UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
washington, d.c. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported): January 18, 2012

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida	**1-13165**	**59-2417093**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1655 Roberts Boulevard, N.W., Kennesaw, Georgia 30144
(Address of principal executive office) (zip code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 8 Other Events

Item 8.01 Other Events.

CryoLife, Inc. ("CryoLife") originally filed the attached exhibits with its Form 10-Q for the quarter ended September 30, 2010, and the exhibits were granted confidential treatment under the Securities Exchange Act of 1934, as amended, through November 5, 2011. CryoLife has requested an extension of confidential treatment for certain portions of the exhibits; however, the exhibits are filed herewith with modified redactions in order to disclose the portions of the previously redacted information for which CryoLife no longer requires confidential treatment.

Section 9 Financial Statements and Exhibits.

Item 9.01(d) Exhibits.

(a) Financial Statements.
Not applicable.

(b) Pro Forma Financial Information.
Not applicable.

(c) Shell Company Transactions.
Not applicable.

(d) Exhibits.

Exhibit Number	Description
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.

\+ CryoLife has requested an extension of 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, CryoLife, Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CRYOLIFE, INC.

Date: January 18, 2012

By: /s/ D.A. Lee
Name: D. Ashley Lee
Title: Executive Vice President, Chief Operating Officer and Chief Financial Officer

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.

[***] – 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.

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.

[***] – 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.

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.

/s/ D.A. Lee
Name: D. Ashley Lee
Title: Executive VP, COO and CFO

STARCH MEDICAL, INC.

/s/ Xin Ji
Name: Xin Ji
Title: Chief Executive Officer

□

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	[***]	PerClot LAP
Greece	[***]	PerClot LAP
New Zealand	[***]	PerClot
UK	[***]	PerClot LAP

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	$525,000
January 1, 2011	December 31, 2011	$1,225,000
January 1, 2012	December 31, 2012	$2,500,000
January 1, 2013	December 31, 2013	$3,500,000
Each Calendar Year commencing on January 1, 2014	$1,750,000	

* 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.

[***] – 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 3.8

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 direct distribution
STA 2003	US$[***] each; US$[***] sold only individually for direct 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 [***].

[***] – 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 3.15

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
    - o [***] ea STA0003
    - o [***] ea STA2003
    - o [***] ea LAP3803
- Quarterly Sample Provisions (starting the first calendar quarter after product launch)
    - o [***] ea STA0003
    - o [***] ea STA2003
    - o [***] ea LAP3803
- Ordering = CryoLife to list non-sterile samples needs with each order

Sterile Samples

- For first three contract years:
    - o Contract Year 1 - [***] units of STA0003 and [***] units of STA2003 and [***] units of LAP3803
    - o 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 12/228029 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 Commercially Distribute Products, 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 sell its entire inventory of HemoStase 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 April 20, 2010, 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.

/s/ D.A. Lee
Name: D. Ashley Lee
Title: Executive VP, COO and CFO

STARCH MEDICAL, INC.

/s/ Xin Ji
Name: Xin Ji
Title: Chief Executive Officer

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 [***].