CRYOLIFE INC
Form 10-K
February 17, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission file number 1-13165

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida	**59-2417093**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1655 Roberts Boulevard N.W., Kennesaw, GA 30144

(Address of principal executive offices) (zip code)
Registrant s telephone number, including area code (770) 419-3355

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $.01 par value	New York Stock Exchange
Preferred Share Purchase Rights	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨

No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K Section 229.405 of this chapter is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Smaller reporting company ¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of June 30, 2011 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $143,673,628 computed using the closing price of $5.60 per share of Common Stock on June 30, 2011, the last trading day of the registrant s most recently completed second fiscal quarter, as reported by the New York Stock Exchange, based on management s belief that Registrant has no affiliates other than its directors and executive officers.

As of February 10, 2012 the number of outstanding shares of Common Stock of the registrant was 27,711,808.

Documents Incorporated By Reference

Document	**Parts Into Which Incorporated**
Proxy Statement for the Annual Meeting of Stockholders	Part III

to be filed within 120 days after December 31, 2011.

PART I

Item 1. Business.

Overview

CryoLife, Inc. (CryoLife , the Company , we , or us), incorporated in 1984 in Florida, preserves and distributes human tissues for transplantation and develops, manufactures, and commercializes medical devices for cardiac and vascular applications. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both processed using CryoLife s proprietary SynerGraft® technology. CryoLife s surgical sealants and hemostats include BioGlue® Surgical Adhesive (BioGlue), BioFoam® Surgical Matrix (BioFoam), and PerClot®, an absorbable powdered hemostat, which the Company distributes for Starch Medical, Inc. (SMI) in the European Community and other select international markets. CryoLife s subsidiary Cardiogenesis Corporation (Cardiogenesis) specializes in the treatment of coronary artery disease using a laser console system and single use, fiber-optic handpieces to treat patients with severe angina.

Preservation Services and Products

Tissue Preservation Services. CryoLife distributes preserved human cardiac and vascular tissues to implanting institutions throughout the U.S., Canada, and Europe. CryoLife processes and preserves cardiac and vascular tissues using proprietary processing and freezing techniques, or cryopreservation. Management believes the human tissues it distributes offer specific advantages over mechanical, synthetic, and animal-derived alternatives. Depending on the alternative, the advantages of the Company s heart valves include more natural blood flow properties, the ability to use with patients who have endocarditis, the elimination of a need for long-term drug therapy to prevent excessive blood clotting, and a reduced risk of catastrophic failure, thromboembolism (stroke), or calcification. The Company s cardiac tissues include the CryoValve SGPV and the CryoPatch SG, both processed with the Company s proprietary SynerGraft technology. CryoLife uses the SynerGraft technology for a portion of its pulmonary valve and pulmonary cardiac patch tissue processing. The Company s vascular tissues, including the CryoVein and CryoArtery, have been used to treat a variety of vascular reconstructions such as peripheral bypass, hemodialysis access, and aortic infections which have saved the lives and limbs of patients.

Surgical Sealants and Hemostats. CryoLife s proprietary product BioGlue, designed for cardiac, vascular, pulmonary, and general surgical applications, is a polymer based on bovine blood protein and an agent for cross-linking proteins. CryoLife distributes BioGlue throughout the U.S. and in more than 75 other countries for designated applications. In the U.S. BioGlue is U.S. Food and Drug Administration (FDA) approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues) in the European Economic Area (EEA) under Conformité Européene Mark product certification (CE Mark). CryoLife distributes BioGlue in Japan for use in the repair of aortic dissections. Additional marketing approvals have been granted for specified applications in several other countries throughout the world, including Canada, Brazil, and Australia.

CryoLife s proprietary product, BioFoam, is a protein hydrogel biomaterial with an expansion agent which generates a mixed-cell foam. The foam creates a mechanical barrier to decrease blood flow and develops pores for the blood to enter, leading to cellular aggregation and enhanced hemostasis. Due to its foaming characteristic, BioFoam has the potential to rapidly seal organs, such as the liver, and may provide hemostasis in penetrating wounds and trauma. CryoLife distributes BioFoam under CE Mark certification for use as an adjunct in the sealing of liver and spleen when cessation of bleeding by ligature or conventional methods is ineffective or impractical. BioFoam has approval by the FDA for an investigational device exemption (IDE) to conduct a human clinical trial with BioFoam to determine its safety and effectiveness in sealing liver tissues in patients for whom cessation of bleeding by ligature or other conventional methods is ineffective or impractical.

CryoLife has a worldwide distribution agreement (except in China and certain related territories and governing areas) and a license and manufacturing agreement with SMI of San Jose, California for PerClot, a polysaccharide hemostatic agent used in surgery. PerClot is an absorbable powdered hemostat that has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. CryoLife plans to file an IDE in early 2012 with the FDA to begin clinical trials for the purpose of obtaining Premarket Approval (PMA) to distribute PerClot in the U.S.

CryoLife distributed HemoStase under a private label Exclusive Distribution Agreement (EDA) with Medafor, from May 2008 to March 2011. CryoLife is currently in litigation with Medafor related to the EDA, discussed further below in Part I, Item 3, Legal Proceedings.

Revascularization Technologies. In May 2011 CryoLife completed its acquisition of Cardiogenesis. Cardiogenesis is a leading developer of surgical products used in the treatment of patients with severe angina resulting from diffuse coronary artery disease. Cardiogenesis markets the Transmyocardial Revascularization (TMR) system, which includes the Holmium: YAG laser console and single use, fiber-optic handpieces. The system is FDA approved for performing a surgical procedure known as TMR, used for treating patients with stable angina that is not responsive to conventional therapy. Patients undergoing TMR treatment with Cardiogenesis products have been shown to have angina reduction, longer event-free survival, reduction in cardiac related hospitalizations, and increased exercise tolerance. Cardiogenesis has also developed the Phoenix System, which is designed to combine the delivery of biologic materials with TMR. The synergy of injecting biologics, such as stem cells or growth factors, with TMR may provide greater angina reduction, and improve cardiac function in patients with diffuse coronary artery disease who are not candidates for surgical bypass or intervention. The Phoenix System has received CE Mark designation allowing commercial distribution into the European Community. CryoLife intends to conduct a pilot clinical evaluation in select European countries in 2012 while also investigating requirements to achieve an IDE approval for clinical evaluation of the Phoenix System in the U.S.

Research and Business Development

Through its continuing research and development activities, CryoLife uses its expertise in protein chemistry, biochemistry, cell biology, and engineering, and its understanding of the cardiac and vascular surgery medical specialties to develop useful technologies, services, and products. In addition, CryoLife uses this expertise to acquire and license supplemental and complimentary products and technologies. CryoLife seeks to identify market areas that can benefit from medical devices, preserved tissues, and other related technologies, to develop innovative products and techniques within these areas, to secure their commercial protection, to establish their efficacy, and then to market these products and techniques. In order to expand CryoLife s service and product offerings, the Company is in the process of developing or investigating several products and technologies. Some of the products in development have not been subject to completed clinical trials and have not received FDA or other regulatory approval, so CryoLife may not derive any revenues from them. CryoLife performs significant research and development work before offering its services and products, building on either existing proprietary and non-proprietary knowledge or acquired technology and know-how. The Company s current tissue preservation services were developed internally. The Company developed its BioGlue and BioFoam products from a technology originally developed by a third party and acquired by CryoLife. The Company purchased the rights to distribute and manufacture PerClot from a third party and is in the process of obtaining FDA approval to distribute PerClot in the U.S. The Company acquired Cardiogenesis and its revascularization technologies and is in the process of conducting preclinical and clinical evaluations of the Phoenix system.

Risk Factors

CryoLife s business is subject to a number of risks. See Part I, Item 1A, Risk Factors below for a discussion of these and other risk factors.

Strategy

The key elements of the Company s strategy relate to growing its business and leveraging its strengths and expertise in its core marketplaces in order to generate revenue and earnings growth. These key elements are described below:

Identify and Evaluate Acquisition and Investment Opportunities of Complementary Product Lines and Companies. Leverage the Company s current distribution channel and its expertise in the cardiac and vascular medical specialties by selectively pursuing the potential acquisition, licensing, or distribution rights of additional technologies that complement existing services and products. Identify potential investment opportunities in companies that have complementary products that could, in the future, enhance the Company s current distribution channel and expertise in the cardiac and vascular specialties.

Expand Core Business. Expand the Company s core business in cardiac and vascular medical specialties by expanding the market penetration of heart valves, cardiac patch tissues, vascular tissues, BioGlue, BioFoam, PerClot, and revascularization technologies.

Develop the Company s Pipeline of Services and Products. Develop the Company s technologies and intellectual property for additional service and product offerings and commercialization of new services and products.

License Company Technology to Third Parties for Non-Competing Uses. Leverage the Company s current technology platforms, including its protein hydrogel technology (PHT) platform and SynerGraft technology, in medical specialties other than cardiac and vascular surgery through strategic alliances, licenses, or distribution arrangements for additional indications or product line extensions. The Company considers licensing or distribution opportunities for existing products or for products in its research and development pipeline if the Company determines that licensing or distribution opportunities could enhance shareholder value.

Analyze and Identify Underperforming Assets for Potential Sale or Disposal. Continue to analyze and identify underperforming assets not complementary to the strategies identified above for potential sale or disposal.

As a result of the above strategies, the Company has pursued several opportunities in the past few years that have resulted in the acquisition of PerClot technologies in September 2010 and 2011 and the acquisition of Cardiogenesis and its revascularization technologies in May 2011, as discussed above. Additionally, in July 2011 the Company purchased approximately 2.4 million shares of Series A Preferred Stock of ValveXchange, Inc. (ValveXchange) for approximately $3.5 million. ValveXchange is a private medical device company that was spun off from Cleveland Clinic to develop a lifetime heart valve replacement technology platform featuring exchangeable bioprosthetic leaflets. CryoLife s investment represents an approximate 19% equity ownership in ValveXchange. Additionally, the Company entered into an agreement with ValveXchange to make available up to $2.0 million to ValveXchange in debt financing through a revolving credit facility.

Services and Products

Preservation Services

The Company s proprietary preservation process involves the recovery of tissue from deceased human donors by tissue banks and organ procurement organizations (OTPOs), the timely and controlled delivery of such tissue to the Company, the screening, dissection, disinfection, processing, and preservation of the tissue by the Company, and the storage and shipment of the preserved tissue. In the operating room, the tissue undergoes a controlled thawing process under the supervision of the medical staff. Thereafter, the tissue is surgically implanted by a surgeon into a human recipient.

The transplant of human tissue that has not been preserved must be accomplished within extremely short time limits. Prior to the advent of human tissue cryopreservation, these time constraints resulted in the inability to use much of the tissue donated for transplantation. The application of the Company s cryopreservation technologies to donated tissue expands the amount of human cardiac and vascular tissues available to physicians for transplantation. Cryopreservation also expands the treatment options available to physicians and their patients by offering alternatives to implantable mechanical, synthetic, and animal-derived devices. The tissues currently preserved by the Company include heart valves, cardiac patch tissues, and vascular tissues.

CryoLife collects and maintains clinical data on the use and effectiveness of implanted human tissues that it has preserved and shares this data with implanting physicians and the OTPOs from which it receives tissue. The Company also uses this data to help direct its continuing efforts to improve its preservation services through ongoing research and development. Its physician relations and education staff, clinical research staff, and field representatives assist physicians by providing educational materials, seminars, and clinics on methods for handling and implanting the tissue preserved by the Company and the clinical advantages, indications, and applications for those tissues. The Company has ongoing efforts to train and educate physicians on the indications for, and uses of, the human tissues preserved by the Company. In addition, the Company sponsors programs where surgeons train other surgeons in best-demonstrated techniques. The Company also assists OTPOs through training and development of protocols and provides materials to improve their tissue recovery techniques and, thereby, increase the yield of usable tissue.

Cardiac Tissue. The human heart valves and cardiac patch tissues preserved by the Company are used in cardiac reconstruction and heart valve replacement surgeries. The Company currently preserves human aortic and pulmonary heart valves for implantation by cardiac surgeons. In addition, the Company preserves human cardiac patches for surgeons who wish to perform certain specialized cardiac repair procedures. The Company currently preserves human cardiac patches in three primarily anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch. Each of these preserved cardiac tissues maintains a structure which more closely resembles and simulates the performance of the patient s own tissue compared to non-human tissue alternatives.

In 2008 CryoLife received 510(k) clearance from the FDA for its CryoValve SGPV, and in 2009 CryoLife received 510(k) clearance from the FDA for its CryoPatch SG, both processed with the Company's proprietary SynerGraft technology. CryoLife uses the SynerGraft technology for a portion of its pulmonary valve and cardiac patch processing. In 2011 66% of pulmonary valves and 27% of cardiac patch tissues shipped by CryoLife were processed with the SynerGraft technology.

Based on CryoLife s records of documented implants, management believes that the acceptance of the Company s heart valves is due in part to physicians recognition of the longevity and natural functionality of the Company s cardiac tissues, the Company s documented clinical data, and the support of the Company s physician relations and education staff, clinical research staff, customer service department, and field representatives. Management believes the Company offers advantages in the areas of clinical data and field services as compared to other human tissue processors and that the Company s tissues offer advantages in certain areas over mechanical, porcine, and bovine heart valve alternatives. Management believes preserved human heart valves and cardiac patch tissues have characteristics that make them the preferred replacement option for many patients. Specifically, human heart valves, such as those preserved by the Company, allow for more normal blood flow and provide higher cardiac output than stented porcine, bovine, and mechanical heart valves. Human heart valves are not as susceptible to progressive calcification, or hardening, as are traditional glutaraldehyde-fixed porcine and bovine heart valves, and do not require anti-coagulation drug therapy, as do mechanical valves. The synthetic sewing rings contained in mechanical and stented porcine and bovine valves may harbor bacteria and lead to endocarditis. Furthermore, prosthetic valve endocarditis can be difficult to treat with antibiotics, and this usually necessitates the surgical removal of these valves at considerable cost, morbidity, and risk of mortality. Consequently, for many physicians, human heart valves are the preferred alternative to mechanical and animal-derived tissue valves for patients who have or are at risk to contract endocarditis.

CryoLife shipped approximately 77,600 heart valves and cardiac patch tissues from 1984 through 2011, including approximately 3,000 shipments in 2011. Revenues from cardiac tissue preservation services accounted for 22%, 24%, and 23% of total Company revenues in 2011, 2010, and 2009, respectively. The Company estimates that in 2011 the total annual heart valve replacement and cardiac patch market in the U.S. was approximately $875 million. Management believes that of the $875 million, approximately $650 million or 75% of the procedures were for aortic, pulmonary, and tricuspid valve replacements for which the Company s tissues can be used. The Company believes that approximately 94,000 aortic, pulmonary, and tricuspid valve replacement surgeries were conducted in the U.S. in 2011.

Vascular Tissue. The human vascular tissues preserved by the Company, including the CryoVein and CryoArtery, are used to treat a variety of vascular reconstructions such as peripheral bypass, hemodialysis access, and aortic infections which have saved the lives and limbs of patients. The Company preserves small diameter human saphenous vein conduits (3mm to 6mm) for use in peripheral vascular reconstructions. Failure to achieve revascularization of an obstructed vessel may result in the loss of a limb or even death of the patient. When patients require peripheral bypass surgery, the surgeon s first choice generally is the patient s own vein tissue. However, in cases of advanced vascular disease, 30% of patients have unsuitable vein tissue for transplantation, and the surgeon must consider using synthetic grafts or preserved human vascular tissue. Small diameter synthetic vascular grafts are generally not optimal for below-the-knee surgeries because they have a tendency to obstruct over time. Preserved human vascular tissues tend to remain open longer and as such are used in indications where synthetics typically fail. In addition, synthetic grafts are not suitable for use in infected areas since they may harbor bacteria and are difficult to treat with antibiotics. Preserved human vascular tissues have advantages for patients with previously infected graft sites. The Company also preserves femoral veins and arteries and aortoiliac arteries for bypass, hemodialysis access, or reconstruction within infected surgical areas.

The Company shipped approximately 66,100 human vascular tissues from 1986 through 2011, including approximately 4,500 shipments in 2011. Revenues from vascular preservation services accounted for 28%, 27%, and 27% of total Company revenues in 2011, 2010, and 2009, respectively. The Company estimates the aggregate U.S. vascular surgical graft market was approximately $120 million in 2011.

Medical Devices

PHT Platform

The effective closure of internal wounds following surgical procedures is critical to the restoration of the function of tissue and to the ultimate success of the surgical procedure. Failure to effectively seal surgical wounds can result in leakage of blood in cardiac surgeries, air in lung surgeries, cerebral spinal fluid in neurosurgeries, and gastrointestinal contents in abdominal surgeries. Air and fluid leaks resulting from surgical procedures can lead to significant post-operative morbidity resulting in prolonged hospitalization, higher levels of post-operative pain, higher costs, and a higher mortality rate.

Sutures and staples facilitate healing by joining wound edges and allowing the body to heal naturally. However, because sutures and staples do not have inherent sealing capabilities, they cannot consistently eliminate air and fluid leakage at the wound site. This is particularly the case when sutures and staples are used to close tissues containing air or fluids under pressure, such as in blood vessels, the lobes of the lung, the dural membrane surrounding the brain and spinal cord, and the gastrointestinal tract. In some cases, the tissues may be friable, which complicates the ability to achieve closure. In addition, in minimally invasive surgical procedures where the physician must operate through small access devices, it can be difficult and time consuming for the physician to apply sutures and staples. The Company believes that the use of surgical adhesives and sealants with or without sutures and staples could enhance the efficacy of these procedures through more effective and rapid wound closure. In order to address the inherent limitations of sutures and staples, the Company developed and commercialized its PHT. PHT is based on a bovine protein that mirrors an array of amino acids that perform complex functions in the human body. Together with a cross-linker, the protein forms a hydrogel, a water-based biomaterial in some ways similar to human tissue. Materials and implantable replacement devices created with PHT may have the potential to provide structure, form, and function similar to certain human tissues.

BioGlue. BioGlue is the first product to be developed from the Company s PHT platform. BioGlue is a polymeric surgical adhesive based on bovine blood protein and an agent for cross-linking proteins. BioGlue has a tensile strength that is four to five times that of fibrin sealants. BioGlue begins to polymerize within 20 to 30 seconds and reaches its bonding strength within two minutes. BioGlue is pre-filled in 2ml, 5ml, and 10ml volumes. BioGlue is dispensed by a controlled delivery system that consists of either a reusable delivery device and disposable syringe or a disposable syringe alone. Both systems use an assortment of applicator tips (standard size tips, 12mm and 16mm spreader tips, and 10cm and 27cm extender tips). CryoLife is in the process of obtaining approvals for another more rigid delivery tip extender (DTE) which will be available in a variety of lengths to accommodate different surgical needs. The DTE has received approval in Canada and is under review for CE Mark and FDA approvals.

CryoLife is authorized to distribute BioGlue throughout the U.S. and in more than 75 other countries for designated applications. In the U.S., BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. The Company estimates that aggregate U.S. sales for surgical internal tissue sealants were approximately $294 million in 2011.

CryoLife distributes BioGlue under CE Mark product certification in the EEA for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). CryoLife has also received approval and distributes BioGlue for soft tissue repairs in Canada, Brazil, and Australia and for the repair of aortic dissections in Japan. Additional marketing approvals have been granted for specified applications in several other countries throughout the world.

Revenues from BioGlue represented 41%, 41%, and 43% of total Company revenues in 2011, 2010, and 2009, respectively.

BioFoam. BioFoam is the second product to be developed from the Company s PHT platform. BioFoam is a protein hydrogel biomaterial with an expansion agent which generates a mixed-cell foam. The foam creates a mechanical barrier to decrease blood flow and develops pores for the blood to enter, leading to cellular aggregation and enhanced hemostasis. It is easily applied and could potentially be used intraoperatively to control internal organ hemorrhage, limit blood loss, and reduce the need for future re-operations in liver resections.

BioFoam received CE Mark certification in August 2009 for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) when cessation of bleeding by ligature or conventional methods is ineffective or impractical. CryoLife began a controlled launch of BioFoam at three clinical centers in Europe in 2009 and in 2010 began distribution of BioFoam in Europe. CryoLife plans to begin distribution of BioFoam in other international markets as required regulatory approvals are obtained.

BioFoam received initial approval by the FDA in October 2009 for an IDE to conduct a human clinical trial with BioFoam to help seal liver tissue in patients for whom cessation of bleeding by ligature or other conventional methods is ineffective or impractical. CryoLife received approval by the U.S. Department of Defense (DOD) in April 2010 to move forward with obtaining necessary Institutional Review Board (IRB) approvals using the FDA approved protocol. The DOD granted approval for the initial clinical trial investigation site in September 2010 and patient screening was initiated in October 2010. The first patient was enrolled into the trial in 2011. Due to slower than expected enrollment, CryoLife worked with the FDA to further modify the protocol to enhance the ability to enroll patients. This protocol amendment was approved in the fourth quarter of 2011 and is currently being implemented. This feasibility trial will involve 20 patients at three centers in the U.S. Upon successful completion of the feasibility study, a follow-on multi-center, randomized, and

controlled pivotal study will be conducted. The Company anticipates that the pilot study and a portion of the follow-up will be funded by grants from the DOD.

Revenues from BioFoam represented less than 1% of total Company revenues in 2011. The Company estimates that the aggregate European market opportunity for BioFoam is approximately $30 million and approximately $100 million worldwide.

Hemostatic Agents

Hemostatic agents are frequently utilized as an adjunct to sutures and staples to control inter-operative bleeding. Hemostatic agents prevent excess blood loss and can help maintain good visibility of the operative site. These products can, in many instances, reduce operating room time and decrease the number of blood transfusions required in surgical procedures. Hemostatic agents are available in various forms including pads, sponges, liquids, and powders.

Revenues from hemostatic agents represented 4% of total Company revenues in 2011. The Company estimates that aggregate U.S. sales for hemostatic agents were approximately $800 million in 2011.

PerClot. PerClot is an absorbable, powdered hemostatic agent used in surgery. The PerClot technology modifies plant starch into ultra-hydrophilic adhesive forming hemostatic polymers. PerClot particles are biocompatible, absorbable polysaccharides containing no animal or human components. Utilizing this purified plant source material aids in minimizing the risks of infection and bleeding-related complications during surgery. PerClot particles have a molecular structure that rapidly absorbs water from blood, creating a high concentration of platelets, red blood cells, and coagulation proteins at the bleeding site, which accelerates the physiologic clotting cascade. Upon contact with blood, PerClot rapidly produces a gelled matrix that adheres to and forms a mechanical barrier with the bleeding tissue. Easy to apply, PerClot does not require additional operating room preparation or special storage conditions. PerClot is readily dissolved by saline irrigation and is totally absorbed within several days. PerClot is currently available in 1 gram, 3 gram, and 5 gram sizes with a 100mm or 200mm applicator tip. PerClot Laparoscopic is available in 1 gram and 3 gram sizes with a 380mm applicator tip.

In September 2010 CryoLife entered into a worldwide distribution agreement and a license and manufacturing agreement with SMI for PerClot, which has CE Mark designation allowing commercial distribution into the European Community and other markets. It is indicated for use in surgical procedures, including cardiac, vascular, orthopaedic, neurological, gynecological, ENT, and trauma surgery as an adjunct hemostat when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical.

CryoLife filed an IDE with the FDA in March 2011 seeking approval to begin clinical trials for the purpose of obtaining a PMA to distribute PerClot in the U.S. In April 2011 the FDA disapproved CryoLife s IDE filing. CryoLife anticipates re-filing its IDE for PerClot in early 2012.

CryoLife began distributing PerClot in Europe in the fourth quarter of 2010. Revenues for PerClot represented approximately 2% of total Company revenues in 2011. CryoLife plans to begin distribution of PerClot in other international markets as required regulatory approvals are obtained.

HemoStase. CryoLife distributed HemoStase under a private label EDA with Medafor from May 2008 to March 2011. Medafor fully, finally, and effectively terminated the agreement. CryoLife believes this termination was wrongful. Revenues for HemoStase represented 2%, 8%, and 5% of total Company revenues in 2011, 2010, and 2009, respectively. See Part I, Item 3, Legal Proceedings.

Revascularization Technologies

CryoLife s subsidiary, Cardiogenesis, markets the TMR system, which includes the Holmium: YAG laser console and single use, fiber-optic handpieces. The system is FDA approved for performing a surgical procedure known as TMR for treating patients with stable angina that is not responsive to conventional therapy. Patients undergoing TMR treatment with Cardiogenesis products have been shown to have angina reduction, longer event-free survival, reduction in cardiac related hospitalizations, and increased exercise tolerance.

During TMR, the surgeon uses one of the flexible, fiber-optic handpieces to deliver precise bursts of Holmium: YAG laser energy directly to an area of heart muscle that is suffering from ischemic heart disease. This condition can manifest itself with severe persistent chest pain, or chronic angina. The surgical procedure is performed through a small incision or small ports with the patient under general anesthesia. The surgeon can position the laser fiber on the surface of the beating

heart. It takes approximately 6 to 10 pulses of the laser to transverse the myocardium and create channels one millimeter in diameter. During a typical procedure, approximately 20 to 40 channels are made in the heart muscle.

The outside punctures seal over with little blood loss while the new channels allow fresh blood to perfuse the heart wall immediately and may provide oxygen in the process. Published research shows evidence that these channels promote the growth of new blood vessels or angiogenesis over time. That, in turn, provides the damaged heart tissue a better supply of blood and oxygen. Angina usually subsides with improved oxygen supply to the targeted areas of the damaged heart muscle.

SolarGen 2100s Console. The SolarGen 2100s Console implements advanced electronic and cooling system technology to greatly reduce the size and weight of the unit, while providing 115V power capability. The SolarGen 2100s was approved by the FDA in 2004 and received a CE Mark in 2005. The Company provides service plan options to ensure that the laser console is operating within the critical factory specifications and to protect the customer s investment.

SoloGrip® III. The SoloGrip III handpiece contains multiple, fine fiber-optic strands in a one millimeter diameter bundle. The flexible fiber-optic delivery system combined with the ergonomic handpiece provides access for treating all regions of the left ventricle. The SoloGrip III handpiece fiber-optic delivery system has an easy to install connector that screws into the laser base unit, and the device is pre-calibrated in the factory so it requires no special preparation. The SoloGrip III handpiece received FDA approval in 1999 and received a CE Mark in 1997.

PEARL 5.0. The minimally invasive Port Enabled Angina Relief with