manufacture, distribute and sell the Products, and use commercially reasonable efforts to secure such right, title, interest, or license to the intellectual property necessary for CryoLife to market, distribute, manufacture and sell the Products.

8.2.2 If SMI is unable to secure sufficient rights to permit CryoLife to Distribute Products in the manner contemplated by this Agreement, SMI may request CryoLife to cease sales of Products if it reasonably determines such action is necessary due to infringement or possible infringement of Third Party intellectual property rights, and in such case CryoLife shall use commercially reasonable efforts to halt sales of Products in the Territory.

8.2.3 If SMI or CryoLife recall or remove any Products from the market or if SMI notifies CryoLife to cease sales pursuant to Section 8.2.2, SMI shall, at CryoLife's option, promptly repurchase from CryoLife all of CryoLife's inventory of Modified Starch at the price paid by CryoLife (including shipping and return shipping) and all of CryoLife's inventory of Products (including all field inventory and Products recalled or returned) at CryoLife's fully loaded cost, including shipping to SMI and CryoLife's cost of securing the return of Products in field inventory or already Distributed. The Parties agree that CryoLife's rights under this Section 8.2.3 shall be in addition to any other rights or remedies available to CryoLife pursuant to this Agreement or in law or equity.

8.3 Infringement Notification. Each Party shall promptly notify the other Party of any and all infringements of the SMI IP of which such Party becomes aware within the Territory. SMI shall, at its own cost, take any and all actions, legal or equitable, necessary to defend the SMI IP against such infringements and to eliminate or minimize the consequences of any infringement of the SMI IP in the Territory. At SMI's request and expense, CryoLife will assist SMI in taking action against any such infringements, and in addition to any responsibility of SMI pursuant to Section 8.2. If SMI fails to take appropriate action against such infringements within sixty (60) days after notice, CryoLife may take such actions as it deems necessary and appropriate, including but not limited to filing a lawsuit against a Third Party (and/or their patents) in SMI's name or its own name and/or requesting that patent offices (or their

equivalents) reconsider Third Party patents and SMI shall reasonably assist CryoLife as directed by CryoLife. If any Product is held to constitute an infringement or misappropriation of any Third Party's Intellectual Property right, if SMI and CryoLife concur that any Products constitute an infringement or misappropriation, or if CryoLife is advised by its legal counsel that any Products potentially infringe or misappropriate any Third Party's Intellectual Property right, SMI will at its expense procure the right for CryoLife to continue Manufacturing, using and Distributing the Products in accordance with this Agreement at no additional cost to CryoLife and, if necessary, replace CryoLife's Modified Starch inventory with a non-infringing and non-misappropriating equivalent product conforming to the Modified Starch Specifications at no additional cost to CryoLife and modify the Modified Starch to make it non-infringing and non-misappropriating while conforming to the Modified Products Specifications at no additional cost to CryoLife. If SMI declines to take the foregoing action within sixty (60) days after notice from CryoLife or if SMI is unable to secure sufficient rights to permit CryoLife to Manufacture, use and Distribute the Products in the manner contemplated by this Agreement within a reasonable time, SMI shall, at CryoLife's option, promptly repurchase CryoLife's entire Product inventory at the original purchase price (including shipping charges) as provided in Section 8.2.3, and CryoLife shall be released of its obligations under this Agreement. CryoLife shall also be authorized in the foregoing event to procure the right for CryoLife to continue Manufacturing, using and Distributing Products in accordance with this Agreement and to offset the cost of obtaining such rights from amounts otherwise due or coming due to SMI under this Agreement, the Distribution Agreement or any other agreement.

8.4 Patent Prosecution. At its own cost, SMI shall apply for, prosecute, and maintain all patent applications and patents or rights to license or use the patents and patent applications included in the SMI IP within the Territory in the manner and according to the schedule set forth in the Patents Protection Plan included as Schedule 8.4. SMI shall keep CryoLife reasonably informed as to the status of the prosecution and maintenance of such patents and patent applications in the Territory and with respect to any actions regarding such patents and patent applications in the Territory

9. Term and Termination

9.1 Term. The term of this Agreement shall take effect as of the Effective Date and be perpetual (the "Term").

9.2 Termination. Notwithstanding anything in Section 9.1, this Agreement may be terminated at any time as follows:

9.2.1 By CryoLife for reason of SMI's material breach of a duty or obligation under this Agreement by giving SMI at least sixty (60) days prior written notice of termination which specifies such default and SMI fails to cure the material default during such sixty (60) day period.

9.2.2 After the fifth anniversary of the Effective Date, by SMI for reason of CryoLife's material breach of a duty or obligation under this Agreement by giving CryoLife at least sixty (60) days prior written notice of termination which specifies such default and CryoLife fails to cure the material default during such sixty (60) day period.

9.2.3 By CryoLife at any time and with or without cause by providing at least one hundred eighty (180) days prior written notice of termination to SMI.

9.2.4 By either Party forthwith on written notice of termination to the other Party for the other Party's Insolvency Event, or winding up of its operations; or in the event of nationalization, in whole or part, of the other Party.

9.2.5 By CryoLife upon sixty (60) days written notice of termination to SMI at any time after SMI fails on any two occasions within any twelve (12) month period to timely deliver Modified Starch, or material quantities of Modified Starch, ordered by CryoLife in a delivery that conforms to Modified Starch Specifications and CryoLife's purchase order, or

9.3 Effect of Termination. Notwithstanding anything to the contrary contained herein, upon and after any termination or expiration of this Agreement, (i) SMI shall continue to fill all CryoLife purchase orders for Modified Starch made in accordance with the provisions of this Agreement prior to the date of the initial notice of such termination or expiration; (ii) CryoLife shall continue to have all rights necessary or appropriate to sell Products (including Products manufactured pursuant to post-termination delivery of Modified Starch ordered by CryoLife prior to termination or expiration), and SMI shall continue to comply with all of its duties and obligations hereunder necessary or appropriate to facilitate such sales by CryoLife; (iii) SMI shall continue to comply with all of its duties and obligations hereunder necessary or appropriate to permit CryoLife to fulfill its obligations to deliver Products pursuant to tenders or sales contracts outstanding at the time of such termination or expiration until such tenders or sales contracts have expired, including SMI's obligation to provide Modified Starch for any related CryoLife purchase orders, and (iv) CryoLife shall continue to comply with its obligations under this Agreement. Termination of this Agreement shall not affect rights and obligations of either Party that may have accrued prior to the effective date of termination or any obligation that by its nature or express terms survives termination. Sections 4, 5, 6, 7, 8, 9, 10, and 11 shall survive the termination or expiration of this Agreement.

9.4 Inventory Repurchases. At SMI's or CryoLife's option upon termination or expiration of this Agreement, SMI shall repurchase from CryoLife all Modified Starch in CryoLife's possession. For Modified Starch to be repurchased (i) either Party must notify the other Party in writing of its election to purchase or sell the CryoLife Modified Starch within twenty (20) days after termination or expiration, (ii) CryoLife must provide SMI with an inventory of Modified Starch in its possession with such notice; and (iii) Modified Starch must be in a saleable condition.

9.5 Renegotiation. If, after October 1, 2017 CryoLife has not received United States Regulatory Approval, SMI may by written notice require CryoLife to terminate CryoLife's exclusive right and license to apply for, pursue and maintain United States Regulatory Approval for Products described in Section 5.2. In such event, both Parties agree to negotiate in good faith to make commercially reasonable modifications to this Agreement.

10. Representations and Warranties

10.1 Representations and Warranties.

10.1.1 SMI hereby represents and warrants that:

(i) it is a duly and validly organized and existing corporation in good standing under the laws of the state of Delaware, and that it or its affiliates that may be performing its obligations under this Agreement are legally qualified to do business in each jurisdiction in which this Agreement may be performed and where its activities hereunder require such qualification,

(ii) the performance of this Agreement and the consummation of the transactions contemplated herein will not result in any breach, conflict, or violation of any terms or provisions of, or constitute a default under, its Certificate of Incorporation or By-Laws, or other

organizational documents, or any material agreement or instrument to which it is a party, by which it is bound, or to which any of its property is subject,

(iii) all requisite corporate action has been taken for the due authorization, execution, delivery, and performance of this Agreement by it, and this Agreement constitutes a legally binding obligation, enforceable against such party, in accordance with its terms, except insofar as enforceability may be limited by bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally,

(iv) it is not a party to any litigation relating to, or that could reasonably be expected to affect, its ability to perform its obligations under this Agreement, or

(v) the Permitted Clinical Applications include all approved clinical applications for products based on the AMP technology within the Territory.

10.1.2 CryoLife hereby represents and warrants that:

(i) it is a duly and validly organized and existing corporation in good standing under the laws of the state of Florida, and that it or its affiliates that may be performing its obligations under this Agreement are legally qualified to do business in each jurisdiction in which this Agreement may be performed and where its activities hereunder require such qualification,

(ii) the performance of this Agreement and the consummation of the transactions contemplated herein will not result in any breach or violation of any terms or provisions of, or constitute a default under, its Certificate of Incorporation or By-Laws, or other organizational documents, or any material agreement or instrument to which it is a party, by which it is bound, or to which any of its property is subject,

(iii) all requisite corporate action has been taken for the due authorization, execution, delivery, and performance of this Agreement by it, and this Agreement constitutes a legally binding obligation, enforceable against such party, in accordance with its terms, except insofar as enforceability may be limited by bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally, and

(iv) it is not a party to any litigation relating to, or that could reasonably be expected to affect, its ability to perform its obligations under this Agreement.

11. General

11.1 Notice. Any notice or other communication required or permitted by this Agreement must be given in writing and must be delivered by personal delivery (including personal delivery by overnight courier such as Federal Express, DHL, or similar overnight courier), first class mail (registered or certified), telecopy (with a copy sent by personal delivery or first class mail), or email (with a copy sent by personal delivery or first class mail) at the address of the Party as set forth herein or such other changed address of the Party as to which notice has been given, and will be deemed as having been given when received or delivered.

11.2 Binding; Assignment. This Agreement shall be binding on CryoLife, SMI, and their respective successors and assigns. Neither Party may assign its obligations under this Agreement or in any way transfer its rights or obligations under this Agreement, directly or indirectly, without the prior

written consent of the other Party, which consent shall not be unreasonably withheld, except that either Party may, without such consent, assign this Agreement in connection with any sale of substantially all of its assets or stock or pursuant to any merger, reclassification, or reorganization.

11.3 Entire Agreement; Modification; Waiver. This Agreement contains the entire agreement between the Parties with respect to the subject matter of the Agreement and shall supersede and terminate all prior agreements, commitments, or understandings, whether oral or written, related to the Products. No waiver or modification of any of the provisions of this Agreement shall be binding unless it is in writing and signed by the Parties. Any waiver of any condition on any one occasion shall not constitute a waiver on any subsequent occasion. A failure to exercise or a delay in exercising a right or remedy provided by this Agreement or by law shall not constitute a waiver of that right or remedy.

11.4 Arbitration; Governing Law; Jurisdiction. The Parties agree that any dispute concerning, relating to, or arising out of this Agreement shall be resolved by final and binding arbitration in accordance with the procedures set forth herein. Provided, however that, notwithstanding any other provision herein, either Party, in its sole and exclusive discretion, may apply to any court with jurisdiction over the Parties for a temporary restraining order, preliminary or permanent injunction, without submission of such claim for equitable relief to arbitration.

11.4.1 In the event a dispute is not resolved informally, the Parties agree that such dispute will be resolved exclusively through arbitration to be conducted in Chicago, Illinois, U.S.A., or any other place selected by mutual agreement of the Parties. The arbitration shall be conducted through the American Arbitration Association ("AAA"), unless the Parties mutually agree to use a different arbitral body or individual arbitrator. In any case, the arbitration shall be administered in accordance with the AAA's commercial arbitration rules (the "Rules"), except as the Rules are modified therein. The Parties consent to the jurisdiction and venue of the state and federal courts located in Chicago, Illinois, U.S.A., and further consent that any process, or notice, or applications to the court, including applications for judgment upon an award, may be served outside of the State of Illinois by overnight mail or by personal service.

11.4.2 Unless otherwise mutually agreed by the Parties, the dispute will be decided by three arbitrators with at least ten (10) years experience in distributorship arrangements. Each Party shall select one of the arbitrators. The third arbitrator shall be mutually selected by the two party-selected arbitrators, or, absent agreement, in accordance with the effective Rules, with such third arbitrator having in addition to the distribution arrangement experience described above, at least ten (10) years experience with medical device distributorship arrangements.

11.4.3 The Parties shall cooperate to the fullest extent practicable in the voluntary exchange of documents and information to expedite the arbitration. The Parties agree that the discovery provisions of the Federal Rules of Civil Procedure shall apply to discovery by the Parties. Any disputes concerning discovery shall be submitted to the arbitrator for resolution.

11.4.4 The arbitrator shall have the same authority to award remedies and damages as provided to a judge and/or jury under applicable law. The arbitrator shall not have the power to alter, amend, or modify any provision of this Agreement. The arbitrator shall have the power to decide only the dispute(s) submitted to the arbitrator. The substantive law of the State of New York, without regard to its conflict of laws principles, shall apply to the interpretation, application and legality of this Agreement.

11.4.5 The arbitrator shall issue a reasoned opinion and award, in writing, within thirty (30) days of closing arguments or the receipt of post-hearing briefs, whichever is later. The opinion and award must be signed and dated and decide all disputes submitted by the Parties. The opinion and award shall set forth the legal principles supporting each part of the opinion. The decision of a majority of the arbitrators shall be binding on the Parties. Judgment on the award rendered pursuant to such arbitration may be entered in any court having jurisdiction thereof, and such judgment may be entered and enforced in any state and any country. The losing party shall pay the fees associated with the costs of the arbitrators and any costs associated with the arbitration proceedings. Each side shall bear their own legal expenses and costs. The Parties agree that any judgment shall be considered confidential information pursuant to this Agreement and subject to the provisions of this Agreement related to confidential information.

11.5 Controlling Language. This Agreement has been written, and all discussions leading up to this Agreement have been conducted, in the English language which both Parties thoroughly understand. Each Party represents that it has read and fully understands this Agreement.

11.6 Independent Contractor. CryoLife shall operate as an independent contractor and nothing contained in this Agreement shall be deemed or construed to recreate an employer/employee, principal/agent, joint venture, partnership, or fiduciary relationship between the Parties.

11.7 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, such provision will be severed from this Agreement without affecting the validity or enforceability of any of the remaining provisions.

11.8 Heading and Captions. Headings and captions used herein are for convenience only and are not to be deemed part of this Agreement.

11.9 Inapplicability of UCC. The Parties agree that neither the Uniform Commercial Code of Georgia nor any other State of the United States shall apply to this Agreement or the activities contemplated by this Agreement. The Parties intend that the provisions of this Agreement, including those relating to purchase of Products and termination, govern their activities exclusively under this Agreement where provisions of the Uniform Commercial Code might otherwise provide.

11.10 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be an original, and all of which together shall constitute one and the same instrument.

11.11 Further Assurances; Force Majeure. Each Party covenants and agrees that, subsequent to the execution and delivery of this Agreement and without any additional consideration, it will execute and deliver any further legal instruments and perform any acts that are or may become reasonably necessary to effectuate the purposes of this Agreement. Neither SMI nor CryoLife will have any liability for any failure or delay in performing any obligation under this Agreement (except the obligation to make payments promptly when and as due) if the failure or delay results from force majeure, understood as a cause which is beyond the control of either Party and one which could not have been avoided even with the exercise of due care. The Party claiming force majeure will give the other Party written notice of the cause within fifteen (15) days after occurrence thereof, and will exercise reasonable diligence to remove the cause and resume performance.

[Signatures on the following page(s)]

IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers, and have duly delivered and executed this Agreement under seal as of the Effective Date.

CRYOLIFE, INC.	**STARCH MEDICAL, INC.**
By: _____	By: _____
Name:	Name:
Title:	Title:

ANNEX A

Defined Terms

The following terms shall have the following meanings:

"AAA" – as defined in Section 14.4.1.

"Acquired Components" – as defined in Section 1.2.1.

"Adjustment Date" – as defined in Section 3.4.

"Agreement" – as defined in the first paragraph.

"AMP™ technology" means SMI's proprietary engineering process that modifies plant starch into ultra-hydrophilic, adhesive forming hemostatic polymers.

"Affiliates" as it relates to a Person, shall mean any Person controlling, controlled by or under common control of such Person.

"Aggregate Net Sales" means the total aggregated Net Sales from the first Net Sales through the applicable end date of calculation.

"Applicable Laws" means all applicable common law, statutes, ordinances, rules, regulations or orders of any Governmental Authority, including Regulatory Laws, within the Territory.

"Business Day" means any day other than a Saturday, a Sunday or a day on which banks in New York are authorized or obligated by law or executive order to remain closed.

"Claim" means any claim, suit, proceeding, action or demand.

"Commercially" or "Commercial" Distribution refers to Distribution of Products that have received Regulatory Approval and are distributed through normal commercial channels. Commercially does not refer to Distribution for the purpose of supporting efforts to obtain Regulatory Approval.

"Competitive Products" – as defined in Section 2.1.

"Confidential Information" – as defined in Section 7.1.

"CryoLife" means CryoLife, Inc., a Florida corporation, as defined in the first paragraph.

"CryoLife Indemnitees" – as defined in Section 6.2.

"CryoLife Facility" means any facility owned and operated by CryoLife or any Affiliate of CryoLife or any Third Party facility approved by SMI, which approval shall not be unreasonably withheld. CryoLife's current facilities are located in Kennesaw, Georgia, U.S.A.

"Development Agreement" – as defined in the Distribution Agreement.

"Distribute" and "Distribution" means collectively, to market, offer for sale, sell, have sold, distribute, or have distributed for Commercial or other purposes, including for the purpose of supporting efforts to obtain Regulatory Approval.

"Distribution Agreement" means distribution agreements for Products between CryoLife and SMI that is being entered into on the Effective Date.

"Distribution License" – as defined in Section 1.1.

"Effective Date" – means September 29, 2010.

"FDA" means the United States Food and Drug Administration or any successor agency having the administrative authority to grant Regulatory Approval in the United States.

"Field Action" means any correction or removal action due to safety, efficacy, quality or regulatory compliance concerns, including actions to recover title to or possession of, or to halt distribution of, Products that previously have been shipped to customers.

"Forecast" – as defined in Schedule 3.6.

"Governmental Authority" means any country in which the Products are manufactured, marketed, sold, tested, investigated or otherwise regulated, and all states or other political subdivisions thereof and supranational bodies applicable thereto, including the European Union, and all agencies, commissions, officials, courts or other instrumentalities of the foregoing.

"Indemnifying Party" – as defined in Section 6.3.

"Indemnitees" – as defined in Section 6.3.

"Insolvency Event" means that the Party (a) has commenced a voluntary proceeding under any insolvency law, (b) had an involuntary proceeding commenced against it under any insolvency law which has continued undismissed or unstayed for sixty (60) consecutive days, (c) had a receiver, trustee or similar official appointed for it or for any substantial part of its property, (d) made an assignment for the benefit of creditors or (e) had an order for relief entered with respect to it by a court of competent jurisdiction under any insolvency law. For purposes hereof, the term "insolvency law" means any applicable bankruptcy, insolvency or other similar law now or hereafter in effect.

"Initial Payment" – as defined in the Distribution Agreement.

"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 and (e) all proprietary rights relating thereto, including all applications, registrations and renewals in connection therewith.

"License" – as defined in Section 1.1 and as may be modified as set forth herein.

"Losses" means and includes any and all liability, damage, loss, expense, including reasonable attorney's fees.

"Manufacture" means collectively to make, process, produce, or manufacture.

"Manufacturing IP" – as defined in Section 1.2.1 and potentially modified pursuant to Section 4.3.3.

"Minimum Requirement" – as defined in Section 3.5.

"Modified Starch" means SMI's proprietary starch produced using the AMP™ technology that meets the Modified Starch Specifications.

"Modified Starch Inventory" means the Modified Starch supplies of SMI at a given time that meet all specifications and if used in the Manufacture of Products within one hundred eighty (180) days will be sufficient to produce Products with a shelf life of at least three (3) years.

"Modified Starch Specifications" means, collectively, (i) SMI's design and functionality specifications relating to the Modified Starch as used by SMI in its production of Products and (ii) any specifications for manufacturing, testing, storing, packaging, shipping or labeling Modified Starch set forth in any approved application for Regulatory Approval and any supplements and amendments thereto. Current Modified Starch Specifications have been delivered to CryoLife under separate cover contemporaneously with the execution of this Agreement. Modified Starch Specifications may only be amended in the manner provided in this Agreement.

"Net Sales" means and includes the receipts of CryoLife from the Commercial Distribution of Products excluding fees, freight and shipping charges and reduced by allowances and returns.

"New Application(s)" – as defined in Section 1.4.

"New Intellectual Property" – as defined in Section 1.3.

"New Product" – as defined in Section 1.5 of the Distribution Agreement.

"Open Negotiation Period" – as defined in Section 1.4 of the Distribution Agreement.

"Other Parties" – as defined in Section 2.3 of the Distribution Agreement.

"Party" and "Parties" – as defined in the first paragraph.

"Party's Product" – as defined in Section 5.6.

"Patents Protection Plan" means the plan for obtaining and maintaining patent protection on the SMI IP within the Territory that is set forth on Schedule 8.4.

"Permitted Clinical Applications" means all clinical applications described and not expressly excluded in Schedule W-2 of the Distribution Agreement.

"Person" means any individual, group or entity, including Governmental Authorities.

"Pre-Clinical Trial Cost" means the costs that CryoLife incurs with Third Parties to run those certain tests necessary, as determined by CryoLife for Pre-IDE Submission.

"Prepaid Royalty Payment" means One Million Five Hundred Thousand U.S. dollars ($1,500,000.00) paid to SMI as part of the Initial Payment under the Distribution Agreement.

"Products Specifications" means, collectively, (i) SMI's design and functionality specifications relating to the Products and (ii) any specifications for manufacturing, testing, storing, packaging, shipping or labeling the Products set forth in any approved application for Regulatory Approval and any supplements and amendments thereto. Current Product Specifications have been delivered to CryoLife under separate cover contemporaneously with the execution of this Agreement. Products Specifications may only be amended in the manner provided in this Agreement.

"Product(s)" mean all products described in Schedule W-1 of the Distribution Agreement.

"Regulatory Approval" means, with respect to any country or jurisdiction, the act of the applicable Regulatory Authority that is necessary under applicable Regulatory Laws for the Manufacture, use and Distribution of Products or Modified Starch in that country or jurisdiction, and satisfaction of all applicable regulatory and notification requirements and, to the extent applicable, the grant of pricing approval.

"QSR" means the quality system regulations of the FDA including master device and lot history records.

"Regulatory Approval Program" – as defined in Section 5.2.

"Regulatory Authority" means, with respect to any country or jurisdiction, any Governmental Authority involved in granting Regulatory Approval or in administering Regulatory Laws in that country or jurisdiction, including the FDA in the United States.

"Regulatory Laws" means all Applicable Laws governing (i) the import, export, testing, investigation, manufacture, marketing or sale of the Product, (ii) establishing recordkeeping or reporting obligations, (iii) any Field Action or (iv) similar regulatory matters.

"Rules" – as defined in Section 11.4.1.

"Schedule W-2" means Schedule W-2 of the Distribution Agreement.

"SMI" means Starch Medical, Inc. a Delaware corporation, as defined in the first paragraph.

"SMI Indemnitees" – as defined in Section 6.1.

"SMI IP" – as defined in Section 8.1.1.

"Specification Changes" – as defined in Section 4.2.

"Term" – as defined in Section 9.1.

"Territory" means and includes all countries in the world except China, Hong Kong, Macau, Taiwan, North Korea, Iran and Syria.

"Third Party" means any Person other than a Party or its Affiliates.

"Trademarks" means all trademarks, service marks, trade dress, logos and trade names, together with all translations, adaptations, derivations and combinations thereof (including all goodwill associated therewith), and all applications, registrations and renewals in connection therewith.

"Trademark License" means the license to CryoLife for SMI's proprietary marks, tradedress, and trademarks being entered into on the Effective Date.

"Transfer Price" means the price charged to CryoLife by SMI for Modified Starch as set forth in Section 3.3, as such prices may be amended from time to time pursuant Section 3.4.

"United States" means the United States of America, including its territories, commonwealths and possessions.

"United States Regulatory Approval" means final approval from the FDA to Commercially Manufacture, use and Distribute Product for Permitted Clinical Applications within the United States.

SCHEDULE 2.1

Exclusions from Competitive Products and New Products

1. SMI's Perclot® endoscopic hemostatic system designed for applications in minimally invasive surgical procedures so long as SMI distributes and sells such product exclusively as a Kitted Product.

2. Products packaged and sold exclusively for topical uses so long as such products (i) do not use the PerClot® name or any name or trade dress that is confusingly similar to the PerClot™ name or any trade dress associated with the Products, (ii) are distributed in packaging that clearly states the product is "NOT FOR INTERNAL USE," (iii) are packaged in single use pouches, (iv) are not usable in a sterile field within a healthcare facility, and (v) are not in quantities of or about 1, 3 grams.

3. Non-powdered format absorbable hemostats, including configurations in freeze-dried foam, sponge, glue, gel film, and microfibrillar fibers.

Topical hemostasis, first aid, woundcare, all non-absorbable hemostatic applications (defined as class I or class II medical device), anti-adhesion film, anti-infection composited and wound healing promotion agents.

SCHEDULE 3.6

Inventory, Supply and Supply Interruption Procedures for Acquired Components

SMI agrees to maintain Acquired Components inventory equal to at least the greater of two (2) times CryoLife's trailing three (3) month order volume or one hundred fifty percent (150%) of CryoLife's forecasted three (3) month demand Acquired Components.

SMI will notify CryoLife immediately in writing upon becoming aware of any supply shortage, or other interruption or potential interruption in the supply of any material or component of Acquired Components. In addition, if reasonably requested in writing by CryoLife, SMI agrees to confirm that it is not aware of any supply shortage, or other interruption or potential interruption in the supply of any material or component of Acquired Components, to confirm within ten (10) days. If at any time SMI does not have enough Acquired Components to fulfill on a timely basis its supply obligations to CryoLife, SMI shall promptly notify CryoLife of the nature and extent of the impairment to SMI's ability to supply and shall allocate its full resources to rectifying the impairment until such impairment is overcome.

Beginning with the first calendar quarter after CryoLife can begin Manufacturing of the Products, on a quarterly basis and twenty (20) days before the end of each quarter, CryoLife shall provide to SMI twelve (12) month rolling forecasts of the anticipated quarterly quantities of Acquired Components that CryoLife expects to order (each, a "Forecast"). Such Forecasts shall not be binding except to the following extent: the first three months of each Forecast shall constitute a firm commitment to order the total dollar volume of Acquired Components. On a quarterly basis and twenty (20) days before the end of each quarter, SMI will provide CryoLife with twelve month rolling forecasts of Acquired Components inventory and production and a report of Acquired Components inventory on hand. Failure of either Party to provide the forecasts or reports required by this Schedule 3.6 shall relieve the other Party of its obligations under this Schedule 3.6. SMI agrees to timely supply CryoLife with the quantities forecasted for the first three months of each forecast against purchase orders from CryoLife. SMI also agrees, at a minimum, to fulfill all firm additional orders for the Acquired Components submitted by CryoLife that are not more than fifty percent (50%) above the amounts forecasted.

[***] – 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.

Schedule 8.1

Intellectual Property

No.	Title	Filing Date	Application No.	Internation Filing Date	Priority Date	International Application No.	Applicants	Inventor	Current Status	National Phase
1(1)		[***]	[***]	/	/	/			[***]	
1(2)	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	Submitted to [***], [***] and [***] via [***]**

** **Application No. for [***]: [***], [***]: [***] and [***]: [***]**

[***] – 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.

Schedule 8.4

Patent Protect Plan

No.	Title	Filing Date	Application No.	Internation Filing Date	Priority Date	International Application No.	Applicants	Inventor
1	[***]	[***]	[***] **	[***]	[***]	[***]	[***]	[***]

** **Application No. for [***]: [***], [***]: [***] and [***]: [***]**

National Phase and Protect Plan:

As part of its efforts, SMI shall prepare quarterly written reports describing the current status of the patent and patent application listed herein and written notifications describing any amendments made to the claims during the prosecution of any application of patent and any receipt of notice from the [***] of its intent to grant a patent on the [***] patent listed above, no later than 30 days before the deadline for CryoLife to select and SMI to effect the national stage entry (i.e. validation) in the designated [***] states of CryoLife's choosing, which states shall include all those nations in which CryoLife [***] its [***] ([***]) and any new countries added in which a [***] can be [***] since that time. SMI will continue to pursue the patent in [***], [***] and [***].

Exhibit 31.1

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: November 5, 2010

/s/ STEVEN G. ANDERSON
Chairman, President, and
Chief Executive Officer

Exhibit 31.2

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: November 5, 2010

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

Exhibit 32

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 September 30, 2010, 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
November 5, 2010

/s/ D. ASHLEY LEE
D. ASHLEY LEE
Executive Vice President,
Chief Operating Officer, and
Chief Financial Officer
November 5, 2010