CRYOLIFE INC
Form 10-K
February 16, 2016
Table of Contents

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, 2015

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

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 non-accelerated 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, 2015 the aggregate market value of the voting stock of the Registrant held by non-affiliates of the registrant was $285,707,713 computed using the closing price of $11.28 per share of Common Stock on June 30, 2015, 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 11, 2016 the number of outstanding shares of Common Stock of the registrant was 32,254,625.

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, 2015.

Table of Contents

TABLE OF CONTENTS

2

Table of Contents

Forward-Looking Statements

We have made forward-looking statements in this Form 10-K that are within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. Forward-looking statements give our current expectations or forecasts of future events. The words could, may, might, will, would, shall, should, pro forma, potential, pending, intend, believe, expect, anticipate, estimate, plan, future, and other similar expressions generally identify forwarding-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned not to place undue reliance on these forward-looking statements. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions, including, without limitation, in addition to those identified in the text surrounding such statements, those identified under Part I, Item 1A, Risk Factors and elsewhere in this Form 10-K.

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

Our beliefs and estimates regarding the potential benefits and additional applications of our surgical adhesives, sealants, hemostats, CardioGenesis cardiac laser therapy, On-X heart valves, PhotoFix, and ProCol products;

Our estimates regarding specific country and worldwide market opportunities for certain types of procedures and products, and our products and tissues;

Our beliefs and estimates regarding our competitors in various geographic, procedure, and product markets, including non-profit competitors;

Our beliefs regarding the potential for competitive products and services to affect the market for our products and services;

Our beliefs regarding the enhanced efficacy of certain procedures provided by using our surgical sealants;

Our plans, costs, and expected timeline regarding regulatory approval for PerClot in the U.S. and additional international markets and the distribution of PerClot in those markets after the requisite regulatory approvals are obtained; and the Company s expectation that it will terminate its minimum purchase requirements after regulatory approval of PerClot;

Our expectations regarding the benefits of the Company s marketing, educational and technical support efforts;

Our beliefs regarding the advantages of the human tissues, heart valves, and other products we preserve and distribute;

The anticipated effect of suppliers /sources inability to deliver critical raw materials or tissues and/or us having to source supply from an alternate supplier;

Our beliefs regarding the importance of, and competitive advantages associated with, our relationships with tissue procurement organizations;

Our belief regarding our compliance with NOTA, state licensing requirements, and environmental laws and regulations;

Our belief that countries in which we distribute our products and tissue may perform inspections of our facilities to ensure compliance with local country regulations;

Our belief that there can be no assurance that the German authorities will continue to allow shipments of our tissues under a special access program in the future;

Our potential attempt to license certain products to corporate partners for further development or seek funding from outside sources to continue commercial development when additional applications for such products are identified, and our potential attempt to acquire or license additional technologies from third-parties to supplement our product lines;

Our plans and expectations regarding research and development of new technologies and products;;

Our expectation to complete the final study report for BioFoam s use in cardiovascular applications in the first quarter of 2016;

Our beliefs regarding the adequacy of, and competitive advantages conferred by, our intellectual property protections;

Table of Contents

Management s beliefs regarding the state of relations with our employees;

Our belief that U.S. and international healthcare policy and regulatory changes may have a material adverse effect on our business;

The potential impact of the FDA s classification of CryoValve SGPV as a class III device;

Our expectations regarding the limitations on the recoverability of our acquired net operating loss carryforwards in future periods;

Our plans regarding acquisition and investment opportunities of complementary product lines and companies;

Our belief that a significant change in management s estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by us and, therefore, could materially impact our financial position and profitability;

Our assessment of the effects of adopting new accounting standards regarding the recognition of revenue from contracts with customers, the simplified measurement of inventory, and the balance sheet classification of deferred taxes;

Our potential plan to pursue expanded U.S. indications for BioGlue and our beliefs regarding the international growth opportunities that would be provided by obtaining regulatory approval for BioGlue in China;

Our beliefs regarding the seasonal nature of the demand for some of our products and services;

The adequacy of our financial resources and our belief that we will have sufficient cash to meet our operational liquidity needs for at least the next twelve months;

The anticipated impact on cash flows of us undertaking significant business development activities in 2016 and the potential need to obtain additional borrowing capacity or financing;

The future cash requirements that we anticipate may have a significant effect on our cash flows during 2016;

Our belief that if we are unable to secure full satisfaction or repayment of the amounts owed to us by Hancock Jaffe related to the ProCol product line, or sell our interest in the agreement for an amount equal to or in excess of the carrying value of the related assets, the prepayment may become impaired in future periods;

Issues that may affect our future financial performance and cash flows; and

Other statements regarding future plans and strategies, anticipated events, or trends.

These forward-looking statements are based on certain of our assumptions and analyses in light of our experience and our perception of historical trends, current conditions, and expected future developments as well as other factors we believe are appropriate in the circumstances. However, whether actual results and developments will conform with our expectations and predictions is subject to a number of risks and uncertainties which could cause actual results to differ materially from our expectations, including, without limitation, in addition to those specified in the text surrounding such statements, the risk factors discussed in Item 1A of this Form 10-K and other factors, many of which are beyond our control. Consequently, all of the forward-looking statements made in this Form 10-K are qualified by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, our business or operations. We assume no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events, or otherwise.

Table of Contents

PART I

Item 1. Business.

Overview

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, is a leader in medical device manufacturing and distribution and in the processing and distribution of implantable human tissues for use in cardiac and vascular surgeries. 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 internationally for Starch Medical, Inc. (SMI). CryoLife s CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used for the treatment of coronary artery disease in patients with severe angina. CryoLife is the exclusive distributor of ProCol® Vascular Bioprosthesis (ProCol) for Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). CryoLife marketed the Hemodialysis Reliable Outflow Graft (HeRO® Graft) through February 3, 2016. Both HeRO Graft and ProCol are solutions for end-stage renal disease (ESRD) in certain hemodialysis patients. CryoLife is the exclusive distributor of PhotoFix™ for Genesee Biomedical, Inc. (GBI). PhotoFix is a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both of which are processed using CryoLife s proprietary SynerGraft® technology.

Recent Events

Acquisition of On-X Life Technologies

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

The On-X catalogue of products includes the On-X prosthetic aortic and mitral heart valve and the On-X ascending aortic prosthesis (AAP). On-X also distributes CarbonAid CO_2 diffusion catheters, manufactures Chord-X ePTFE sutures for mitral chordal replacement, and offers pyrolytic carbon coating services to other medical device manufacturers.

The On-X heart valve is a bileaflet mechanical valve composed of a graphite substrate coated with On-X s pyrolytic carbon coating. The On-X heart valve is available for both aortic and mitral indications and with a variety of sewing ring options to suit physician s preferences. The On-X AAP is an On-X aortic valve combined with a Vascutek Gelweave Valsava™ Graft to allow physicians to more conveniently treat patients requiring both an aortic valve replacement and an aortic graft.

All mechanical valve patients require anticoagulation therapy with warfarin which creates a risk of harmful bleeding. The On-X aortic heart valve is the only mechanical valve U.S. Food and Drug Administration (FDA) approved and clinically proven to be safer with less warfarin. In a prospective randomized clinical trial comparing reduced warfarin to standard warfarin dose in On-X aortic heart valve patients, the reduced warfarin dose group had 65% fewer harmful bleeding events without an increase in stroke risk.

The On-X heart valve is FDA approved for the replacement of diseased, damaged, or malfunctioning native or prosthetic heart valves in the aortic and mitral positions, and is classified as a Class III medical device. On-X

distributes the On-X heart valve under Conformité Européene Mark product certification (CE Mark) in the EEA. Additional marketing approvals have been granted in several other countries throughout the world. On-X s heart valves compete primarily with mechanical valves from St. Jude Medical, Inc., Medtronic, Inc., and LivaNova PLC based on its benefits and features, such as its lower warfarin requirement, low turbulence, and increased thromboresistance.

The On-X facility consists of approximately 75,000 square feet of combined manufacturing, warehouse, and office space in Austin, Texas. As of December 31, 2015 On-X had approximately 135 employees.

Divestiture of the HeRO Graft Product Line

On February 3, 2016 the Company sold its HeRO Graft product line to Merit Medical Systems, Inc. (Merit) for $18.5 million in cash. Under terms of the agreement, Merit acquired the HeRO Graft product line, including worldwide marketing

Table of Contents

rights, customer relationships, intellectual property, inventory, and certain property and equipment. The Company will continue to manufacture the HeRO Graft for up to six months under a transition supply agreement, after which Merit will be responsible for manufacturing. The disposal of the HeRO Graft is part of a strategic shift of the Company to focus on cardiac surgery products, including the On-X heart valve.

The HeRO Graft product line was included as part of the Company s Medical Devices segment. The Company is in the process of completing the accounting related to this sale, including an allocation of its medical device segment goodwill to the divested business using a relative fair value allocation method. The Company anticipates recording a gain on the transaction upon the completion of the accounting. The assets divested in this transaction did not meet the criteria to be reported as assets held for sale as of December 31, 2015.

Corporate Structure

CryoLife s main operating subsidiaries include CryoLife Europa Ltd. (Europa), established in 2000 to provide marketing and distribution support in the European Economic Area (EEA), the Middle East, and Africa (collectively EMEA), CryoLife Asia Pacific, Pte. Ltd. (CryoLife Asia Pacific), established in Singapore in 2013 to provide sales and marketing support for the Asia Pacific region, CryoLife France, SAS, established in 2015 to provide direct sales operations in France, and On-X, acquired on January 20, 2016 as discussed above. CryoLife acquired Cardiogenesis Corporation and its cardiac laser therapy product line in May 2011 and Hemosphere, Inc. (Hemosphere) and its HeRO Graft product in May 2012. These companies were operated as subsidiaries of CryoLife from their respective acquisition dates until December 31, 2014, when they were merged into the CryoLife, Inc. parent entity.

Segments and Geographic Information

CryoLife has two reportable segments organized according to its products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Graft, and ProCol. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. See also Part II, Item 8, Note 19 of the Notes to Consolidated Financial Statements for further information on the Company s segments and for the Company s geographic information.

Strategy

The Company s strategic plan is focused on four growth vectors in the cardiac surgery space which are expected to drive the Company s business expansion in the near term. These growth vectors and their key elements are described below:

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

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

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

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

Products, Services, Markets, and Competition

The Company s products and preservation services are used to treat a variety of medical conditions. A discussion of each market in which the Company competes and a description of the Company s products and/or services that compete within each market are discussed below.

The Company faces competition from several domestic and international medical device, pharmaceutical, and biopharmaceutical companies and from both for profit and non-profit tissue banks. Many of the Company s current and potential competitors have substantially greater financial and personnel resources than the Company. These competitors may also have greater experience in developing products, procuring tissues, conducting clinical trials, and obtaining regulatory approvals and may have large contracts with hospitals under which they can impose purchase requirements that place the

Table of Contents

Company s products at a disadvantage. Certain of these competitors may obtain patent protection or approval or clearance by the FDA or foreign regulators earlier than the Company. The Company may also compete with companies that have superior manufacturing efficiency, tissue processing capacity, and/or marketing capabilities. Additional competitive products may be under development which could compete with the Company s products or services in the future. There can be no assurance that the Company s current or future competitors will not succeed in developing alternative technologies, products, or services that have significant advantages over those that have been, or are being developed, by the Company or that would render the Company s products or technology obsolete and non-competitive. Any of these competitive disadvantages could materially, adversely affect the Company. Specific competitive products currently on the market are discussed in the sections below.

Surgical Sealants

Closing internal wounds effectively 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, cerebrospinal fluid in neurosurgeries, and gastrointestinal contents in abdominal surgeries. Fluid, air, and content leakage resulting from surgical procedures can lead to prolonged hospitalization, higher levels of post-operative pain, higher costs, and a higher mortality rate.

Sutures and staples facilitate healing by joining wound edges to allow the body to heal naturally. However, sutures and staples cannot consistently eliminate air and fluid leakage at the wound site, particularly when 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, it can be difficult and time consuming for the physician to apply sutures and staples in minimally invasive surgical procedures where the physician must operate through small access openings. 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 protein hydrogel technology (PHT) platform. The PHT platform 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 somewhat 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. CryoLife developed and currently markets the surgical sealants BioGlue and BioFoam from its PHT platform.

BioGlue

CryoLife s proprietary product, BioGlue, is a polymer consisting of bovine blood protein and an agent for cross-linking proteins, which was developed for use in cardiac, vascular, pulmonary, and general surgical applications. BioGlue has a tensile strength that is four to five times that of fibrin sealants, and it is stronger than other cardiovascular sealants. BioGlue begins to polymerize within 20 to 30 seconds and reaches its bonding strength within two minutes. BioGlue is dispensed by a controlled delivery system that consists of a disposable syringe, which may be used with, or without, a multi-use delivery device, and various applicator tips. BioGlue is pre-filled in 2ml, 5ml, and 10ml volumes. Applicator tips are available in standard size, 12mm and 16mm spreader tips, 10cm and 27cm flexible extender tips, and 10cm, 27cm, and 35cm delivery tip extenders.

BioGlue is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. CryoLife distributes BioGlue under Conformité Européene Mark product certification (CE Mark) in the EEA for repair of soft tissues (which include cardiac, vascular, pulmonary, and additional soft tissues). CryoLife also distributes BioGlue in Japan which is indicated for adhesion and support of hemostasis for aortotomy closure sites,

suture/anastomosis sites (including aortic dissection and anastomosis sites with use of a prosthetic graft), and suture sites on the heart. Additional marketing approvals have been granted for specified applications in several other countries throughout the world.

CryoLife distributes BioGlue throughout the U.S. and in approximately 80 other countries. Revenues from BioGlue represented 40%, 43%, and 41%, of total Company revenues in each of 2015, 2014, and 2013, respectively.

The Company s BioGlue products compete primarily with sealants from Baxter International, Inc., Ethicon, Inc. (a Johnson & Johnson Company), Integra LifeSciences Holdings Corporation, C.R. Bard, Inc. (Bard), and Mallinckrodt PLC. The Company s BioGlue competes with these products based on its benefits and features, such as strength and ease of use.

Table of Contents

BioFoam

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. BioFoam was developed to rapidly seal organs, such as the liver, and for use in cardiovascular surgeries, and may provide hemostasis in penetrating wounds and trauma. It is easily applied and could potentially be used intra-operatively to control internal organ hemorrhage, limit blood loss, and reduce the need for future re-operations in liver resections.

CryoLife distributes BioFoam in Europe under a CE Mark for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) and as an adjunct to hemostasis in cardiovascular surgery when cessation of bleeding by ligature or other conventional methods is ineffective or impractical.

CryoLife distributes BioFoam in approximately 44 countries, primarily in Europe. Revenues from BioFoam represented less than 1% of total Company revenues in each of 2015, 2014, and 2013.

The Company s BioFoam product competes with sealants from Pfizer, Inc., Baxter International, Inc., Ethicon, Inc., Bard, and Orthovita, Inc. The Company s BioFoam product competes on the basis of its clinical efficacy and ease of use.

Hemostats

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 may 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. CryoLife currently markets the hemostatic agent PerClot.

PerClot

PerClot is an absorbable powdered hemostat, consisting of plant starch modified into ultra-hydrophilic, adhesive-forming hemostatic polymers. PerClot granules are biocompatible, absorbable polysaccharides containing no animal or human components. The purified plant source material helps to minimize the risks of infection and bleeding-related complications during surgery. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier to further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) at the site of application. This gelled adhesive matrix promotes the normal physiological clotting cascade. PerClot does not require additional operating room preparation or special storage conditions and is easy to apply. PerClot is readily dissolved by saline irrigation and is totally absorbed by the body within several days. PerClot is currently available in 1 gram, 3 gram, and 5 gram configurations with a 100mm or 200mm applicator tip for certain sizes. PerClot Laparoscopic is available in a 3 gram configuration with a 380mm applicator tip. In September 2010 CryoLife entered into a distribution agreement and a license and manufacturing agreement with SMI, which allows CryoLife to distribute PerClot worldwide, except in China, Hong Kong, Macau, Taiwan, North Korea, Iran, and Syria.

PerClot has a CE Mark allowing commercial distribution into the EEA and other markets. PerClot 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, venular, or arteriolar vessels by pressure, ligature, and other conventional means is either ineffective or impractical. CryoLife distributes PerClot in Europe and

other international countries. CryoLife plans to begin distribution of PerClot in additional international markets as required regulatory approvals are obtained.

In April 2014 CryoLife received 510(k) clearance from the FDA to market PerClot Topical in the U.S. PerClot Topical is a version of the Company s PerClot product, which was manufactured by the Company at its headquarters and labeled for use in certain topical indications. CryoLife launched PerClot Topical in August 2014. However, in March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot, including PerClot Topical, in the U.S. in accordance with the U.S. District Court for the District of Delaware (the Court) order that granted the motion of Medafor Inc. (Medafor) for a preliminary injunction in its patent dispute with CryoLife. In November 2015 CryoLife and Medafor entered into a resolution to end this patent dispute. As part of the resolution, the Court s preliminary injunction entered in March 2015 precluding CryoLife s marketing, sale, or distribution of PerClot in the U.S. will remain in effect until the expiration of Medafor s U.S. Patent No. 6,060,461 (the 461 Patent) on February 8, 2019. See Part I, Item 3, Legal Proceedings for discussion of the Company s litigation with Medafor.

Table of Contents

CryoLife has received approval to begin clinical trials for the purpose of obtaining FDA Premarket Approval (PMA) to distribute PerClot in the U.S., as discussed further in Research and Development and Clinical Research below.

CryoLife distributes PerClot in approximately 58 countries. Revenues from PerClot represented 3% of total Company revenues in each of 2015, 2014, and 2013, respectively.

The Company s PerClot products compete with various hemostats including thrombin products from Pfizer, Inc., Mallinckrodt PLC, and Ethicon, Inc., and surgical hemostats from Pfizer, Inc., Bard, Baxter International, Inc., Ethicon, Inc., and BioCer Entwicklungs-GmbH. Other competitive products may include argon beam coagulators, which provide an electrical source of hemostasis. A number of companies have surgical hemostat products under development. The Company s PerClot Topical product competes with many of the same products listed above, but also competes with products from Medtronic, Inc., Polyganics B.V., and Hemostasis, LLC, as well as gauze and chemical cauterization. The Company s PerClot products compete on the basis of safety, clinical efficacy, absorption rates, and ease of use.

Angina Treatment

Angina consists of pressure, discomfort, and/or pain in the chest typically due to narrowed or blocked arteries, resulting in ischemic heart disease. Patients with severe angina are often treated with surgical procedures including angioplasty or coronary artery bypass or with medications such as aspirin, nitrates, beta blockers, statins, or calcium channel blockers. Pain may be chronic or may become pronounced with exercise. Angina can also be treated with Transmyocardial Revascularization (TMR), a procedure that can be performed as an open surgical procedure or through a minimally invasive surgery either as a stand-alone procedure or concurrently with coronary artery bypass. During TMR, the surgeon uses a disposable handpiece to deliver precise bursts of laser energy directly to an area of heart muscle that is suffering from ischemic heart disease through a small incision or small ports with the patient under general anesthesia and without stopping the heart. TMR is typically performed with a CO_2 or Holmium: YAG laser. It takes approximately 6 to 10 pulses of the laser to traverse the myocardium and create channels of one millimeter in diameter. During a typical procedure, approximately 20 to 40 channels are made in the heart muscle. The external openings seal with little blood loss. Published research provides 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. CryoLife currently sells the CardioGenesis cardiac laser therapy product line to perform TMR.

CardioGenesis Cardiac Laser Therapy

CryoLife s CardioGenesis cardiac laser therapy product line consists of Holmium: YAG laser consoles, related service and maintenance, and single-use, fiber-optic handpieces, which are used in TMR to treat patients with severe angina resulting from diffuse coronary artery disease. 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. CryoLife s SolarGen 2100s Console (Console) uses the solid state technology of the Holmium: YAG laser system to provide a stable and reliable energy platform that is designed to deliver precise energy output. The Console has an advanced electronic and cooling system technology, which allows for a smaller and lighter system, while providing 115V power capability. The Company also provides service plan options to ensure that the Console is operating within the critical factory specifications. CryoLife distributes the SoloGrip® III, and the Port Enabled Angina Relief with Laser (PEARL) 5.0 disposable handpieces, which consist of multiple, fine fiber-optic strands in a one millimeter diameter bundle and are designed to work with the Console. The SoloGrip III handpiece has an ergonomic design and is pre-calibrated in the factory to provide easy and convenient access for treating all regions of the left ventricle. The PEARL 5.0 handpiece is compatible for use with Intuitive Surgical s da Vinci

Surgical System for use in minimally invasive surgeries.

The CardioGenesis cardiac laser therapy product line is FDA approved for treating patients with severe angina that is not responsive to conventional therapy. CryoLife began distributing the CardioGenesis cardiac laser therapy product line, primarily in the U.S., in May 2011 when it completed the acquisition of Cardiogenesis Corporation. Although the CardioGenesis cardiac laser therapy product line has a CE Mark allowing commercial distribution into the EEA, CryoLife does not actively market the product line internationally.

CryoLife distributes handpieces and CardioGenesis laser consoles primarily in the U.S. Revenues from CardioGenesis cardiac laser therapy represented 6% of total Company revenues in each of 2015, 2014, and 2013.

The Company s CardioGenesis cardiac laser therapy competes with other methods for the treatment of coronary artery disease, including drug therapy, percutaneous coronary intervention, coronary artery bypass surgery, and enhanced external

Table of Contents

counterpulsation. Currently, the only directly competitive laser technology for the performance of TMR is the CO_2 Heart Laser System manufactured by Novadaq Technologies, Inc. The Company s revascularization technology competes on the basis of its ease of use, versatility, size of laser console, and improved access to the treatment area with a smaller fiber-optic system.

Vascular Access

ESRD refers to the stage of renal disease when the kidneys do not work well enough for the patient to live without dialysis or transplant. This can result in severe electrolyte disturbance and toxic levels of waste products in the blood which are normally filtered and eliminated by the kidneys. Patients with ESRD often undergo hemodialysis to remove waste products and fluid from the blood, which can take several hours per treatment and often must be performed multiple times each week. Individuals may seek a kidney transplant for a more permanent solution to ESRD, but may wait for months or years before a donor organ is available. In order to perform hemodialysis, blood must be taken from the body, cleaned, and returned to the body through an access site. Typical access sites used to perform hemodialysis include arteriovenous (AV) fistulas, synthetic or biologic vascular access grafts, or catheters. AV fistulas and vascular access grafts may take weeks or months to mature before they can be used as an access site. Catheters are often the last option for vascular access as they tend to have a higher risk of becoming occluded or infected. CryoLife currently markets ProCol and previously marketed the HeRO Graft for vascular access.

ProCol

ProCol is a biological graft derived from a bovine mesenteric vein that provides vascular access for ESRD hemodialysis patients. ProCol provides vascular access for ESRD patients in an earlier stage of the treatment protocol than the HeRO Graft. In March 2014 CryoLife entered into a distribution agreement with Hancock Jaffe, which grants CryoLife the exclusive right to distribute ProCol worldwide. Clinical data shows that ProCol provides excellent patency for patients who have had repeated failures of other grafts. ProCol is FDA approved for sale in the U.S. as a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft.

CryoLife distributes ProCol in the U.S. Revenues from ProCol represented 1% of total Company revenues in 2015 and less than 1% of total Company revenues in 2014.

ProCol competes with products including balloon angioplasty products from Bard and Boston Scientific Corp., bare metal stents from Boston Scientific Corp., and covered stents from W.L. Gore & Associates (Gore). ProCol competes on the basis of its superior handling characteristics, long-term patency, and lower rates of infection, thrombosis, and intervention compared to synthetic grafts.

HeRO Graft

The HeRO Graft is a proprietary graft-based solution for ESRD hemodialysis patients with limited access options and central venous stenosis (narrowing of the venous system).

The HeRO Graft has a 510(k) clearance from the FDA for ESRD patients who are either catheter dependent or approaching catheter dependency, on long-term hemodialysis, and have exhausted all other access options, as well as for patients with failing fistulas and grafts due to central venous stenosis. The HeRO Graft received a CE Mark in 2013. CryoLife began distributing the HeRO Graft in the U.S. in May 2012 when it acquired Hemosphere and distributed the product until the Company divested the product line in February 2016.

CryoLife distributed the HeRO Graft in the U.S. and approximately 40 other countries. Revenues from the HeRO Graft represented 5%, 5%, and 4% of total Company revenues in 2015, 2014, and 2013, respectively.

Cardiac and Vascular Repair and Reconstruction

Patients with congenital cardiac defects such as Tetralogy of Fallot, Truncus Arteriosis, and Pulmonary Atresia can require complex cardiac reconstructive surgery to repair the defect. Patients with heart disease can experience valve insufficiency, regurgitation, or stenosis that may require heart valve repair or replacement surgery. Cardiac surgery can include the implantation of biological tissues, such as donated human tissues or animal-derived (xenograft) tissues, synthetic tissues, or mechanical valves. Human heart valves allow for more normal blood flow and provide higher cardiac output than animal-derived and mechanical heart valves. Human heart valves are not as susceptible to progressive calcification, or hardening, as are traditional glutaraldehyde-fixed, animal-derived heart valves, and do not require anti-coagulation drug

Table of Contents

therapy, as do mechanical valves. The synthetic sewing rings contained in many animal based or mechanical valves may harbor bacteria and lead to endocarditis, which 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 animal-derived and mechanical valves for patients who have, or are at risk to contract, endocarditis.

The 2013 Society of Thoracic Surgeons Guidelines, as published in the Annals of Thoracic Surgery, have increased the indication (from Class II to Class I) and broadened the scope for using an aortic homograft during aortic valve replacement surgery due to endocarditis. This means that when endocarditis has functionally destroyed the aortic valve annulus, an aortic homograft is the recommended course of treatment. Previously, the Guidelines indication for aortic homograft use was Class II, which meant only that it was an acceptable course of treatment.

Patients with peripheral vascular disease can experience reduced blood flow, usually in the arms and legs. This can result in poor circulation, pain, and sores that do not heal. 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 tissue (autograft). However, in cases of advanced vascular disease, patients may not have suitable vascular tissue for transplantation, and the surgeon must consider using synthetic grafts or donated human vascular tissue. Synthetic vascular grafts are generally not optimal for below-the-knee surgeries because they have a tendency to obstruct over time. Human vascular tissues tend to remain open longer and, as such, are used in indications where synthetic grafts 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. Therefore, human vascular tissues have advantages for patients with previously infected graft sites. Human vascular and arterial tissues are used in a variety of other reconstruction procedures such as cardiac bypass surgery and as vascular access grafts for hemodialysis. However, for each procedure that may utilize vascular human tissue, there are alternative treatments including the repair, partial removal, or complete removal of the damaged tissue.

Tissue procured from deceased human donors can be used in a variety of medical procedures to treat both congenital and acquired conditions as discussed above. The transplant of human tissue that has not been preserved must be accomplished within extremely short time limits. Cryopreservation, or cooling and storing at extremely cold temperatures, expands the treatment options available by extending these timelines.

CryoLife currently markets its cardiac preservation services, including its CryoValve and CryoValve SG tissues for heart valve replacement surgeries and its CryoPatch and CryoPatch SG tissues for cardiac repair procedures. CryoLife currently markets its vascular preservation services, including its CryoVein® and CryoArtery® tissues for vascular reconstruction surgeries. CryoLife currently distributes PhotoFix for cardiac and vascular repair.

PhotoFix

In 2014 CryoLife entered into an exclusive supply and distribution agreement with GBI to acquire the distribution rights to PhotoFix, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix, which was last commercially available in 2010, has received FDA 510(k) clearance and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure.

In January 2015 the Company received its initial shipments and launched its distribution of PhotoFix in the U.S. Revenues from PhotoFix represented 1% of total Company revenues in 2015.

Cardiac and Vascular Preservation Services

The Company s proprietary preservation process involves dissection, processing, preservation, and storage of tissues by the Company, until they are shipped to an implanting physician. The tissues currently preserved by the Company include aortic and pulmonary heart valves; cardiac patches in three primary anatomic configurations: pulmonary hemi-artery, pulmonary trunk, and pulmonary branch; and vascular tissues including, saphenous veins, aortoilliac arteries, and femoral veins and arteries. Each of these tissues maintains a structure which more closely resembles and simulates the performance of the patient s own tissue compared to non-human tissue alternatives. The Company s cardiac tissues have been used in a variety of valve replacement and cardiac reconstruction surgeries. The Company s vascular tissues 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. 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

Table of Contents

valves include more natural blood flow properties, the ability to use the valve 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 decellularization technology. CryoLife uses the SynerGraft technology for a significant portion of its pulmonary valve and pulmonary cardiac patch tissue processing.

CryoLife distributes human cardiac and vascular tissues to implanting institutions throughout the U.S. CryoLife also distributes tissues in Canada and has limited distribution through a special access program in Germany. The Company s CryoValve SGPV and CryoPatch SG are distributed under 510(k) clearance from the FDA.

Revenues from cardiac tissue preservation services accounted for 19%, 20%, and 21% of total Company revenues in 2015, 2014, and 2013, respectively. Revenues from vascular preservation services accounted for 24%, 23%, and 25% of total Company revenues in 2015, 2014, and 2013, respectively.

Management believes that at least one domestic tissue bank, LifeNet Health, Inc. (LifeNet), offers preserved human heart valves and patches in competition with the Company. Alternatives to human heart valves processed by the Company include valve repair and valve replacement with xenograft valves or mechanical valves. The Company competes with xenograft or mechanical valves from companies including Medtronic, Inc., Edwards Life Sciences, Inc., LivaNova and St. Jude Medical, Inc. Alternatives to the Company s human cardiac patches include xenograft small intestine submucosa (SIS) and xenograft patches. The Company competes with xenograft and SIS products from companies including CorMatrix Cardiovascular, Inc., Edwards Life Sciences, Inc., Admedus, Inc., St. Jude Medical, Inc., and Synovis Surgical Innovations.

Management believes that the human heart valves preserved by the Company compare favorably with xenograft and mechanical valves, for certain indications and patient populations, and that the human cardiac patches preserved by the Company compare favorably with xenograft SIS and xenograft patches, due to the benefits of human tissue discussed above. In addition, human tissue is the preferred replacement alternative with respect to certain medical conditions, such as pediatric cardiac reconstruction, congenital cardiac defect repair, valve replacements for women in their child-bearing years, and valve replacements for patients with endocarditis. In addition, implantation of the SynerGraft treated cardiac tissue reduces the risk for induction of class I and class II alloantibodies, based on Panel Reactive Antibody (PRA) measured at up to one year, compared to standard processed cardiac tissues. The Company believes that this may provide a competitive advantage for CryoValve SGPV and CryoPatch SG for potential whole organ transplant recipients, as an increased PRA can decrease the number of possible donors for subsequent organ transplants and increase time on transplant waiting lists.

Management believes that at a small number of domestic tissue banks, including LifeNet, Restoreflow Allografts, and Vascular Transplant Services, offer vascular tissue in competition with the Company. There are also a number of providers of synthetic alternatives to veins preserved by the Company and those alternatives are available primarily in medium and large diameters. The Company s vascular tissues compete with products from Gore, Bard, Artegraft, Inc., and Maquet, Inc.

Management believes that it competes with other entities that preserve human tissue on the basis of the preference of surgeons, documented clinical data, technology, customer service, and quality assurance. Management believes the Company offers advantages in the areas of clinical data and customer service, particularly with respect to the capabilities of our field representatives, as compared to other human tissue processors.

Marketing and Distribution

In the U.S. the Company markets its products and preservation services primarily to physicians, and distributes its products through its direct sales team to hospitals and other healthcare facilities. During 2015 the Company s cardiac specialists focused primarily on marketing the Company s products and services to cardiac surgeons, and cardiovascular field service representatives focused primarily on vascular surgeons. In January 2016 the Company reorganized its U.S. salesforce such that each domestic sales representative markets, with limited exception, the entire suite of CryoLife s product offerings. The Company also has a team of region managers, national accounts managers, and sales and marketing management. Through its field representatives, the Company conducts field training for surgeons regarding the surgical applications of its products and tissues.

CryoLife s physician relations and education staff, clinical research staff, and field representatives assist physicians by providing educational materials, seminars, and clinics on methods for using Company products and implanting tissue

Table of Contents

preserved by the Company. The Company sponsors programs where surgeons train other surgeons in best-demonstrated techniques. In addition, the Company hosts several workshops throughout the year including the Central Venous Pathology Summit, Aortic Root Bootcamp, Aortic Allograft Workshops, and TMR Workshops. These workshops aim to provide didactic and hands-on training to surgeons. The Company also produces educational videos for physicians and coordinates peer-to-peer training at various medical institutions. Management believes that these activities enhance the medical community s acceptance of the products and tissues offered by the Company and help to differentiate the Company from other medical device companies and tissue processors. To assist organ and tissue procurement organizations (OTPOs), the Company provides educational materials and training on procurement, dissection, packaging, and shipping techniques. The Company produces educational videos and coordinates laboratory sessions for OTPO personnel to improve their recovery techniques and increase the yield of usable tissue. The Company also maintains a staff 24 hours per day, 365 days per year for OTPO support.

The Company markets its products in the EMEA region through its European subsidiary, Europa, based in Guildford, England. Europa employs direct field service representatives in the U.K., Germany, Austria, Switzerland, Ireland, and France and manages relationships with other independent distributors in the EMEA region. Europa provides customer service, logistics, marketing, and clinical support to cardiac, vascular, thoracic, and general surgeons throughout the EMEA region.

The Company markets and distributes its products in other international markets through independent distributors in Canada, Asia Pacific, and the Americas. The Company s Singapore subsidiary, CryoLife Asia Pacific, provides sales and marketing support for the Asia Pacific region.

Suppliers, Sources, and Availability of Raw Materials and Tissues

The Company obtains many of its raw materials and supplies from a small group of suppliers or a single-source supplier. CryoLife also distributes various products through distribution agreements with the manufacturers. Certain raw materials and components used in the Company s products and tissue processing have stringent specifications. Supply interruptions or supplier quality, financial, or operational issues could cause the Company to have to temporarily reduce, temporarily halt, or permanently halt manufacturing, processing, or distribution activities. Qualifying alternative suppliers could result in additional costs or lengthy delays, or may not be possible. Any of these adverse outcomes could have a material, adverse effect on the Company s revenues or profitability. Supplies of materials are discussed for each of the Company s main products and services below. See also Part I, Item 1A, Risk Factors.

The Company s BioGlue and BioFoam products have three main product components: bovine protein, a cross linker, and a molded plastic resin delivery device. The bovine protein and cross linker are obtained from a small number of qualified suppliers. The delivery devices are manufactured by a single supplier, using resin supplied by a single resin supplier. The Company maintains a significant inventory of finished delivery devices to help mitigate the effects of a potential supply interruption.

The Company purchases PerClot from SMI pursuant to a distribution agreement. The Company maintains an inventory of PerClot purchased from SMI to satisfy its distribution needs and places regular orders for additional product. CryoLife s business is subject to interruption if SMI were unable or became unwilling to supply PerClot to CryoLife.

The Company purchases laser consoles and handpieces for its CardioGenesis cardiac laser therapy product line each from a separate single-source contract manufacturer. Using a secondary supplier for the laser consoles may be difficult because of certain of this manufacturer s patent rights. In addition, these manufacturers obtain certain laser and

fiber-optic components and subassemblies from single sources. CryoLife s business is subject to interruption if either of these contract manufacturers or their suppliers became unable or unwilling to do business with CryoLife.

Several HeRO Graft components are purchased from single sources, including key components such as the ePTFE arterial graft and nitinol braid. As discussed in Recent Events above, CryoLife divested the HeRO Graft product line in February 2016. CryoLife will continue to manufacture product during a short transition period of up to six months after the divestiture, and Merit will provide the necessary components during this transition period.

The Company s preservation services business and its ability to supply needed tissues is dependent upon donation of tissues from human donors by donor families. Donated human tissue is procured from deceased human donors by OTPOs. The Company must rely on the OTPOs that it works with to educate the public on the need for donation, to foster a willingness to donate tissue, to follow CryoLife s donor screening and procurement procedures, and to send donated tissue to CryoLife. Since 1984 the Company has received tissue from over 136,000 donors. The Company has active relationships

Table of Contents

with approximately 50 OTPOs throughout the U.S. Management believes these relationships are critical in the preservation services industry and that the breadth of these existing relationships provides the Company with a significant advantage over potential new entrants to this market. The Company also uses various raw materials, including medicines and solutions in its processing. Some of these raw materials are manufactured by single suppliers or by a small group of suppliers. All of these factors subject CryoLife to risk of supply interruption.

Operations, Manufacturing, and Tissue Preservation

The Company maintains a corporate headquarters and laboratory and an additional off-site warehouse both located in Kennesaw, Georgia. The Company manufactures BioGlue, BioFoam, and PerClot, and processes tissues at the Company s headquarters facility. The Company s corporate headquarters also includes a CardioGenesis cardiac laser therapy maintenance and evaluation laboratory space. The Company maintains a secondary facility consisting of manufacturing and office space in Atlanta, Georgia. The Company currently manufactures HeRO Grafts at the Atlanta, Georgia facility. The Company s European subsidiary, Europa, leases office space in Guildford, England, and shared warehousing space through its third-party shipper. See also Part I, Item 2, Properties.

In all of the Company s facilities, the Company is subject to regulatory standards for good manufacturing practices, including current Quality System Regulations, which are the FDA regulatory requirements for medical device manufacturers, and current Good Tissue Practices (cGTPs), which are the FDA regulatory requirements for the processing of human tissue. The Company also operates according to International Organization for Standardization (ISO) 13485 Quality System Requirements, an internationally recognized voluntary system of quality management for companies that design, develop, manufacture, distribute, and service medical devices. The Company maintains a Certification of Approval to the ISO 13485. Lloyd s Register Quality Assurance Limited (LRQA) issues this approval. LRQA is a Notified Body officially recognized by the EU to perform assessments of compliance with ISO 13485 and the Medical Device Directive. The Medical Device Directive is the governing document for the EEA that details requirements for safety and risk. LRQA also performs assessments of compliance with the Canadian Medical Devices Conformity Assessment System (CMDCAS).

The Company employs a comprehensive quality assurance program in all of its product manufacturing and tissue preservation activities. All materials, solutions, and components utilized in the Company s manufacturing and tissue processing are received and inspected by trained quality control personnel according to written specifications and standard operating procedures, and only items found to comply with Company standards are utilized in the Company s operations. Materials, components, sub-assemblies, and tissues are documented throughout manufacturing or processing to assure traceability.

The Company evaluates and inspects both its manufactured and distributed products to ensure conformity to product specifications. Processes are validated to produce products meeting the Company s specifications. Each process is documented along with all inspection results, including final finished product inspection and acceptance. Records are maintained as to the consignees of products to track product performance and to facilitate product removals or corrections, if necessary.

The Company maintains controls over its tissue processing to ensure conformity with Company procedures. OTPOs must follow the Company s policies related to tissue recovery practices, and are subject to periodic audits to confirm compliance. Samples are taken from donated tissue for microbiological testing, and tissue must be shown to be free of certain detectable microbial contaminants before being released for distribution. Tissue processing records and donor information is reviewed to identify characteristics which would disqualify the tissue for processing or implantation. Once tissue is released for distribution, it is moved from quarantine to an implantable status. Tissue is stored by the Company until it is shipped to a hospital, where the tissue is thawed and implanted immediately or held in a liquid

nitrogen freezer pending implantation.

Government Regulation

Medical devices and human tissues are subject to a number of regulations from various government bodies including in the U.S., federal, state, and local governments, as well as various regulatory bodies internationally. Government regulations are continually evolving, and requirements may change with or without notice. Changes in government regulations or changes in the enforcement of existing government regulations could have a material, adverse impact on the Company. See also Part I, Item 1A, Risk Factors.

Table of Contents

U.S. Federal Regulation of Medical Devices

The Federal Food, Drug, and Cosmetic Act (FDCA) provides that, unless exempted by regulation, medical devices may not be distributed in the U.S. unless they have been approved or cleared for marketing by the FDA. Medical devices may receive such approval or clearance through either a 510(k) process or an investigational device exemption (IDE) and PMA process.

Under a Section 510(k) process, a medical device manufacturer provides a premarket notification that it intends to begin marketing a product and shows that the product is substantially equivalent to another legally marketed predicate product. To be found substantially equivalent to a predicate device, the device must be for the same intended use and have either the same technological characteristics or different technological characteristics that do not raise new questions of safety or effectiveness. In some cases, the submission must include data from clinical studies in order to demonstrate substantial equivalency to a predicate device. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence.

FDA regulations require approval through the IDE/PMA process for all Class III medical devices and for medical devices not deemed substantially equivalent to a predicate device. An IDE authorizes distribution of devices that lack PMA or 510(k) clearance for clinical evaluation purposes. Devices subject to an IDE are subject to various restrictions imposed by the FDA, including restrictions on the number of patients to be treated and the number of institutions at which the device may be used. Patients must give informed consent to be treated with an investigational device and review by an Institutional Review Board is needed. The device must be labeled that it is for investigational use and may not be advertised or promoted. The price charged for the device may be limited. Unanticipated adverse events for devices used in an IDE must be reported to the FDA. After a product is subjected to clinical testing under an IDE, the Company may file a PMA application. PMA applications must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device for its intended use. A PMA application is typically a complex submission, usually including the results of human clinical studies, and preparing an application is a detailed and time-consuming process. Once a PMA application has been submitted, the FDA s review may be lengthy and may include requests for additional data, which may require the Company to undertake additional human clinical studies. Marketing of the device may begin when the FDA has approved the PMA.

FDCA requires all medical device manufacturers and distributors to register with the FDA annually and to provide the FDA with a list of those medical devices they distribute commercially. FDCA also requires manufacturers of medical devices to comply with labeling requirements and to manufacture devices in accordance with Quality System Regulations, which require that companies manufacture their products and maintain their documents in a prescribed manner with respect to good manufacturing practices, including: design, document production, process, labeling and packaging controls, process validation, and other quality control activities. The FDA s medical device reporting regulation requires that a device manufacturer provide information to the FDA on death or serious injuries alleged to have been associated with the use of its products, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. The FDA further requires that certain medical devices that may not be sold in the U.S. follow certain procedures before they are exported. The FDA periodically inspects Company facilities to review Company compliance with these and other regulations and has authority to seize non-complying medical devices, enjoin and/or impose civil penalties on manufacturers and distributors marketing non-complying medical devices, criminally prosecute violators, and order recalls in certain instances.

The following Company products are, or would, upon approval, be classified as Class III medical devices: BioGlue, BioFoam, PerClot, ProCol, and CardioGenesis cardiac laser therapy. CryoPatch SG and HeRO Graft are classified as Class II medical devices. CryoLife obtained 510(k) clearance from the FDA to market the CryoValve SGPV; however, these tissues are not officially classified as Class II or III medical devices.

U.S. Federal Regulation of Human Tissue

The FDA regulates human tissues pursuant to Section 361 of the Public Health Services Act, which in turn provides the regulatory framework for regulation of human cellular and tissue products. The FDA regulations focus on donor screening and testing to prevent the introduction, transmission, and spread of HIV-1 and -2, Hepatitis B and C, and other communicable diseases and disease agents. The regulations set minimum requirements to prevent the transmission of communicable diseases from human tissue used for transplantation. The regulations define human tissue as any tissue derived from a human body which is (i) intended for administration to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease and (ii) recovered, preserved, stored, or distributed by methods not intended to change tissue function or characteristics. The FDA definition excludes, among other things, tissue that currently is regulated as a human drug, biological product, or medical device, and it also excludes kidney, liver, heart, lung, pancreas, or any other vascularized

Table of Contents

human organ. The current regulations applicable to human tissues include requirements for donor suitability, processing standards, establishment registration, product listing, testing, and screening for risks of communicable diseases. The FDA periodically audits the Company s tissue preservation facilities for compliance with its requirements and has the authority to enjoin, force a recall, or require the destruction of tissues that do not meet its requirements.

NOTA Regulation

The Company s activities in preserving and transporting human hearts and certain other organs are also subject to federal regulation under the National Organ Transplant Act (NOTA), which makes it unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. NOTA excludes from the definition of valuable consideration reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ. The purpose of this statutory provision is to allow for compensation for legitimate services. The Company believes that to the extent its activities are subject to NOTA, it meets this statutory provision relating to the reasonableness of its charges. There can be no assurance, however, that restrictive interpretations of NOTA will not be adopted in the future that would call into question one or more aspects of the Company s methods of charging for its preservation services.

State Licensing Requirements

Some states have enacted statutes and regulations governing the preservation, transportation, and storage of human organs and tissues. The activities the Company engages in require it to be either licensed or registered as a clinical laboratory or tissue bank under California, Delaware, Florida, Georgia, Illinois, Maryland, New York, Oregon, and Pennsylvania law. The Company has such licenses or registrations, and the Company believes it is in compliance with applicable state laws and regulations relating to clinical laboratories and tissue banks that store, preserve, and distribute human tissue designed to be used for medical purposes in human beings. However, there can be no assurance that more restrictive state laws or regulations will not be adopted in the future that could materially, adversely affect the Company s operations. Certain employees of the Company have obtained other required state licenses. The regulatory bodies of the above states may perform inspections of the Company s facilities as required to ensure compliance with state laws and regulations.

International Approval Requirements

Sales of medical devices and shipments of human tissues outside the U.S. are subject to international regulatory requirements that vary widely from country to country. Approval of a product by comparable regulatory authorities of other countries must be obtained and compliance with applicable regulations for tissues must be met prior to commercial distribution of the products or human tissues in those countries. The time required to obtain these approvals may be longer or shorter than that required for FDA approval. Countries in which CryoLife distributes products and tissue may perform inspections of the Company facilities to ensure compliance with local country regulations.

The EEA recognizes a single medical device approval, called a CE Mark, which allows for distribution of an approved product throughout the EEA without additional general applications in each country. However, individual EEA members reserve the right to require additional labeling or information to address particular patient safety issues prior to allowing marketing. Third-parties called Notified Bodies award the CE Mark. These Notified Bodies are approved and subject to review by the Competent Authorities of their respective countries. The Company s Notified Body, LRQA, performs periodic on-site inspections, generally at least annually, to independently review the Company s

compliance with its systems and regulatory requirements. A number of countries outside of the EEA accept the CE Mark in lieu of marketing submissions as an addendum to that country s application process. The Company has been issued CE Marks for BioGlue, BioFoam, CardioGenesis cardiac laser therapy consoles and handpieces, and the HeRO Graft. Additionally, PerClot, which the Company distributes, has a CE Mark.

The EU Tissue and Cells Directives (EUTCD) established an approach to the regulation of tissues and cells across Europe. Pursuant to the EUTCD, each country in the EEA has responsibility for regulating tissues and cells and the procurement and distribution of tissues and cells for use in humans through a Competent Authority. The Competent Authority in the U.K. is the Human Tissue Authority (HTA). Europa was a Licensed Establishment under HTA Directions. In 2013 the HTA temporarily suspended Europa s licenses but shortly thereafter reinstated them subject to certain conditions, which allowed Europa to continue importing tissues into Europe. Subsequently, the HTA imposed certain additional tissue processing requirements for tissues imported into Europe through the HTA license. Management did not believe those requirements were necessary in order to ensure the safety of the processed tissue, and, as a result, Europa ceased importing tissues into Europe through the HTA licenses as of March 31, 2014.

Table of Contents

CryoLife currently distributes tissues through a special access program in Germany. In the first half of 2015 Germany s regulatory authorities and Europa were in discussions regarding requirements to allow Europa to market tissue in Germany. Europa was unable to reach a satisfactory agreement with the German authorities regarding those requirements, and although nominal shipments under the special access program have continued in 2015, there can be no assurance that the German authorities will continue to allow shipments of tissues under this program in the future.

Recent Regulatory Approvals

In July 2015 Japanese Pharmaceuticals and Medical Device Agency approval was received for an expanded indication for use of BioGlue for adhesion and support of hemostasis for aortotomy closure sites, suture/anastomosis sites (including aortic dissection and anastomosis sites with a use of a prosthetic graft), and suture sites on the heart.

In addition, several new country listings were obtained during 2015 to allow additional distribution of certain products into international markets, including BioGlue, BioFoam, PerClot, HeRO Grafts, and Cardiogenesis cardiac laser therapy products.

Certifications, Accreditations, and Inspections

In March 2015 the FDA conducted a re-inspection of CryoLife, Inc. On April 23, 2015 the FDA notified CryoLife that the company had addressed the violations contained in the FDA s January 29, 2013 warning letter, related to the Company s manufacture of products and processing, preservation, and distribution of human tissue, and the FDA s subsequent 2014 Form 483.

In September 2015 LRQA conducted a routine surveillance assessment to ISO 13485:2003 and Canadian CMDCAS requirements. No nonconformities were identified.

All registrations, licensures, certifications, and accreditations were renewed or continued and no regulatory actions are pending from state inspections.

Backlog

The Company currently does not have a backlog of orders related to BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Grafts, PhotoFix, or ProCol. The limited supply of certain types or sizes of preserved tissue can result in a backlog of orders for these tissues. The amount of backlog fluctuates based on the tissues available for shipment and varies based on the surgical needs of specific cases. The Company s backlog is generally not considered firm and must be confirmed with the customer before shipment.

Research and Development and Clinical Research

The Company uses its technical and scientific expertise to identify market opportunities for new products or services or to expand the use of its current products and services, through expanded indications or product or tissue enhancements. The Company s research and development strategy is to allocate available resources among the Company s core market areas based on the potential market size, estimated development time and cost, and the expected efficacy for any potential product or service offering. To the extent the Company identifies additional applications for its products, the Company may attempt to license these products to corporate partners for further development or seek funding from outside sources to continue commercial development. The Company may also attempt to acquire or license additional technologies from third-parties to supplement its product lines.

Research on these and other projects is conducted in the Company s research and development laboratory or at universities or clinics where the Company sponsors research projects, under the supervision of the Company s medical and scientific advisory board. The Company also conducts preclinical and clinical studies at universities and other third-party locations under contract with the Company. Research is inherently risky, and any potential products or tissues under development may not ultimately be deemed safe and effective and, therefore, may not generate any revenues for the Company. The Company s clinical research department also collects and maintains clinical data on the use and effectiveness of its products and services. The Company uses this data to provide feedback to physicians on the benefits of the Company s products and services and to help direct its continuing improvement efforts.

The Company s research and development and clinical research staff includes individuals with advanced degrees, including Ph.Ds., with specialties in the fields of chemistry (protein, material, organic, and bio); biomaterials; molecular

Table of Contents

biology; and engineering. In 2015, 2014, and 2013 the Company spent approximately $10.4 million, $8.7 million, and $8.5 million, respectively, on research and development activities on new and existing products. These amounts represented approximately 7%, 6%, and 6% of the Company s revenues for each of 2015, 2014, and 2013, respectively.

CryoLife is in the process of developing or investigating several new products and technologies, as well as changes and enhancements to its existing products and services.

In March 2014 CryoLife received approval of its IDE for PerClot from the FDA. IDE approval allows the Company to begin clinical trials for the purpose of obtaining a PMA to distribute PerClot in the U.S. As part of the approval for the PerClot IDE, the FDA recommended several study design considerations. The Company made revisions to the investigational study protocol and most recently refiled the IDE submission on December 2, 2014. In December 2014 CryoLife received approval of the supplement to its IDE for PerClot from the FDA. This approval allows the Company to begin its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company began enrollment in the second quarter of 2015. Enrollment in the clinical trial was slower than anticipated, and the Company voluntarily suspended enrollment in the clinical trial pending discussions with the FDA to modify the IDE study protocol. These planned modifications will need to be approved by the FDA in an IDE supplement. Depending on the outcome of those discussions, the Company will determine when it anticipates resuming enrollment in the clinical trial. If the Company is able to resume enrollment in the clinical trial during 2016, the Company would expect to receive PMA from the FDA in early 2019. See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S.

In November 2012 CryoLife received an additional indication in Europe to market its BioFoam as an adjunct to hemostasis in cardiovascular surgery when cessation of bleeding by ligature or other conventional methods is ineffective or impractical. In 2015 the Company completed enrollment of a 75 patient post-market study at two centers in Europe on BioFoam used in cardiovascular applications. The Company expects to complete the final study report in the first quarter of 2016.

At the FDA s request, the Company conducted a post-clearance study to collect long-term clinical data for the CryoValve SGPV. Data collected in this study was compared to data from a defined control group implanted with a standard processed human pulmonary heart valve. The information obtained from this study demonstrated the ten-year durability of the CryoValve SGPV. The study was completed in December 2014, and the results were submitted to the FDA. The results from the study will be presented at the American Association for Thoracic Surgery annual meeting in May 2016.

The Company s strategies for driving growth include new product indications and global expansion. These activities will likely require additional research, new clinical studies, and/or compilation of clinical data. The Company is currently seeking regulatory approval for BioGlue in China. In addition, the Company may decide to pursue expanded U.S. indications for BioGlue and approvals for the Company s products in new international markets.

Patents, Licenses, and Other Proprietary Rights

The Company relies on a combination of patents, trademarks, confidentiality agreements, and security procedures to protect its proprietary products, preservation technology, trade secrets, and know-how. The Company believes that its patents, trade secrets, trademarks, and technology licensing rights provide it with important competitive advantages. The Company has also obtained additional rights through license and distribution agreements for additional products and technologies, including PerClot, ProCol, and PhotoFix. The Company owns or has licensed rights to 45 U.S.

patents and 18 foreign patents, including patents that relate to its technology for BioGlue and BioFoam, PHT, PerClot, CardioGenesis cardiac laser therapy, HeRO Graft, cardiac and vascular tissue preservation, and decellularization of tissue. The Company has 6 pending U.S. patent applications and 14 pending foreign applications that relate to the Company s products and services. There can be no assurance that any patent applications pending will ultimately be issued as patents.

The remaining duration of the Company s issued patents range from 3 months to 17 years. The main patent for BioGlue expired in mid-2012 in the U.S. and expired in mid-2013 in the majority of the rest of the world. Although the patent for BioGlue has expired, this technology is still protected by trade secrets and manufacturing know-how, as well as the time and expense to obtain regulatory approvals. See also Part II, Item 8 Note 4 and Note 13 of the Notes to Consolidated Financial Statements for additional discussion of the Company s contractual rights related to PerClot, ProCol, and PhotoFix.

The Company has confidentiality agreements with its employees, several of its consultants, and third-party vendors to maintain the confidentiality of trade secrets and proprietary information. There can be no assurance that the obligations of

Table of Contents

the Company s employees and third-parties, with whom the Company has entered into confidentiality agreements, will effectively prevent disclosure of the Company s confidential information, or provide meaningful protection for the Company s confidential information if there is unauthorized use or disclosure, or that the Company s trade secrets or proprietary information will not be independently developed by the Company s competitors.

See Part I, Item 1A, Risk Factors for a discussion of risks related to the Company s patents, licenses, and other proprietary rights.

Seasonality

See Part II, Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations Seasonality, regarding seasonality of the Company s products and services.

Employees

As of December 31, 2015 CryoLife and its subsidiaries had approximately 540 employees. None of the Company s employees are represented by a labor organization or covered by a collective bargaining agreement, and the Company has never experienced a work stoppage or interruption due to labor disputes. Management believes its relations with its employees are good.

Environmental Matters

The Company s tissue preservation activities generate some biomedical wastes, consisting primarily of human and animal pathological and biological wastes, including human and animal tissue and body fluids removed during laboratory procedures. The biomedical wastes generated by the Company are placed in appropriately constructed and labeled containers and are segregated from other wastes generated by the Company. The Company contracts with third-parties for transport, treatment, and disposal of biomedical waste. Although the Company believes it is in compliance in the disposal of its waste with applicable laws and regulations promulgated by the U.S. Environmental Protection Agency and the Georgia Department of Natural Resources, Environmental Protection Division, the failure by the Company, or the companies with which it contracts, to comply fully with any such regulations could result in an imposition of penalties, fines, or sanctions, which could materially, adversely affect the Company s business.

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.

Available Information

It is the Company s policy to make all of its filings with the Securities and Exchange Commission, including, without limitation, its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, available free of charge on the Company s website, *www.cryolife.com*, on the day of filing. All such filings made on or after November 15, 2002 have been made available on this website.

Table of Contents

Item 1A. Risk Factors.

Risks Relating To Our Business

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

BioGlue® Surgical Adhesive (BioGlue) is a significant source of our revenues. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows:

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

- Other companies have obtained regulatory approval for competitive products from the FDA, and we expect commercialization of some of these competitive products in the U.S. in 2016. These companies have greater financial, technical, manufacturing, and marketing resources than we do and are well established in their markets. Companies other than these may also pursue regulatory approval for competitive products;

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

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

- If BioGlue is the subject of adverse developments with regard to its safety, efficacy, or reimbursement practices, or if our rights to manufacture and market this product are challenged.

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

Tissue Preservation Services are a significant source of our revenues. The following could materially, adversely affect our revenues, financial condition, profitability, and cash flows, if we are unable to:

- Source sufficient quantities of tissue from human donors. We rely primarily upon the efforts of third-party procurement organizations, tissue banks, most of which are not-for-profit, and others to educate the public and foster a willingness to donate tissue. Factors beyond our control such as regulatory changes, negative publicity concerning methods of tissue recovery or disease transmission from donated tissue, or public opinion of the donor process as well as our own reputation in the industry can negatively impact the supply of tissue;

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

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

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

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

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

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

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

Table of Contents

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

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

On January 20, 2016, we acquired On-X, at a price of $130.0 million, which is the largest acquisition we have ever made, and pursuant to which we borrowed $75.0 million through a senior secured credit facility, subject to certain restrictions on our business, and we issued shares of common stock worth approximately $39.0 million.

Our ability to realize the anticipated benefits of the On-X acquisition will depend, in large part, on our ability to integrate the On-X business into CryoLife, which can be a complex, costly and time-consuming process. As a result, we will be required to devote significant management attention and resources to integrating the business practices and operations of On-X into CryoLife. The integration process may disrupt both the CryoLife and On-X businesses and, if implemented ineffectively or impacted by unforeseen negative economic or market conditions or other factors, we may not realize the full anticipated benefits of the acquisition. Our failure to meet the challenges involved in integrating the two businesses to realize the anticipated benefits of the acquisition could cause an interruption or loss of momentum in our existing activities and could adversely affect our profitability. In addition the overall integration of On-X into CryoLife may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management attention. The difficulties of integrating the operations of On-X into CryoLife include, among others, difficulties in:

Diverting management s attention to integration matters;

Achieving anticipated business opportunities, growth prospects, cost savings and synergies;

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

Managing independent sales representative and distributor relationships, particularly internationally;

Moving to a direct sales model with the On-X product in markets in which CryoLife currently operates through a direct sales model;

Attracting and retaining key personnel;

Integrating operations and systems;

Executing on existing On-X clinical trials; and

Retaining existing and obtaining new customers.

Many of these factors will be outside of our control and any one of them could result in increased costs, decreased revenues and diversion of management s time and energy, which could materially impact our business, financial condition, and profitability. In addition, even if the operations of On-X are successfully integrated into CryoLife, we may not realize the full benefits of the acquisition, including achieving anticipated sales, capitalizing on growth opportunities, capturing market share from major competitors, all of whom are substantially larger and better resourced than CryoLife, or realizing expected synergies and costs savings. These benefits may not be achieved within the anticipated time frame or at all. Furthermore, additional anticipated costs may be incurred in the integration of On-X into CryoLife. All of these factors could negatively impact our earnings per share, decrease or delay the expected accretive effect of the acquisition, and negatively impact the price of our common stock. As a result, we cannot provide assurance that our acquisition of On-X will result in the realization of the full benefits we anticipate.

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

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

Table of Contents

In March 2014, we received approval of our investigational device exemption (IDE) for PerClot from the FDA, pursuant to which we began, in the first half of 2015, our pivotal clinical trial for surgical indications. We spent approximately $2.0 million in 2015 to pursue U.S. regulatory approval and anticipate that we will spend another $6.0 to $7.0 million over the next several years to obtain such approval, most of which we expect to incur in 2016 and 2017. Our costs to obtain FDA approval for PerClot are estimates only and may ultimately be greater than anticipated.

Enrollment in the IDE clinical trial in 2015 has been slower than anticipated and we have currently suspended enrollment in the IDE pending discussions with the FDA to revise the IDE study protocol. Should the FDA approve a revised protocol, we may resume enrollment, but we would not anticipate FDA Premarket Approval until early 2019. Under our agreements with SMI, we could lose our exclusive license to pursue, obtain, and maintain the Premarket Approval, if we do not secure such approval for PerClot by October of 2017. Should the FDA fail to approve any revised protocol, we may not be able to continue or may elect to discontinue the PerClot IDE. Finally, under the terms of our resolution with Medafor, we are precluded from marketing, selling or distributing PerClot in the U.S. until February 8, 2019, even if we obtain FDA Premarket Approval for PerClot before that date. See Part I, Item 3, Legal Proceedings for discussion of our litigation with Medafor.

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

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

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

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

We have continued to process and ship our CryoValve SGPV tissues. However, if the FDA ultimately classifies our CryoValve SGPV as a class III medical device, we anticipate requesting a meeting with the FDA to determine the

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

Table of Contents

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

In 2014 we entered into an exclusive supply and distribution agreement for PhotoFix with Genesee BioMedical, Inc. (GBI). We also acquired the option to purchase the PhotoFix product line from GBI beginning in March 2015. We began distribution of PhotoFix in the first quarter of 2015.

We are reliant on GBI to produce quality products in the quantities we and our customers require. If GBI experiences quality, supply or production challenges, its products could be subject to recall or other quality action; its business operations and/or its facilities that make the products could be shut down temporarily or permanently, whether by government order, natural disaster, or otherwise; and there may not be sufficient product to enable us to meet demand. We may also be unable to exercise our option to purchase the product line from GBI due to, among other things, our other financial commitments, product quality issues, or other factors beyond our control. Even if we are able to exercise our option, we may not be able to do so in a manner that permits us to continue to manufacture, market, and distribute the product consistent with our current projections or within the time frame anticipated. Further, we may be unable to secure anticipated approvals from the FDA or international regulatory bodies to remove certain labelling restrictions or to be able to commercialize PhotoFix in key international markets, such as Europe. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

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

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

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

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

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

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

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

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

The materials and supplies used in our product manufacturing and our tissue processing are subject to stringent quality standards and requirements, and many of these materials and supplies are subject to regulatory oversight and action. If materials or supplies used in our processes fail to meet these standards and requirements or are subject to recall or other

Table of Contents

quality action, an outcome could be the rejection or recall of our products or tissues and/or the immediate expense of the costs of the manufacturing or preservation. In addition, if these materials and supplies are recalled or the suppliers and/or their facilities that make them are shut down temporarily or permanently, whether by government order, natural disaster, or otherwise, there may not be sufficient materials or supplies available for purchase to allow us to manufacture our products or process tissues. Any of these occurrences or actions could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

We are dependent on sole source suppliers and single facilities.

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

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

Although we have insurance for products, tissues, securities, and property, it is possible that:

- We could be exposed to product and tissue processing liability claims, and security claims greater than the amount that we have insured;
- We may be unable to obtain future insurance policies in an amount sufficient to cover our anticipated claims at a reasonable cost or at all; or
- Because we are not insured against all potential losses, national disasters or other catastrophes could adversely impact our business.

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

If we are unsuccessful in arranging acceptable settlements of future product or tissue processing liability claims or future securities class action or derivative claims, we may not have sufficient insurance coverage and liquid assets to meet these obligations. If we are unable to obtain satisfactory insurance coverage in the future, we may be subject to additional future exposure from product or tissue processing liability or securities claims. Additionally, if one or more claims with respect to which we may become, in the future, a defendant should result in a substantial verdict rendered in favor of the plaintiff(s), such verdict(s) could exceed our available insurance coverage and liquid assets. If we are

unable to meet required future cash payments to resolve any outstanding or any future claims, this will materially, adversely affect our financial condition, profitability, and cash flows. Further, although we have an estimated reserve for our unreported product and tissue processing liability claims for which we do expect that we will obtain recovery under our insurance policies, these costs could exceed our current estimates. In addition, insurance rates could be significantly higher than in the past, and insurers may provide less coverage than we have estimated or expected. Finally, our facilities could be materially damaged by tornadoes, flooding, other natural disasters, or catastrophic circumstances, for which we are not fully covered by business interruption and disaster insurance, and, even with such coverage, we could suffer substantial losses in our operational capacity, along with a potential adverse impact on our customers and opportunity costs for which our insurance would not compensate us.

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

Table of Contents

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

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

- The marketing of mechanical, synthetic, and animal-based tissue valves for implantation;
- The marketing of synthetic and animal-based patches for implantation;
- The marketing of surgical adhesives, surgical sealants, and hemostatic agents;
- The marketing of cardiac laser therapy for use in TMR procedures; and
- The processing and preservation of human tissue.

In 2015, a significant percentage of market revenues from these products was generated by Baxter International Inc., Ethicon (a Johnson & Johnson Company), Medtronic, Inc., St. Jude Medical, Inc., LivaNova PLC, Edwards Life Sciences Corp., C.R., Bard, Inc., or, Integra Life Sciences Holdings. Several of our competitors enjoy competitive advantages over us, including:

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

Our competitors may develop services, products or processes with significant advantages over the products, services and processes that we offer or are seeking to develop, and our products and tissues may not be able to compete successfully. In addition, if we are unable to successfully market and sell innovative and in-demand products and services, our competitors may gain competitive advantages that may be difficult to overcome. If we fail to compete effectively, this could materially, adversely affect our revenues, financial condition, profitability, and cash flows.

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

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

Table of Contents

Our key growth vectors may not generate anticipated benefits.

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

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

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

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

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

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

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

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

Issue additional equity securities that would dilute our stockholders value;

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

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

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

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

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

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

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

Assume material unknown liabilities associated with the acquired business.

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

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

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

Our indebtedness could:

Limit our ability to borrow money for our working capital, capital expenditures, development projects, strategic initiatives, or other purposes;

Table of Contents

Require us to dedicate a substantial portion of our cash flow from operations to the repayment of our indebtedness, thereby reducing funds available to us for other purposes;

Limit our flexibility in planning for, or reacting to, changes in our operations or business;

Make us more vulnerable to downturns in our business, the economy, or the industry in which we operate;

Restrict us from making strategic acquisitions, introducing new technologies, or exploiting business opportunities; or

Expose us to the risk of increased interest rates as most of our borrowings are at a variable rate of interest.

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

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

Incur or guarantee additional debt;

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

Repurchase or redeem capital stock or subordinated indebtedness;

Transfer or sell certain assets;

Create liens on certain assets;

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

Enter into certain transactions with our affiliates;

Pledge the capital stock of any of our subsidiaries;

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

Make material changes in our equity capital structure;

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

Make certain investments, including strategic acquisitions.

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

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

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

Will not be required to lend any additional amounts to us;

Could elect to declare all indebtedness outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit, if applicable; or

Could require us to apply all of our available cash to repay such indebtedness.

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

Table of Contents

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

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

- Difficulties and costs associated with staffing and managing foreign operations, including foreign distributor relationships and developing direct sales operations in key foreign countries;
- Expanded compliance obligations, including with the Foreign Corrupt Practices Act, the U.K. Bribery Law, and local anti-corruption laws;
- Broader exposure to corruption;
- Overlapping and potentially conflicting international legal and regulatory requirements, as well as unexpected changes in international legal and regulatory requirements or reimbursement, policies and programs;
- Longer accounts receivable collection cycles in certain foreign countries and additional cost of collection of those receivables;
- Diminished protection for intellectual property and the presence of a growing number of generic or smaller competitors in some countries;
- Changes in currency exchange rates, particularly fluctuations in the British Pound and Euro as compared to the U.S. Dollar;
- Differing local product preferences and product requirements;
- Adverse economic or political changes or political instability;
- Potential trade restrictions, exchange controls, and import and export licensing requirements including tariffs; and
- Potential adverse tax consequences of overlapping tax structures.

Our failure to adequately address these risks could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

We are dependent on our key personnel.

Our business and future operating results depend in significant part upon the continued contributions of our key personnel, including qualified personnel with medical device and tissue processing experience, and senior management, many of whom would be difficult to replace. Our business and future operating results, including production at our tissue processing facilities, also depend in significant part upon our ability to attract and retain qualified management, and tissue processing, marketing, sales, and support personnel for our operations. Our main facility is in the Atlanta, Georgia area, where the local supply of qualified personnel in the medical device and tissue processing industries is limited. Competition for such personnel is intense, and we cannot ensure that we will be successful in attracting and retaining such personnel. If we lose any key employees, if any of our key employees fail to perform adequately, or if we are unable to attract and retain skilled employees as needed, this could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

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

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

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

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to personal information, intellectual property, and, in some instances, patient data). We have also outsourced elements of our

Table of Contents

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

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

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010. Certain provisions of the law will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the law. The legislation imposed significant new taxes on medical device makers in the form of a 2.3 percent excise tax on all U.S. medical device sales that commenced in January 2013. Under the legislation, the total cost to the medical device industry was expected to be approximately $20 billion over 10 years. While this tax has been suspended temporarily for 2016 and 2017, there is no guarantee that it will not be re-instated. The law also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions may have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the law includes a reduction in the annual rate of inflation for Medicare payments to hospitals that began in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what health care programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any changes that lower reimbursement for our products or reduce medical procedure volumes could adversely affect our business and profitability.

Our sales are affected by challenging domestic and international economic conditions and their constraining effect on hospital budgets, and demand for our products and tissues could decrease in the future, which could materially,

***adversely affect our business*.**

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

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

Table of Contents

We may not be successful in obtaining necessary clinical results and regulatory approvals for products and services in development, and our new products and services may not achieve market acceptance.

Our growth and profitability will depend, in part, upon our ability to complete development of, and successfully introduce, new products and services, or expand upon existing indications, which requires that we invest significant time and resources to obtain required regulatory approvals, including significant investment of time and resources into clinical trials. Although we have conducted clinical studies on certain products and services under development, which indicate that such products and services may be effective in a particular application, we cannot be certain that we will be able to successfully execute on these clinical trials or that the results we obtain from clinical studies will be sufficient for us to obtain any required regulatory approvals or clearances. We cannot give assurance that the relevant regulatory agencies will clear or approve these or any new products and services, or new indications, on a timely basis, if ever, or that the new products and services, or new indications, will adequately meet the requirements of the applicable market or achieve market acceptance. We may encounter delays or rejections during any stage of the regulatory approval process if clinical or other data fails to satisfactorily demonstrate compliance with, or if the service or product fails to meet, the regulatory agency s requirements for safety, efficacy, and quality. Those requirements may become more stringent due to changes in applicable laws, regulatory agency policies, or the adoption of new regulations. Clinical trials may also be delayed or halted due to the following:

Unanticipated side effects;

Lack of funding;

Inability to locate or recruit clinical investigators;

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

Redesign of clinical trial programs;

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

Changes in development focus; or

Disclosure of trial results by competitors.

Our ability to complete the development of any of our products and services is subject to all of the risks associated with the commercialization of new products and services based on innovative technologies. Such risks include unanticipated technical or other problems, manufacturing or processing difficulties, and the possibility that we have allocated insufficient funds to complete such development. Consequently, we may not be able to successfully introduce and market our products or services which are under development, or we may not be able to do so on a

timely basis. These products and services may not meet price or performance objectives and may not prove to be as effective as competing products and services.

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

Even if we are able to obtain regulatory approval for any products or services offered, the scope of the approval may significantly limit the indicated usage for which such products or services may be marketed. The unapproved use of our products or tissues could adversely impact the reputation of our Company and our products and services. Products or services marketed pursuant to FDA or foreign oversight or foreign approvals are subject to continuing regulation and periodic inspections. Labeling and promotional activities are also subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of devices and biologics is also subject to regulation and may require FDA approval. From time to time, the FDA may modify such regulations, imposing additional or different requirements. If we fail to comply with applicable FDA requirements, many of which are complex, we could face civil and criminal enforcement actions, warnings, citations, product recalls or detentions, and other penalties. This could have a material, adverse impact on our revenues, financial condition, profitability, and cash flows.

Table of Contents

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

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

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

Healthcare providers, facilities, and government agencies are unlikely to purchase our products or implant our tissues if they are not adequately reimbursed for these procedures. Unless a sufficient amount of conclusive, peer-reviewed clinical data about our products and tissues has been published, third-party payors, including insurance companies and government agencies, may refuse to provide reimbursement. Furthermore, even if reimbursement is provided, it may not be adequate to fully compensate the clinicians or hospitals. Some third-party payors may impose restrictions on the procedures for which they will provide reimbursement. If healthcare providers cannot obtain sufficient reimbursement from third-party payors for our products or tissues or the screenings conducted with our products, we may not achieve significant market acceptance. Acceptance of our products in international markets will depend upon the availability of adequate reimbursement or funding within prevailing healthcare payment systems. Reimbursement, funding, and healthcare payment systems vary significantly by country. We may not obtain approvals for reimbursement in a timely manner or at all.

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

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

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation, or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid, or other government-sponsored healthcare programs. We have entered into consulting agreements, speaker agreements, research agreements, and product development agreements with healthcare professionals, including some who may order our products or make

decisions to use them. While these transactions were structured with the intention of complying with all applicable laws, including state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties. We have also adopted the AdvaMed Code of Conduct into our Code of Business Conduct, which governs our relationships with healthcare professionals including our payment of travel and lodging expenses, research and educational grant procedures, and sponsorship of third-party conferences. In addition, we regularly conduct training sessions on these principles. However, there can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws or that one or more of our employees or agents will not disregard the rules we have established. Because our strategy relies on the involvement of healthcare professionals who consult with us on the design of our products, perform clinical research on our behalf, or educate the market about the efficacy and uses of

Table of Contents

our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with healthcare professionals who refer, or order, our products to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the healthcare professionals we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally-funded healthcare programs, including Medicare and Medicaid, for non-compliance.

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

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

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the scarcity of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition, and profitability. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going-forward basis only.

Risks Related to Ownership of our Common Stock

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

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

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

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

Table of Contents

Item 1B. Unresolved Staff Comments.

The Company has no unresolved written comments received from the staff of the Securities and Exchange Commission regarding its periodic or current reports under the Securities Exchange Act of 1934 not less than 180 days before December 31, 2015 (the end of the fiscal year to which this Form 10-K relates).

Item 2. Properties.

The Company s corporate headquarters and laboratory facilities consist of approximately 190,400 square feet of leased manufacturing, administrative, laboratory, and warehouse space located on a 21.5-acre setting, with an additional 14,400 square feet of off-site warehouse space both located in Kennesaw, Georgia. The manufacturing and tissue processing space includes approximately 20,000 square feet of class 10,000 clean rooms and 8,000 square feet of class 100,000 clean rooms. This extensive clean room environment provides a controlled aseptic environment for manufacturing and tissue preservation. Two back-up emergency generators assure continuity of Company manufacturing operations and liquid nitrogen freezers maintain preserved tissue at or below 135°C. The Company manufactures products from its Medical Devices segment, including: BioGlue, BioFoam, and PerClot, and processes and preserves tissues from its Preservation Services segment at the Company s headquarters facility. The Company s corporate headquarters also includes a CardioGenesis cardiac laser therapy maintenance and evaluation laboratory space.

The Company s corporate complex includes the Ronald C. Elkins Learning Center, a 3,600 square foot auditorium that holds 225 participants, and a 1,500 square foot training lab, both equipped with closed-circuit and satellite television broadcast capability allowing live broadcasts from and to anywhere in the world. The Elkins Learning Center provides visiting surgeons with a hands-on training environment for surgical and implantation techniques for the Company s technology platforms.

The Company maintains a secondary facility which consists of 15,600 square feet of combined manufacturing and office space in Atlanta, Georgia. The Company currently manufactures HeRO Grafts from its Medical Devices segment at this Atlanta, Georgia manufacturing facility.

In October 2014 the Company entered into a lease for approximately 24,980 square feet of additional office space in Kennesaw, GA. The Company took possession of the facility in February 2015 and may use the premises for general office purposes, research and development, light manufacturing, storage of medical devices, tissues, and materials, or other uses permitted by the lease.

The Company s European subsidiary, Europa, maintains a leased facility located in Guildford, England, which contains approximately 3,400 square feet of office space. In addition, Europa leases shared warehousing space through its third-party shipper.

Item 3. Legal Proceedings.

Except as noted below, there are no material legal proceedings pending, or known by the Company to be contemplated, to which the Company is a party or to which any of its property is subject.

In April 2014 CryoLife filed a declaratory judgment lawsuit against C.R. Bard, Inc. (Bard), and its subsidiaries Davol, Inc. (Davol) and Medafor, Inc. (Medafor) (collectively, Defendants), in the U.S. District Court for the District of Delaware (the District Court). CryoLife requested that the District Court declare that CryoLife s manufacture, use, offer for sale, and sale of PerClot in the U.S. does not, and would not, infringe Bard s U.S. Patent No. 6,060,461 (the

461 Patent). In addition, CryoLife requested that the District Court declare that the claims of the 461 Patent are invalid. CryoLife also requested injunctive relief and an award of attorneys fees.

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

Table of Contents

In August 2014 Medafor filed a counterclaim against CryoLife for infringement of the 461 Patent. In September 2014 Medafor filed a motion for a preliminary injunction, asking the District Court to enjoin CryoLife s marketing, sale and distribution of PerClot in the U.S. In March 2015 the District Court ruled that CryoLife s declaratory judgment lawsuit against Medafor may proceed but dismissed Bard and Davol from the lawsuit. The District Court also granted Medafor s motion for a preliminary injunction, which prohibited CryoLife from marketing, selling, and distributing PerClot in the U.S. while the litigation proceeded. In March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot in the U.S., including PerClot Topical, in accordance with the District Court s order. In April 2015 CryoLife appealed the District Court s ruling to the U.S. Court of Appeals for the Federal Circuit. CryoLife dismissed this appeal in June 2015. On November 18, 2015, the lawsuit was resolved by entry by the District Court of the Parties Joint Stipulation for Dismissal, which resulted in the dismissal with prejudice of all parties claims and counterclaims in the lawsuit, the continuation of the preliminary injunction prohibiting CryoLife from marketing, selling, or distributing PerClot in the U.S. until expiration of the 461 Patent on February 8, 2019, each party bearing its own attorneys fees and costs associated with the lawsuit, and the continuation of the District Court s jurisdiction over the parties to enforce the resolution.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 4A. Executive Officers of the Registrant

The following table lists the executive officers of CryoLife as of December 31, 2015 and their ages, positions with CryoLife, and the dates from which they have continually served as executive officers with CryoLife. Each of the executive officers of CryoLife was elected by the Board of Directors to serve until the Board of Directors meeting immediately following the next annual meeting of shareholders or until his or her earlier removal by the Board of Directors or his or her resignation.

Name	Service as Executive	Age	Position
J. Patrick Mackin	Since 2014	49	Chairman, President, and Chief Executive Officer
Scott B. Capps	Since 2007	49	Vice President, Clinical Research
John E. Davis	Since 2015	51	Senior Vice President, Global Sales and Marketing
David C. Gale, Ph.D.	Since 2012	48	Vice President, Research and Development
Jean F. Holloway	Since 2015	58	Vice President, General Counsel, Chief Compliance Officer, and Secretary
Amy D. Horton, CPA	Since 2006	45	Chief Accounting Officer
D. Ashley Lee, CPA	Since 2000	51	Executive Vice President, Chief Operating Officer, and Chief Financial Officer
William R. Matthews	Since 2015	61	Senior Vice President, Operations, Regulatory, and Quality

J. Patrick Mackin assumed the position of President and Chief Executive Officer in September 2014, was appointed to the Board of Directors in October 2014 and was appointed Chairman in May 2015. Mr. Mackin has more than 20 years of experience in the medical device industry. Prior to joining CryoLife, Mr. Mackin served as President of Cardiac Rhythm Disease Management, the largest operating division of Medtronic, Inc. At Medtronic, he previously held the positions of Vice President, Vascular, Western Europe and Vice President and General Manager,

Endovascular Business Unit. Prior to joining Medtronic in 2002, Mr. Mackin worked for six years at Genzyme, Inc. serving as Senior Vice President and General Manager for the Cardiovascular Surgery Business Unit and as Director of Sales, Surgical Products division. Before joining Genzyme, Mr. Mackin spent four years at Deknatel/Snowden-Pencer, Inc. in various roles and three years as a First Lieutenant in the U.S. Army. Mr. Mackin received an MBA from Northwestern University s Kellogg Graduate School of Management and is a graduate of the U.S. Military Academy at West Point.

Scott B. Capps was appointed to the position of Vice President of Clinical Research in November 2007. Prior to this position, Mr. Capps served as Vice President, General Manager of CryoLife Europa, Ltd. in the U.K. from February 2005 to November 2007 and Director, European Clinical Affairs from April 2003 to January 2005. Mr. Capps joined CryoLife in 1995 as Project Engineer for the allograft heart valve program and was promoted to Director, Clinical Research in 1999. Mr. Capps is responsible for overseeing and implementing clinical trials to achieve FDA and International approval of CryoLife s

Table of Contents

medical products in cardiac, vascular, and orthopaedic clinical areas. Before joining CryoLife, Mr. Capps was a Research Assistant in the Department of Bioengineering at Clemson University working to develop a computerized database and radiographic image analysis system for total knee replacement. Mr. Capps received his Bachelor of Industrial Engineering from the Georgia Institute of Technology and his M.S. in Bioengineering from Clemson University.

John E. Davis was appointed to the position of Senior Vice President, Global Sales and Marketing in September 2015. He has over 20 years of experience in Sales and Marketing and Executive Leadership. Prior to joining CryoLife, he served as Executive Vice President of Sales and Marketing at CorMatrix, a privately held medical device company creating innovative biomaterial devices to repair damaged heart tissue from March 2012 to September 2015. Prior to CorMatrix, he served for four years as a Vice President of Sales in the Cardiac Rhythm Management Devices business at St. Jude Medical. Before St. Jude Medical, he served for 14 years with Medtronic in the Cardiac Rhythm Disease Management division in senior sales leadership roles. In his early career he served with Roche Diagnostics and Ciba-Geigy Corporation. Mr. Davis received a Bachelor s degree from Western Carolina University.

David C. Gale, Ph.D. has served as Vice President, Research and Development since January 2012. Dr. Gale joined the Company in August 2009 as the Director, Biomaterials and Product Development. He was promoted to Senior Director, Biomaterials and Device Engineering in April 2011. Prior to joining CryoLife, Dr. Gale was with Sinexus, Inc., a start-up medical device company, from January 2007 to August 2009. He joined Sinexus as their Vice President of Research and was promoted to the position of Vice President, Research and Development in July 2007. Dr. Gale has 17 years of experience in biomaterials and medical device product research and development including roles at Abbott Vascular and Guidant Corporation. Dr. Gale is the inventor or co-inventor on over 70 issued U.S. patents related to the design and manufacture of medical devices. He received his Ph.D. in Materials Science from the University of Alabama at Birmingham, his M.S. in Chemical Engineering from Auburn University and has received both an M.Sc. in Instrumentation and Analysis and a B.Sc. in Chemistry from Manchester University in the U.K.

Jean F. Holloway, Esq was appointed to the position of Vice President, General Counsel, and Secretary in April 2015 and subsequently appointed to the additional position of Chief Compliance Officer in October 2015. Prior to joining CryoLife, she held various positions, including Vice President, General Counsel and Secretary of C.R. Bard, Inc., Deputy General Counsel, Medtronic, Inc., Vice President, Litigation, Boston Scientific, Inc., and Deputy General Counsel, Guidant Corporation. Ms. Holloway also spent nearly 15 years in private practice as a trial lawyer at Dorsey & Whitney, Faegre & Benson and Sidley & Austin. She clerked for two years on the Seventh Circuit Court of Appeals for the Honorable Luther M. Swygert. Ms. Holloway has a J.D./M.B.A. from the University of Chicago, and two undergraduate degrees from Yale University in engineering and political science.

Amy D. Horton, CPA, has served as Chief Accounting Officer of CryoLife since 2006. She has been with the Company since January 1998, serving as Controller from April of 2000 to August 2006 and as Assistant Controller prior to that. From 1993 to 1998, Ms. Horton was employed as a Certified Public Accountant with Ernst & Young, LLP. She received her B.S. and Master s degrees in Accounting from Brigham Young University in Provo, Utah.

D. Ashley Lee, CPA has served as Executive Vice President, Chief Operating Officer, and Chief Financial Officer since November 2004. Mr. Lee has been with the Company since December 1994 serving as Vice President of Finance, Chief Financial Officer, and Treasurer from December 2002 to November 2004; as Vice President, Finance and Chief Financial Officer from April 2000 to December 2002; and as Controller of the Company from December 1994 until April 2000. From 1993 to 1994, Mr. Lee served as the Assistant Director of Finance for Compass Retail, Inc., a wholly owned subsidiary of Equitable Real Estate. From 1987 to 1993, Mr. Lee was employed as a certified public accountant with Ernst & Young, LLP. Mr. Lee received his B.S. in Accounting from the University of Mississippi.

William R. Matthews was appointed to the position of the Senior Vice President of Operations, Quality, and Regulatory in May 2015. Before joining CryoLife, he was the Managing Partner at BioDevice Solutions, a Medical device consultancy firm from 2002 to 2014, where he served as a Senior Operations, Quality, and Regulatory Consultant, recognized for his experience in FDA compliance, manufacturing, new technology start-ups, and product submissions. Prior to that, he was Vice President of Government Affairs and Quality Systems for Cardinal Health s Viasys Healthcare, Executive Vice President of Operations, Regulatory Affairs, and Quality Systems at Xylum Corporation, and the Corporate Director of Regulatory, Quality, Manufacturing, and Engineering at Fresenius Medical Care (formerly Grace National Medical Care division). Mr. Matthews obtained a Bachelor s degree in Chemistry from St. Peter s University and also attended the Business Administration Programs at Rutgers University and Fairleigh Dickinson University.

Table of Contents

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.

Market Price of Common Stock

The Company s common stock is traded on the New York Stock Exchange (NYSE) under the symbol CRY. The following table sets forth, for the periods indicated, the intra-day high and low sale prices per share of common stock on the NYSE.

2015	High	Low
First quarter	$ 12.29	$ 9.60
Second quarter	11.50	9.50
Third quarter	11.75	9.41
Fourth quarter	11.31	9.59

2014	High	Low
First quarter	$ 12.14	$ 8.64
Second quarter	10.80	8.40
Third quarter	10.69	8.55
Fourth quarter	12.00	9.16

As of February 11, 2016 the Company had 310 shareholders of record.

Dividends

The Company s Board of Directors approved the initiation of a quarterly cash dividend of $0.025 per share of common stock outstanding in the third quarter of 2012. The Board of Directors increased this dividend to $0.0275 per share in the second quarter of 2013, and to $0.03 per share in the second quarter of 2014. Cash dividends have been paid every three months since their initiation in September 2012 through December 2015. In December 2015 the Company s Board of Directors discontinued dividend payments for the foreseeable future.

On January 20, 2016 the Company entered into the Third Amended and Restated Credit Agreement (Amended Debt Agreement) with Capital One, National Association; Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association, collectively the (Lending Parties). The Amended Debt Agreement prohibits the payment of cash dividends. See also Part II, Item 8, Note 12 of the Notes to Consolidated Financial Statements for further discussion of the Company s credit agreement.

Table of Contents

Issuer Purchases of Equity Securities

The following table provides information about purchases by the Company during the quarter ended December 31, 2015 of equity securities that are registered by the Company pursuant to Section 12 of the Securities Exchange Act of 1934.

Issuer Purchases of Equity Securities

Common Stock

Period	Total Number of Common Shares Purchased	Average Price Paid per Common Share	Total Number of Common Shares Purchased as Part of Publicly Announced Plans or Programs	Dollar Value of Common Shares That May Yet Be Purchased Under the Plans or Programs
10/01/15 - 10/31/15	--	$ --	--	$ --
11/01/15 - 11/30/15	11,942	10.99	--	--
12/01/15 - 12/31/15	--	--	--	--
Total	11,942	10.99	--	--

The common shares purchased during the quarter ended December 31, 2015 were tendered to the Company in payment of taxes on stock compensation and were not part of a publicly announced plan or program.

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

Table of Contents

Item 6. Selected Financial Data.

The following Selected Financial Data should be read in conjunction with the Company s consolidated financial statements and notes thereto, Management s Discussion and Analysis of Financial Condition and Results of Operations, and other financial information included elsewhere in this report.

Selected Financial Data

(in thousands, except percentages, current ratio, and per share data)

	December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
Operations					
Revenues	$ 145,898	$ 144,641	$ 140,763	$ 131,718	$ 119,626
Operating income	5,354	8,838	13,820	12,612	11,643
Net income[1]	4,005	7,322	16,172	7,946	7,371
Net income applicable to common shareholders - diluted	3,918	7,164	15,813	7,768	7,224
Research and development expense as a percentage of revenues	7.2%	6.0%	6.0%	5.5%	5.8%
Income Per Common Share					
Basic	$ 0.14	$ 0.26	$ 0.59	$ 0.29	$ 0.26
Diluted	$ 0.14	$ 0.25	$ 0.57	$ 0.28	$ 0.26
Dividend Declared Per Common Share	$ 0.120	$ 0.118	$ 0.108	$ 0.050	$ --
Year-End Financial Position					
Total assets	$ 181,179	$ 176,157	$ 174,683	$ 157,156	$ 147,864
Working capital	90,058	85,401	85,605	56,073	62,413
Long-term liabilities	6,323	6,845	9,214	7,614	4,869
Shareholders equity	155,251	148,685	144,747	128,112	121,538
Current ratio[2]	6:1	5:1	5:1	4:1	4:1

1 The fourth quarter 2013 net income and income per common share-diluted includes the favorable effect of a $12.7 million pre-tax gain on the sale of an investment in the common stock of Medafor, Inc. as a result of C.R. Bard, Inc. completing its acquisition of the outstanding common shares of Medafor, Inc.

2 Current assets divided by current liabilities.

Table of Contents

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

Overview

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, is a leader in medical device manufacturing and distribution and in the processing and distribution of implantable human tissues for use in cardiac and vascular surgeries. 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 internationally for Starch Medical, Inc. (SMI). CryoLife s CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used for the treatment of coronary artery disease in patients with severe angina. CryoLife is the exclusive distributor of ProCol® Vascular Bioprosthesis (ProCol) for Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). CryoLife marketed the Hemodialysis Reliable Outflow Graft (HeRO® Graft) through February 3, 2016. Both HeRO Graft and ProCol are solutions for end-stage renal disease (ESRD) in certain hemodialysis patients. CryoLife is the exclusive distributor of PhotoFix™ for Genesee Biomedical, Inc. (GBI). PhotoFix is a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both of which are processed using CryoLife s proprietary SynerGraft® technology.

For the year ended December 31, 2015 CryoLife reported record annual revenues of $145.9 million, increasing 1% over the prior year. The Company generated $11.4 million in cash flows from operations during 2015. See the Results of Operations section below for additional analysis of the fourth quarter and full year 2015 results. See Part I, Item 1, Business, for further discussion of the Company s business and activities during 2015.

Recent Events

Acquisition of On-X Life Technologies

On December 22, 2015 the Company entered into the Agreement and Plan of Merger (On-X Agreement) to acquire On-X Life Technologies Holdings, Inc., (On-X), an Austin, Texas-based, privately held mechanical heart valve company, for approximately $130.0 million, subject to certain adjustments, consisting of approximately $91.0 million in cash and $39.0 million of CryoLife s common stock. The transaction closed on January 20, 2016 and On-X will be operated as a wholly-owned subsidiary of CryoLife. Per the Company s preliminary analysis, the purchase price of the transaction totaled approximately $128.0 million, consisting of cash of $93.4 million and 3,703,699 shares of CryoLife common stock, with a value of $34.6 million as determined on the date of the closing. This purchase price is subject to several potential adjustments, including a working capital adjustment, which has not yet been finalized.

Debt Agreement

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

Divestiture of the HeRO Graft Product Line

On February 3, 2016 the Company sold its HeRO Graft product line to Merit Medical Systems, Inc. (Merit) for $18.5 million in cash. Under terms of the agreement, Merit acquired the HeRO Graft product line, including worldwide marketing rights, customer relationships, intellectual property, inventory, and certain property and equipment. The Company will continue to manufacture the HeRO Graft for up to six months under a transition supply agreement, after which Merit will be responsible for manufacturing. The disposal of the HeRO Graft is part of a strategic shift of the Company s focus to selling its expanded portfolio of cardiac surgery products, including the On-X heart valve.

During 2015 and in prior periods, the Company recorded activities related to its HeRO Graft product line as part of its Medical Devices segment. The assets divested in this transaction did not meet the criteria to be reported as assets held for

Table of Contents

sale as of December 31, 2015. The Company is in the process of completing the accounting related to this sale, including an allocation of its medical device segment goodwill to the divested business using a relative fair value allocation method. The Company anticipates recording a gain on the transaction upon the completion of the accounting.

Direct Sales in France

In June 2015 CryoLife signed a Business Transfer Agreement with its French distribution partner to facilitate an orderly transition of the Company to a direct sales model in France. In October 2015 the Company completed the acquisition of a portion of the business of its French distribution partner. The Company acquired in the transaction certain intangible assets, including commercial and business information, assignment of contracts, and a non-compete agreement with its former French distribution partner for a purchase price of 1.2 million Euros. During the third quarter of 2015, the Company established a wholly owned subsidiary in France, CryoLife France SAS, and certain members of the distributor s sales team who were responsible for selling the Company s products in France became employees of the Company s newly created subsidiary.

Critical Accounting Policies

A summary of the Company s significant accounting policies is included in Part II, Item 8, Note 1 of the Notes to Consolidated Financial Statements. Management believes that the consistent application of these policies enables the Company to provide users of the financial statements with useful and reliable information about the Company s operating results and financial condition. The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. which require the Company to make estimates and assumptions. The following are accounting policies that management believes are most important to the portrayal of the Company s financial condition and results of operations and may involve a higher degree of judgment and complexity.

Fair Value Measurements

The Company records certain financial instruments at fair value, including: cash equivalents, certain marketable securities, certain restricted securities, contingent consideration, and derivative instruments. The Company may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis; although as of December 31, 2015 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

The Company also measures certain non-financial assets at fair value on a non-recurring basis. These non-recurring valuations include evaluating assets such as cost method investments, long-lived assets, and non-amortizing intangible assets for impairment; allocating value to assets in an acquired asset group; and applying accounting for business combinations. The Company uses the fair value measurement framework to value these assets and reports these fair values in the periods in which they are recorded or written down.

The fair value measurement framework includes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data; and

Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available. The determination of fair value and the assessment of a measurement s placement within the hierarchy requires judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Level 3 valuations may require the use of various cost, market, or income valuation methodologies applied to unobservable management estimates and assumptions. Management s assumptions could vary depending on the asset or liability valued and the valuation method used. Such assumptions could include: estimates of prices, earnings, costs, actions of market participants, market factors, or the weighting of various valuation methods. The Company may also engage external advisors to assist in determining fair value, as appropriate.

Although the Company believes that the recorded fair value of its financial instruments is appropriate, these fair values may not be indicative of net realizable value or reflective of future fair values.

Table of Contents

Deferred Preservation Costs

Deferred preservation costs includes costs of cardiac and vascular tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status. By federal law, human tissues cannot be bought or sold, therefore, the tissues the Company preserves are not held as inventory. The costs the Company incurs to procure and process cardiac and vascular tissues are instead accumulated and deferred. Deferred preservation costs are stated at the lower of cost or market value on a first-in, first-out basis and are deferred until revenue is recognized. Upon shipment of tissue to an implanting facility, revenue is recognized and the related deferred preservation costs are expensed as cost of preservation services. Cost of preservation services also includes, as applicable, lower of cost or market write-downs and impairments for tissues not deemed to be recoverable, and includes, as incurred, idle facility expense, excessive spoilage, extra freight, and rehandling costs.

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations (OTPOs), which consign the tissue to the Company for processing, preservation, and distribution. Deferred preservation costs consist primarily of the procurement fees charged by the OTPOs, direct labor and materials (including salary and fringe benefits, laboratory supplies and expenses, and freight-in charges), and indirect costs (including allocations of costs from support departments and facility allocations). Fixed production overhead costs are allocated based on actual tissue processing levels, to the extent that they are within the range of the facility s normal capacity.

These costs are then allocated among the tissues processed during the period based on cost drivers, such as the number of donors or number of tissues processed. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management estimates quarantine yields based on its experience and reevaluates these estimates periodically. Actual yields could differ significantly from the Company s estimates, which could result in a change in tissues available for shipment, and could increase or decrease the balance of deferred preservation costs. These changes could result in additional cost of preservation services expense or could increase per tissue preservation costs, which would impact gross margins on tissue preservation services in future periods.

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company also evaluates its deferred preservation costs for costs not deemed to be recoverable, including tissues not expected to ship prior to the expiration date of their packaging. Lower of cost or market value write-downs are recorded if the tissue processing costs incurred exceed the estimated market value of the tissue services, based on recent average service fees at the time of the evaluation. Impairment write-downs are recorded based on the book value of tissues deemed to be impaired. Actual results may differ from these estimates. Write-downs of deferred preservation costs are expensed as cost of preservation services, and these write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if the Company s estimates change.

The Company recorded write-downs to its deferred preservation costs totaling $483,000, $540,000, and $448,000 for the years ended December 31, 2015, 2014, and 2013, respectively.

Deferred Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company periodically assesses the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially

affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance against its deferred tax assets when, as a result of this analysis, management believes it is more likely than not that some portion or all of its deferred tax assets will not be realized.

Assessing the recoverability of deferred tax assets involves judgment and complexity. Estimates and judgments used in the determination of the need for a valuation allowance and in calculating the amount of a needed valuation allowance include, but are not limited to, the following:

Projected future operating results;

Anticipated future state tax apportionment;

Timing and amounts of anticipated future taxable income;

Timing of the anticipated reversal of book/tax temporary differences;

Table of Contents

Evaluation of statutory limits regarding usage of certain tax assets; and

Evaluation of the statutory periods over which certain tax assets can be utilized.

Significant changes in the factors above, or other factors, could affect the Company s ability to use its deferred tax assets. Such changes could have a material, adverse impact on the Company s profitability, financial position, and cash flows. The Company will continue to assess the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially affect its prior determination of the recoverability of its deferred tax assets.

The Company believes that the realizability of its acquired net operating loss carryforwards will be limited in future periods due to a change in control of its former subsidiaries Hemosphere, Inc. (Hemosphere) and Cardiogenesis Corporation (Cardiogenesis), as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisitions of these companies each constituted a change in control, and that prior to the Company s acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. The deferred tax assets recorded on the Company s Consolidated Balance Sheets exclude amounts that it expects will not be realizable due to these changes in control. A portion of the acquired net operating loss carryforwards is related to state income taxes for which management believes it is more likely than not that these deferred tax assets will not be realized. Therefore, the Company recorded a valuation allowance against these state net operating loss carryforwards.

Valuation of Acquired Assets or Businesses

As part of its corporate strategy, the Company is seeking to identify and capitalize upon acquisition opportunities of complementary product lines and companies. The Company evaluates and accounts for acquired patents, licenses, distribution rights, and other tangible or intangible assets as the purchase of an asset or asset group, or as a business combination, as appropriate. The determination of whether the purchase of a group of assets should be accounted for as an asset group or as a business combination requires significant judgment based on the weight of available evidence.

For the purchase of an asset group, the Company allocates the cost of the asset group, including transaction costs, to the individual assets purchased based on their relative estimated fair values. In-process research and development acquired as part of an asset group is expensed upon acquisition. The Company accounts for business combinations using the acquisition method. Under this method, the allocation of the purchase price is based on the fair value of the tangible and identifiable intangible assets acquired and the liabilities assumed as of the date of the acquisition. The excess of the purchase price over the estimated fair value of the tangible net assets and identifiable intangible assets is recorded as goodwill. Transaction costs related to a business combination are expensed as incurred. In-process research and development acquired as part of a business combination is accounted for as an indefinite-lived intangible asset until the related research and development project gains regulatory approval or is discontinued.

The Company typically engages external advisors to assist it in determining the fair value of acquired asset groups or business combinations, using valuation methodologies such as: the excess earnings, the discounted cash flow, or the relief from royalty methods. The determination of fair value in accordance with the fair value measurement framework requires significant judgments and estimates, including, but not limited to: timing of product life cycles, estimates of future revenues, estimates of profitability for new or acquired products, cost estimates for new or changed manufacturing processes, estimates of the cost or timing of obtaining regulatory approvals, estimates of the success of competitive products, and discount rates. Management, in consultation with its advisor(s), makes these estimates based on its prior experiences and industry knowledge. Management believes that its estimates are reasonable, but

actual results could differ significantly from the Company s estimates. A significant change in management s estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by the Company and, therefore, could materially impact the Company s financial position and profitability. If the value of the liabilities assumed by the Company, including contingent liabilities, is determined to be significantly different from the amounts previously recorded in purchase accounting, the Company may need to record additional expenses or write-downs in future periods, which could materially impact the Company s financial position and profitability.

New Accounting Pronouncements

In May 2014 the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers,* which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. On July 9, 2015, the FASB approved the deferral of the effective date of ASU 2014-09 by one year. The new standard is effective for annual

Table of Contents

and interim reporting periods beginning after December 15, 2017, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2014-09 to have a material impact on its financial position, results of operations, or cash flows.

In July 2015 FASB issued ASU No. 2015-11, *Inventory Simplifying the Measurement of Inventory,* which requires that inventory be measured at the lower of cost and net realizable value. Prior to the issuance of the new guidance, inventory was measured at the lower of cost or market. Replacing the concept of market with the single measurement of net realizable value is intended to create efficiencies for preparers. Inventory measured using the last-in, first-out (LIFO) method and the retail inventory method are not impacted by the new guidance. The ASU becomes effective for fiscal years beginning after December 15, 2016, including interim periods with those fiscal years and early application is permitted. The Company is evaluating the effect that ASU 2015-11 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2015-11 to have a material impact on its financial position, results of operations, or cash flows.

In November 2015 the FASB issued ASU 2015-17, *Income Taxes (Topic 740) Related to the Balance Sheet Classification of Deferred Taxes* which requires entities to present deferred tax assets (DTA s) and deferred tax liabilities (DTL s) as noncurrent in a classified balance sheet. The ASU simplifies the current guidance (ASC 740-10-45-4), which requires entities to separately present DTAs and DTLs as current and noncurrent in a classified balance sheet. ASU 2015-17 is effective for annual reporting periods beginning on or after December 15, 2016 and interim periods within those annual periods. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The Company elected to early adopt ASU 2015-17 prospectively as of December 31, 2015. Accordingly, deferred tax assets in the amount of $5.3 million, which would have been classified as a current asset, have been classified as a non-current asset on the Company s Consolidated Balance Sheet as of December 31, 2015.

Table of Contents

Results of Operations

(In thousands)

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Products:				
BioGlue and BioFoam	$ 16,488	$ 16,346	41%	44%
PerClot	1,096	1,232	3%	3%
CardioGenesis cardiac laser therapy	3,487	2,151	9%	6%
HeRO Graft	2,008	1,827	5%	5%
ProCol	397	117	1%	--%
PhotoFix	437	--	1%	--%
Total products	23,913	21,673	60%	58%
Preservation services:				
Cardiac tissue	6,970	7,456	18%	20%
Vascular tissue	8,955	8,022	22%	22%
Total preservation services	15,925	15,478	40%	42%
Total	$ 39,838	$ 37,151	100%	100%

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Products:				
BioGlue and BioFoam	$ 59,332	$ 62,091	41%	43%
PerClot	4,083	4,289	3%	3%
CardioGenesis cardiac laser therapy	9,419	8,225	6%	6%
HeRO Graft	7,546	7,131	5%	5%
ProCol	1,305	147	1%	--%
PhotoFix	1,396	--	1%	--%

Total products	83,081	81,883	57%	57%
Preservation services:				
Cardiac tissue	28,059	29,437	19%	20%
Vascular tissue	34,758	33,321	24%	23%
Total preservation services	62,817	62,758	43%	43%
Total	$ 145,898	$ 144,641	100%	100%

Revenues increased 7% and 1% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2015 is presented below.

Table of Contents

Products

Revenues from products increased 10% and 1% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. These increases were primarily due to increases in CardioGenesis cardiac laser therapy, ProCol, and PhotoFix revenues. In the twelve months ended December 31, 2015, this increase was partially offset by a decrease in BioGlue revenues. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot; CardioGenesis cardiac laser therapy; HeRO Graft; and ProCol and PhotoFix is presented below.

The Company s sales of products through its direct sales force to U.K. hospitals are denominated in British Pounds, and its sales to German, Austrian, and Irish hospitals and certain distributors are denominated in Euros and are, therefore, subject to changes in foreign exchange rates. During 2015, the U.S. Dollar strengthened materially, as compared to the British Pound and Euro and, as a result, the Company s revenues denominated in these currencies decreased when translated into U.S. Dollars. Any further change in these exchange rates could have a material, adverse effect on the Company s revenues denominated in these currencies. Additionally, the Company s sales to many distributors around the world are denominated in U.S. Dollars, and, although these sales are not directly impacted by the strong U.S. Dollar, the Company believes that its distributors may be delaying or reducing purchases of products in U.S. Dollars due to the relative price of these goods in their local currencies.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 1% for the three months ended December 31, 2015, as compared to the three months ended December 31, 2014. This increase was primarily due to an increase in average sales prices, which increased revenues by 4%, partially offset by the unfavorable impact of foreign exchange rates, which decreased revenues by 2%, and unfavorable volume, which decreased revenues by 1%.

Revenues from the sale of surgical sealants decreased 4% for the twelve months ended December 31, 2015, as compared to the twelve months ended December 31, 2014. This decrease was primarily due to a 4% decrease in the volume of milliliters sold, which decreased revenues by 4% and the unfavorable impact of foreign exchange rates, which decreased revenues by 2%, partially offset by an increase in average sales prices, which increased revenues by 2%.

The increase in average sales prices for the three and twelve months ended December 31, 2015 was primarily due to the favorable impact of the transition to a direct sales model in France, list price increases in domestic markets, and the routine negotiation of pricing contracts with certain customers.

The decrease in sales volume of surgical sealants for the twelve months ended December 31, 2015 was primarily due to a lack of shipments of BioGlue to the Company s French distributor during the first nine months of 2015, as the Company transitioned this market from a distributor to a direct sales model effective October 1, 2015 and due to a reduction in shipments to the Company s distributor in Brazil, as a result of factors such as economic instability and local currency devaluation in Brazil. To a lesser extent the decrease in volume is due to a decrease in sales in domestic markets primarily due to declining procedure volume, as doctors are performing more minimally invasive procedures, and hospitals seeking to control costs by reducing spending on consumable items such as BioGlue.

Revenues from shipments to Japan were $1.5 million and $5.5 million for the three and twelve months ended December 31, 2015, respectively, and $1.1 million and $5.0 million for the three and twelve months ended December 31, 2014, respectively. The Company received an expanded indication for BioGlue in Japan in mid-2015.

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

Domestic revenues accounted for 55% and 58% of total BioGlue revenues for the three and twelve months ended December 31, 2015, respectively, and 55% and 56% of total BioGlue revenues for the three and twelve months ended December 31, 2014, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2015 and 2014. BioFoam is currently approved for sale in certain international markets.

PerClot

Revenues from the sale of PerClot decreased 11% for the three months ended December 31, 2015 as compared to the three months ended December 31, 2014. This decrease was primarily due to an 11% decrease in the volume of grams sold, which decreased revenues by 5%, the unfavorable effect of foreign currency exchange, which decreased revenues by 4%, and a decrease in average selling prices, which decreased revenues by 2%.

Table of Contents

Revenues from the sale of PerClot decreased 5% for the twelve months ended December 31, 2015 as compared to the twelve months ended December 31, 2014. This decrease was primarily due to the unfavorable effect of foreign currency exchange, which decreased revenues by 7%, and a decrease in average selling prices, which decreased revenues by 3%, partially offset by favorable sales volume, which increased revenues by 5%.

Revenues during these three and twelve month periods were largely for sales in certain international markets, as PerClot was only distributed domestically from August 2014 to March 2015 as discussed in Note 8 of the Notes to Consolidated Financial Statements.

The decrease in revenues for the three months ended December 31, 2015 was primarily due to decreased sales in the Company s markets in Asia Pacific and Latin America, as large orders in the fourth quarter of 2014 did not recur in 2015. The increase in revenues for the twelve months ended December 31, 2015 was primarily due to increased sales in the U.K., largely for use in gynecology procedures.

The decrease in average selling prices for the three and twelve months ended December 31, 2015 was primarily due to price reductions to certain distributors in Europe, as a result of pricing pressures from competitive products and to offset the relatively higher price of PerClot due to the strengthening of the U.S. Dollar. The effect of foreign exchange rate changes discussed above had a larger impact on the Company s PerClot revenues, as a larger percentage of these revenues are denominated in foreign currencies than revenues from the Company s other products.

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. The Company began enrollment in the second quarter of 2015 but has suspended enrollment in the trial pending discussions with the FDA regarding the protocol for the clinical trial. Depending on the results of these discussions, the Company could receive Premarket Approval (PMA) from the FDA in early 2019. See Part I, Item 1A, Risk Factors for a discussion of risks related to the Company s ability to obtain FDA approval and to successfully commercialize PerClot in the U.S.

CardioGenesis Cardiac Laser Therapy

Revenues from the Company s CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from cardiac laser therapy increased 62% for the three months ended December 31, 2015 as compared to the three months ended December 31, 2014. Revenues from the sale of laser consoles were $1.1 million and $240,000 for the three months ended December 31, 2015 and 2014, respectively. Revenues from the sale of handpieces increased 29% for the three months ended December 31, 2015 as compared to the three months ended December 31, 2014. This increase was primarily due to a 23% increase in unit shipments of handpieces, which increased revenues by 26%, and an increase in average sales prices, which increased revenues by 3%.

Revenues from cardiac laser therapy increased 15% for the twelve months ended December 31, 2015 as compared to the twelve months ended December 31, 2014. Revenues from the sale of laser consoles were $1.2 million and $384,000 for the twelve months ended December 31, 2015 and 2014, respectively. Revenues from the sale of handpieces increased 6% for the twelve months ended December 31, 2015 as compared to the twelve months ended December 31, 2014. This increase was primarily due to a 4% increase in unit shipments of handpieces, which increased revenues by 4%, and an increase in average sales prices, which increased revenues by 2%.

Revenues from laser console sales increased for both the three and twelve months ended December 31, 2015 due primarily to an increase in the average price paid per laser console and, to a lesser extent, due to an increase in the number of laser consoles sold during the 2015 periods.

HeRO Graft

Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. HeRO Grafts are primarily distributed in domestic markets as a solution for ESRD in certain hemodialysis patients. HeRO Graft revenues increased 10% for the three months ended December 31, 2015, as compared to the three months ended December 31, 2014. This increase was primarily due to a 5% increase in number of kits sold, which increased revenues by 5%, and an increase in average sales prices, which increased revenues by 6%, partially offset by the unfavorable effect of foreign currency exchange, which decreased revenues by 1%.

Table of Contents

HeRO Graft revenues increased 6% for the twelve months ended December 31, 2015, as compared to the twelve months ended December 31, 2014. This increase was primarily due to a 4% increase in number of kits sold, which increased revenues by 3% and an increase in average sales prices, which increased revenues by 4%, partially offset by the unfavorable effect of foreign currency exchange, which decreased revenues by 1%.

The increase in HeRO Graft volume for the three months ended December 31, 2015 was primarily due to a increase in the volume of kits sold in domestic markets due to the timing of surgical cases. The increase in HeRO Graft volume for the twelve months ended December 31, 2015 was primarily due to an increase in the volume of kits sold in international markets as a result of an increase in procedure volume and an increase in the number of implanting physicians, partially offset by a decrease in domestic sales volume. As discussed above the Company divested its HeRO Graft business in February 2016.

ProCol and PhotoFix

In 2014 CryoLife acquired the exclusive worldwide distribution rights from Hancock Jaffe for ProCol, a biological graft derived from a bovine mesenteric vein. ProCol is distributed in the U.S. to provide vascular access for ESRD hemodialysis patients. The Company began limited distribution of ProCol in the second quarter of 2014 and began its full U.S. launch in the fourth quarter of 2014.

In 2014 CryoLife acquired the distribution rights from GBI for PhotoFix, a bovine pericardial patch. PhotoFix is distributed in the U.S. and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure. The Company launched its distribution of PhotoFix in the first quarter of 2015.

Preservation Services

Revenues from preservation services increased 3% and less than 1% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. The increase in revenues for the three and twelve month periods was primarily due to an increase in vascular preservation services revenues, partially offset by a decrease in cardiac preservation services revenues. See further discussion of cardiac and vascular preservation services revenues below.

During 2014 the Company made significant changes to various tissue processing and quality procedures, which resulted in a decrease in tissue processing throughput and an increase in the Company s cost of processing tissues. Preservation services revenues and costs were negatively impacted during 2014 due to these factors. These factors continued to impact revenues and costs during 2015 as the Company continued to ship tissues that were processed in 2014. The Company continues to review and modify its procedures as part of its ongoing compliance efforts and in an effort to improve tissue processing throughput and reduce costs. These efforts have begun to increase tissue availability, particularly vascular tissue availability as discussed further below, and have begun to reduce costs.

Preservation services revenues, particularly revenues for certain high-demand cardiac tissues, can vary from quarter to quarter and year to year due to a variety of factors including: quantity and type of incoming tissues, yields of tissue through the preservation process, timing of receipt of donor information, timing of the release of tissues to an implantable status, demand for certain tissue types due to the number and type of procedures being performed, and pressures from competing products or services. See further discussion below of specific items affecting cardiac and vascular preservation services revenues for the three and twelve months ended December 31, 2015.

Cardiac Preservation Services

Revenues from cardiac preservation services, consisting of revenues from the distribution of heart valves and cardiac patch tissues, decreased 7% for the three months ended December 31, 2015 as compared to the three months ended December 31, 2014. This decrease was primarily due to a 13% decrease in unit shipments of cardiac tissues, which decreased revenues by 10%, partially offset by an increase in average service fees, which increased revenues by 3%.

Revenues from cardiac preservation services decreased 5% for the twelve months ended December 31, 2015 as compared to the twelve months ended December 31, 2014. This decrease was primarily due to an 11% decrease in unit shipments of cardiac tissues, which decreased revenues by 9%, partially offset by an increase in average service fees, which increased revenues by 4%.

Table of Contents

The decrease in volume for the three and twelve months ended December 31, 2015 was primarily due to a decrease in the volume of pulmonary valve and patch shipments. The Company believes that the decrease in cardiac tissue shipments during these periods was due to increasing competition from lower cost bioprosthetic valves and patches.

The increase in average service fees for the three and twelve months ended December 31, 2015 was primarily due to list fee increases in domestic markets and due to the routine negotiation of pricing contracts with certain customers.

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 62% and 63% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2015, respectively, and 66% and 64% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2014, respectively.

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

Vascular Preservation Services

Revenues from vascular preservation services increased 12% for the three months ended December 31, 2015 as compared to the three months ended December 31, 2014. This increase was primarily due to an increase in average service fees, which increased revenues by 6%, and favorable tissue volume, which increased revenues by 6%.

Revenues from vascular preservation services increased 4% for the twelve months ended December 31, 2015 as compared to the twelve months ended December 31, 2014. This increase was primarily due to an increase in average service fees, which increased revenues by 5%, partially offset by an unfavorable tissue volume, which decreased revenues by 1%.

The increase in average service fees for the three and twelve months ended December 31, 2015 was primarily due to list fee increases in domestic markets, fee differences due to physical characteristics of vascular tissues, and the routine negotiation of pricing contracts with certain customers.

The increase in vascular volume for the three months ended December 31, 2015 was primarily due to increases in shipments of saphenous veins and aortoilliac arteries, due to improving tissue availability as discussed above.

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

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Cost of products	$ 5,108	$ 5,068	$ 18,663	$ 17,167

Cost of products increased 1% and 9% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. Cost of products in 2015 and 2014 includes costs related to BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Grafts, and ProCol. Cost of products in 2015 also includes costs related to PhotoFix.

The increase in cost of products was primarily due to sales of the Company s new distributed products, PhotoFix and ProCol, partially offset by a decrease in the per unit cost of manufacturing BioGlue. The increase in cost of products in the twelve months ended December 31, 2015 was also affected by the write-down of PerClot inventory manufactured for the U.S. market following the Company s cessation of marketing, sales, and distribution of PerClot in the U.S.

Table of Contents

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Cost of preservation services	$ 8,214	$ 9,448	$ 36,516	$ 36,183

Cost of preservation services decreased 13% and increased 1% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

Cost of preservation services decreased in the three months ended December 31, 2015 primarily due to a decrease in unit shipments of cardiac tissues and due to a decrease in the per unit cost of processing tissues, as a result of processing changes implemented in 2015. Cost of preservation services increased in the twelve months ended December 31, 2015 primarily due to an increase in the per unit cost of processing tissues, as a result of lower processing throughput of tissues, increased compliance and personnel costs, and an increase in the cost of materials for tissues processed in 2014 and in the beginning of 2015. This was partially offset by a decrease in the unit shipments of cardiac and vascular tissue for the twelve months ended December 31, 2015. See Preservation Services above for a further discussion of the factors impacting tissue processing costs.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Gross margin	$ 26,516	$ 22,635	$ 90,719	$ 91,291
Gross margin as a percentage of total revenues	67%	61%	62%	63%

Gross margin increased 17% and decreased 1% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. Gross margin as a percentage of total revenues increased in the three months ended December 31, 2015 as compared to the three months ended December 31, 2014, primarily due to decreases in the per unit cost of processing tissues and per unit cost of BioGlue. Gross margin as a percentage of total revenues decreased in the twelve months ended December 31, 2015 as compared to the twelve months ended December 31, 2014, primarily due to an increase in the per unit cost of processing tissues and due to the write-down of PerClot inventory, as discussed above.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
General, administrative, and marketing expenses	$ 19,139	$ 18,638	$ 74,929	$ 73,754

General, administrative, and marketing expenses as a percentage of total revenues	48%	50%	51%	51%

General, administrative, and marketing expenses increased 3% and 2% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively.

General, administrative, and marketing expenses for the twelve months ended December 31, 2015 included severance and termination benefits of approximately $3.0 million, related to one-time expenses associated with certain employee departures, including the retirement of Mr. Anderson, the Company s former President, Chief Executive Officer (CEO), and Executive Chairman, in April 2015. General, administrative, and marketing expenses included $1.1 million and $3.0 million for the three and twelve months ended December 31, 2015, respectively, in business development expenses, primarily related to the acquisition of On-X. General, administrative, and marketing expenses included $565,000 and $2.0 million for

Table of Contents

the three and twelve months ended December 31, 2014, respectively, in compensation charges related to personnel changes, including the appointment of Mr. Mackin as President and CEO in the third quarter of 2014 and one-time expenses associated with certain employee departures. The increase in general, administrative, and marketing expenses in the current year periods was also due to higher expenses to support the Company s increasing revenue base, international expansion, new product offerings, and increasing employee headcount. The increase in expenses for the twelve months ended December 31, 2015 included the impairment of a PerClot Topical intangible asset and higher legal fees related to the litigation with Medafor, Inc. (Medafor). See Part I, Item 3, Legal Proceedings for discussion of the Company s litigation with Medafor.

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Research and development expenses	$ 2,540	$ 2,092	$ 10,436	$ 8,699
Research and development expenses as a percentage of total revenues	6%	6%	7%	6%

Research and development expenses increased 21% and 20% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. Research and development spending in these periods was primarily focused on clinical and pre-clinical work with respect to PerClot, the Company s tissue processing, and BioGlue and BioFoam.

Gain on Sale of Medafor Investment

On October 1, 2013 Bard completed its acquisition of all outstanding shares of Medafor common stock. The Company recorded gain on sale of investment of zero and $891,000 for the three and twelve months ended December 31, 2015 and $530,000 for the three and twelve months ended December 31, 2014. The gain on the sale of Medafor investment in 2015 represents additional consideration received by the Company in April 2015 related to the release of transaction consideration from escrow. Based on a September 2015 letter from the representative of Medafor s former shareholders, the Company does not anticipate recording any additional gain on sale of Medafor Investment in 2016. The final release of funds from escrow is expected to be received in October 2017 and is expected to be nominal.

Earnings

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
Income before income taxes	$ 4,617	$ 1,625	$ 5,868	$ 8,703
Income tax (benefit) expense	1,981	(151)	1,863	1,381
Net income	$ 2,636	$ 1,776	$ 4,005	$ 7,322
Diluted income per common share	$ 0.09	$ 0.06	$ 0.14	$ 0.25

Diluted weighted-average common shares outstanding	28,687	28,238	28,542	28,313

Income before income taxes increased 184% and decreased 33% for the three and twelve months ended December 31, 2015, respectively, as compared to the three and twelve months ended December 31, 2014, respectively. The increase in income before income taxes for the three months ended December 31, 2015 was due to an increase in gross margins, partially offset by an increase in operating expenses, as discussed above. The decrease in income before income taxes for the twelve months ended December 31, 2015 was primarily due to an increase in operating expenses, as discussed above.

The Company s effective income tax rate was 43% and 32% for the three and twelve months ended December 31, 2015, respectively, as compared to a benefit of 9% and expense of 16% for the three and twelve months ended December 31, 2014, respectively. The Company s income tax rate for the twelve months ended December 31, 2015 was favorably affected by the reversal of $869,000 in uncertain tax positions, primarily related to research and development tax credits for which the statute of limitations has expired, partially offset by the expiration of certain state net operating losses and other permanent differences.

Table of Contents

The Company s income tax rate for the three and twelve months ended December 31, 2014 was favorably affected by the reduction in uncertain tax positions, nontaxable gains recorded as change in stock basis of subsidiary, and favorable deductions taken on the Company s 2013 federal tax return, which was filed in 2014.

Net income and diluted income per common share increased for the three months ended December 31, 2015 as compared to the three months ended December 31, 2014, primarily due to the increase in income before income taxes, partially offset by an increase in income tax expense, as discussed above. Net income and diluted income per common share decreased for the twelve months ended December 31, 2015 as compared to the twelve months ended December 31, 2014, primarily due to the decrease in income before income taxes, and by an increase in income tax expense, as discussed above.

Diluted income per common share could be affected in future periods by changes in the Company s common stock outstanding.

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Revenues

	Revenues for the Three Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Three Months Ended December 31,	
	2014	**2013**	**2014**	**2013**
Products:				
BioGlue and BioFoam	$ 16,346	$ 14,766	44%	42%
PerClot	1,232	808	3%	2%
CardioGenesis cardiac laser therapy	2,151	2,128	6%	6%
HeRO Graft	1,827	1,668	5%	5%
ProCol	117	--	--%	--%
Total products	21,673	19,370	58%	55%
Preservation services:				
Cardiac tissue	7,456	7,488	20%	21%
Vascular tissue	8,022	8,599	22%	24%
Total preservation services	15,478	16,087	42%	45%
Total	$ 37,151	$ 35,457	100%	100%

Table of Contents

	Revenues for the Twelve Months Ended December 31,		Revenues as a Percentage of Total Revenues for the Twelve Months Ended December 31,	
	2014	2013	2014	2013
Products:				
BioGlue and BioFoam	$ 62,091	$ 58,004	43%	41%
PerClot	4,289	3,494	3%	3%
CardioGenesis cardiac laser therapy	8,225	8,965	6%	6%
HeRO Graft	7,131	5,731	5%	4%
ProCol	147	--	--%	--%
Total products	81,883	76,194	57%	54%
Cardiac tissue	29,437	29,523	20%	21%
Vascular tissue	33,321	34,975	23%	25%
Total preservation services	62,758	64,498	43%	46%
Other	--	71	--%	--%
Total	$ 144,641	$ 140,763	100%	100%

Revenues increased 5% and 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. A detailed discussion of the changes in product revenues and preservation services revenues for the three and twelve months ended December 31, 2014 is presented below.

Products

Revenues from products increased 12% and 7% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. These increases were primarily due to an increase in BioGlue revenues and, to a lesser extent, an increase in PerClot and HeRO Graft revenues. A detailed discussion of the changes in product revenues for BioGlue and BioFoam; PerClot; CardioGenesis cardiac laser therapy; and HeRO Graft is presented below.

BioGlue and BioFoam

Revenues from the sale of surgical sealants, consisting of BioGlue and BioFoam, increased 11% for the three months ended December 31, 2014, as compared to the three months ended December 31, 2013. This increase was primarily due to a 12% increase in the volume of milliliters sold, which increased revenues by 10%, and an increase in average sales prices, which increased revenues by 2%, partially offset by the unfavorable impact of foreign exchange rates, which decreased revenues by 1%.

Revenues from the sale of surgical sealants increased 7% for the twelve months ended December 31, 2014, as compared to the twelve months ended December 31, 2013. This increase was primarily due to a 6% increase in the volume of milliliters sold, which increased revenues by 5%, and by an increase in average sales prices, which

increased revenues by 2%.

The increase in sales volume of surgical sealants for the three and twelve months ended December 31, 2014 was primarily due to an increase in shipments of BioGlue in international markets and, to a lesser extent, an increase in the Company s domestic markets. International sales of BioGlue increased in all major market areas including Latin America, Asia Pacific, including Japan, and the Company s direct and indirect markets in Europe, which includes sales for neurosurgical indications.

The increase in average sales prices for the three and twelve months ended December 31, 2014 was primarily due to list price increases in domestic markets and due to the routine negotiation of pricing contracts with certain customers.

Revenues from shipments to Japan were $1.1 million and $5.0 million for the three and twelve months ended December 31, 2014, respectively, and $801,000 and $4.8 million for the three and twelve months ended December 31, 2013, respectively.

Table of Contents

Domestic revenues accounted for 55% and 56% of total BioGlue revenues for the three and twelve months ended December 31, 2014, respectively, and 58% and 57% of total BioGlue revenues for the three and twelve months ended December 31, 2013, respectively. BioFoam sales accounted for less than 1% of surgical sealant sales for the three and twelve months ended December 31, 2014 and 2013. BioFoam is currently approved for sale in certain international markets.

PerClot

Revenues from the sale of PerClot, including PerClot and PerClot Topical, increased 52% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. This increase was primarily due to an increase in the volume of grams sold, which increased revenues by 64%, partially offset by a decrease in average selling prices, which decreased revenues by 8%, and the unfavorable effect of foreign currency exchange, which decreased revenues by 4%.

Revenues from the sale of PerClot increased 23% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This increase was primarily due to an increase in the volume of grams sold, which increased revenues by 27%, and the favorable effect of foreign currency exchange, which increased revenues by less than 1%, partially offset by a decrease in average selling prices, which decreased revenues by 5%.

Revenues during these three and twelve month periods were largely for sales in certain international markets, as PerClot Topical was only recently approved for domestic distribution, as discussed below. The increase in revenues for the three and twelve months ended December 31, 2014 was primarily due to increased sales in the Company s markets in Europe, Asia Pacific, and Latin America, partially due to growth in both new geographies and new surgical indications.

CardioGenesis Cardiac Laser Therapy

Revenues from the Company s CardioGenesis cardiac laser therapy product line consist primarily of sales of handpieces and, in certain periods, revenues from the sale of laser consoles. Revenues from cardiac laser therapy increased 1% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. Revenues from the sale of laser consoles were $240,000 and $470,000 for the three months ended December 31, 2014 and 2013, respectively. Revenues from the sale of handpieces increased 17% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013, primarily due to a 19% increase in unit shipments of handpieces.

Revenues from cardiac laser therapy decreased 8% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. Revenues from the sale of laser consoles were $384,000 and $932,000 for the twelve months ended December 31, 2014 and 2013, respectively. Revenues from the sale of handpieces decreased 3% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This decrease was primarily due to a 4% decrease in unit shipments of handpieces, which decreased revenues by 5%, partially offset by an increase in average sales prices, which increased revenues by 2%.

Revenues from laser console sales decreased for both the three and twelve months ended December 31, 2014 due to both fewer laser console sales and a reduction in the average price paid per laser console as hospitals are increasingly reluctant to make large capital equipment purchases.

In June 2013 the FDA approved the Company s new handpiece design, and the Company made the decision to exclusively distribute the new handpiece beginning late in the second quarter of 2013. The Company s handpiece

revenues were negatively impacted in the second half of 2013 and the first half of 2014, due to the slower than anticipated adoption of the new handpiece design. The decrease in handpiece revenues for the twelve months ended December 31, 2014 is a result of a decrease in revenues in the first half of 2014 as compared to the first half of 2013.

HeRO Graft

Revenues from HeRO Grafts include revenues related to the sale of vascular grafts, venous outflow components, and accessories, which are generally sold together as a kit. HeRO Grafts are primarily distributed in domestic markets as a solution for ESRD in certain hemodialysis patients. HeRO Graft revenues increased 10% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. HeRO Grafts revenues increased 24% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013.

The increase in sales of HeRO Grafts for the three months ended December 31, 2014 was primarily due to an increase in shipments in direct markets in Europe. The increase in sales of HeRO Grafts for the twelve months ended December 31,

Table of Contents

2014 was primarily due to an increase in shipments in domestic markets, as a result of increased procedure volume and an increase in the number of implanting physicians, and to a lesser extent, due to shipments to direct markets in Europe. Sales of the HeRO Graft have increased significantly in Europe since the Company launched the product in September 2013.

Preservation Services

Revenues from preservation services decreased 4% and 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. The decrease in revenues for the three and twelve month periods was primarily due to a decrease in vascular tissue services revenues. See further discussion of cardiac and vascular preservation services revenues below.

During the second quarter of 2014 the Company voluntarily restricted the distribution of certain cardiac and vascular tissues while it performed a review of its internal training programs. The Company gradually resumed shipments of tissues during the second quarter of 2014, in accordance with its procedures.

The Company made significant changes to various tissue processing and quality procedures in an effort to address a warning letter received from the FDA in January 2013, related to the manufacture of the Company s products and processing, preservation, and distribution of human tissue, as well as a subsequent 2014 Form 483. These efforts have resulted in a decrease in tissue processing throughput and an increase in the Company s cost of processing tissues. Preservation services revenues were negatively impacted during the second, third, and fourth quarters of 2014 due to these efforts, as well as the internal training program review discussed above.

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

Cardiac Preservation Services

Revenues from cardiac preservation services (consisting of revenues from the distribution of heart valves and cardiac patch tissues) decreased slightly for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. This decrease was primarily due to a 2% decrease in unit shipments of cardiac tissues, which decreased revenues by 5%, largely offset by an increase in average service fees, which increased revenues by 5%.

Revenues from cardiac preservation services decreased slightly for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This decrease was primarily due to a 4% decrease in unit shipments of cardiac tissues, which decreased revenues by 6%, largely offset by an increase in average service fees, which increased revenues by 6%.

The decrease in volume for the three and twelve months ended December 31, 2014 was primarily due to a decrease in volume of cardiac valve shipments in domestic markets and due to a significant decrease in cardiac shipments in Europe, as discussed further below, partially offset by an increase in shipments of cardiac patches in domestic markets. The decrease in cardiac valve shipments in domestic markets was due to the timing of tissue releases, which were unfavorably impacted by reduced tissue availability as discussed above, as compared to the prior year periods.

The Company ceased the routine distribution of tissues into Europe as of March 31, 2014, although a limited number of tissues have shipped and may continue to be shipped through a special regulatory process. During the twelve months ended December 31, 2014 the Company s revenues from shipments of cardiac tissues into Europe were $253,000, as compared to $1.1 million in the corresponding period in 2013.

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

Revenues from SynerGraft processed tissues, including the CryoValve SGPV and CryoPatch SG, accounted for 66% and 64% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2014, respectively, and 53% and 52% of total cardiac preservation services revenues for the three and twelve months ended December 31, 2013, respectively. Domestic revenues accounted for 96% of total cardiac preservation services revenues for both the three and twelve months ended December 31, 2014, and 93% of total cardiac preservation services revenues for both the three and twelve months ended December 31, 2013.

Table of Contents

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

Vascular Preservation Services

Revenues from vascular preservation services decreased 7% for the three months ended December 31, 2014 as compared to the three months ended December 31, 2013. This decrease was primarily due to a 12% decrease in unit shipments of vascular tissues, which decreased revenues by 12%, partially offset by an increase in average service fees, which increased revenues by 5%.

Revenues from vascular preservation services decreased 5% for the twelve months ended December 31, 2014 as compared to the twelve months ended December 31, 2013. This decrease was primarily due to a 10% decrease in unit shipments of vascular tissues, which decreased revenues by 11%, partially offset by an increase in average service fees, which increased revenues by 6%.

The decrease in vascular volume for the three and twelve months ended December 31, 2014 was primarily due to decreases in shipments of saphenous veins, which was impacted by reduced tissue availability as discussed above.

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

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

Cost of Products and Preservation Services

Cost of Products

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	**2013**	**2014**	**2013**
Cost of products	$ 5,068	$ 4,417	$ 17,167	$ 15,147

Cost of products increased 15% and 13% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Cost of products in 2014 and 2013 includes costs related to BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Grafts, and ProCol.

The increase in cost of products was primarily due to an increase in the volume of products sold, an increase in the per unit cost of manufacturing HeRO Grafts, as a result of the transfer of manufacturing to a new location and lower manufacturing throughput, and an increase in the cost of manufacturing BioGlue, partially offset by a decrease in inventory impairment charges and write-downs.

Cost of products for the twelve months ended December 31, 2013 included $483,000 in additional costs for CardioGenesis cardiac laser therapy handpieces that were made obsolete by the Company s decision to exclusively distribute the new handpiece design, which was approved by the FDA in June 2013. Cost of products for the three and

twelve months ended December 31, 2013 included $684,000 in additional contractual costs and inventory impairment costs primarily related to a BioGlue accessory product.

Table of Contents

Cost of Preservation Services

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Cost of preservation services	$ 9,448	$ 8,758	$ 36,183	$ 35,230

Cost of preservation services increased 8% and 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Cost of preservation services includes costs for cardiac and vascular tissue preservation services.

The increase in cost of preservation services was primarily due to an increase in the per unit cost of processing tissues, as a result of lower processing throughput of tissues, increased compliance and personnel costs, and an increase in the cost of materials, partially offset by a decrease in volume of tissues shipped during the period.

Gross Margin

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Gross margin	$ 22,635	$ 22,282	$ 91,291	$ 90,386
Gross margin as a percentage of total revenues	61%	63%	63%	64%

Gross margin increased 2% and 1% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Gross margin as a percentage of total revenues decreased in the three and twelve months ended December 31, 2014 as compared to the three and twelve months ended December 31, 2013, respectively, primarily due to an increase in the per unit cost of processing tissues, partially offset by a mix shift as a higher percentage of the Company s revenues were related to products, which generate higher margins.

Operating Expenses

General, Administrative, and Marketing Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
General, administrative, and marketing expenses	$ 18,638	$ 16,671	$ 73,754	$ 68,112
General, administrative, and marketing expenses as a percentage of total revenues	50%	47%	51%	48%

General, administrative, and marketing expenses increased 12% and 8% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively.

The increase in general, administrative, and marketing expenses in the current year periods was due to $565,000 and $2.0 million for the three and twelve months ended December 31, 2014, respectively, in compensation charges related to personnel changes, including the appointment of Mr. Mackin as President and CEO in the third quarter of 2014 and one-time expenses associated with certain employee departures. In addition, the increase was due to higher legal fees related to the litigation with C.R. Bard, Inc. (Bard) and certain of its subsidiaries, higher professional fees related to FDA compliance, and higher expenses to support the Company s increasing revenue base, international expansion, new product offerings, and increasing employee headcount.

Table of Contents

Research and Development Expenses

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Research and development expenses	$ 2,092	$ 2,478	$ 8,699	$ 8,454
Research and development expenses as a percentage of total revenues	6%	7%	6%	6%

Research and development expenses decreased 16% and increased 3% for the three and twelve months ended December 31, 2014, respectively, as compared to the three and twelve months ended December 31, 2013, respectively. Research and development spending in these periods was primarily focused on clinical and pre-clinical work with respect to PerClot, the Company s tissue processing, and BioGlue and BioFoam.

Gain on Sale of Medafor Investment

The gain on sale of Medafor, Inc. (Medafor) investment was $530,000 for the three and twelve months ended December 31, 2014 as compared to $12.7 million for the three and twelve months ended December 31, 2013. This gain was recorded upon the sale of the Company s 2.4 million shares of Medafor common stock to Bard in connection with its October 2013 acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately $15.4 million in the fourth quarter of 2013, and it received an additional payment of $530,000 in the fourth quarter of 2014 related to the release of funds in escrow.

Other Than Temporary Investment Impairment

Based on available information, the Company determined that the fair value of its investment in ValveXchange, Inc. (ValveXchange) preferred stock had declined significantly in the fourth quarter of 2013 and that any of that remaining value was nominal. Therefore, the Company recorded an other than temporary investment impairment of $3.2 million for the three and twelve months ended December 31, 2013 to fully impair the value of its investment. The carrying value of the Company s investment in ValveXchange preferred stock after this write-down was zero as of December 31, 2013.

Other Expense (Income)

Other expense (income) for the three and twelve months ended December 31, 2014 includes $2.0 million in expense to write-down the Company s long-term receivable from ValveXchange, as this loan became fully impaired during the fourth quarter of 2014. This expense was largely offset by a gain of $1.4 million and $1.9 million for the three and twelve months ended December 31, 2014, respectively, on the remeasurement of contingent consideration related to the Company s acquisition of Hemosphere. During the fourth quarter of 2014 the Company s estimate of the likelihood of achieving the minimum revenue target to trigger this payment become remote.

Earnings

	Three Months Ended December 31,	Twelve Months Ended December 31,

	2014	2013	2014	2013
Income before income taxes	$ 1,625	$ 12,881	$ 8,703	$ 23,292
Income tax expense	(151)	3,855	1,381	7,120
Net income	$ 1,776	$ 9,026	$ 7,322	$ 16,172
Diluted income per common share	$ 0.06	$ 0.31	$ 0.25	$ 0.57
Diluted weighted-average common shares outstanding	28,238	28,208	28,313	27,698

Income before income taxes decreased significantly for the three and twelve months ended December 31, 2014 as compared to the three and twelve months ended December 31, 2013, respectively. This decrease was primarily due to the gain on sale of Medafor investment recorded in the fourth quarter of 2013 and an increase in operating expenses, as discussed above, partially offset by an increase in product revenues, which increased margins.

Table of Contents

The Company s effective income tax rate was a benefit of 9% and expense of 16% for the three and twelve months ended December 31, 2014, respectively, as compared to expense of 30% and 31% for the three and twelve months ended December 31, 2013, respectively. The Company s income tax rate for the three and twelve months ended December 31, 2014 was favorably affected by the reduction in uncertain tax positions, nontaxable gains recorded as change in stock basis of subsidiary, and favorable deductions taken on the Company s 2013 federal tax return, which was filed in 2014. The Company s income tax rate for the twelve months ended December 31, 2013 was favorably affected by the full year 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company s tax expense during 2013 and adjustments to valuation allowances on certain of the Company s state net operating loss carryforwards, based on revised estimates of utilization of these carryforwards.

Net income and diluted income per common share decreased for the three and twelve months ended December 31, 2014 as compared to the three and twelve months ended December 31, 2013, primarily due to the decrease in income before income taxes, partially offset by a reduction in income tax expense, as discussed above.

Seasonality

The Company believes the demand for BioGlue is seasonal, with a decline in demand generally occurring in the third quarter followed by stronger demand in the fourth quarter. Management believes that this trend for BioGlue may be due to the summer holiday seasons in Europe and the U.S. The Company believes that demand for BioGlue in Japan may continue to be lowest in the second quarter of each year due to distributor ordering patterns driven by the slower summer holiday season in Japan.

The Company does not believe the demand for CardioGenesis cardiac laser therapy or HeRO Grafts is seasonal, as the Company s data does not indicate a significant trend.

The Company is uncertain whether the demand for PerClot, ProCol, or PhotoFix will be seasonal, as these products have not fully penetrated many markets and, therefore, the nature of any seasonal trends may be obscured.

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

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

Liquidity and Capital Resources

Net Working Capital

At December 31, 2015 net working capital (current assets of $109.7 million less current liabilities of $19.6 million) was $90.1 million, with a current ratio (current assets divided by current liabilities) of 6 to 1, compared to net working capital of $85.4 million and a current ratio of 5 to 1 at December 31, 2014.

Overall Liquidity and Capital Resources

The Company s largest cash requirements for the twelve months ended December 31, 2015 were cash for general working capital needs, capital expenditures, and cash dividend payments. The Company funded its cash requirements through its existing cash reserves and its operating activities, which generated cash during the period.

The Company believes that its cash from operations and existing cash and cash equivalents will enable the Company to meet its current operational liquidity needs for at least the next twelve months. The Company s cash requirements in 2016 are expected to include cash for the acquisition and integration of On-X discussed further below, to fund the PerClot clinical trials, to fund additional research and development expenditures, for general working capital needs, for capital expenditures, and for other corporate purposes. These items may have a significant effect on the Company s cash flows during 2016. The Company may seek additional borrowing capacity or financing, pursuant to its current or any future shelf registration statement, for general corporate purposes or to fund other future cash requirements. If the Company undertakes any further significant business development activity in 2016, it may need to finance such activities by drawing down monies under its credit agreement, discussed below, obtaining additional debt financing, or using a shelf registration statement to sell equities.

Table of Contents

Significant Sources and Uses of Liquidity

On December 22, 2015 the Company, entered into the Agreement and Plan of Merger (On-X Agreement) to acquire On-X, an Austin, Texas-based, privately held mechanical heart valve company for $130.0 million, subject to certain adjustments, consisting of $91.0 million in cash and approximately $39.0 million or 3,703,699 shares of CryoLife s common stock. The transaction closed on January 20, 2016 and On-X will be operated as a wholly-owned subsidiary of CryoLife.

As of December 31, 2015 CryoLife had outstanding an amended and restated credit agreement with General Electric Capital Corporation (the GE Credit Agreement) with an outstanding balance of zero and $20.0 million in available borrowing capacity. In January 2016 in connection with the closing of the On-X acquisition, the Company entered into the Third Amended and Restated Credit Agreement (Amended Debt Agreement) with Capital One, National Association; Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association, collectively the (Lending Parties). The Amended Debt Agreement provides the Company with a senior secured credit facility in an aggregate principal amount of $95 million, which includes a $75 million term loan and a $20 million revolving credit facility. The $75 million term loan was used to finance, in part, the acquisition of On-X discussed above. The Company and its domestic subsidiaries, subject to certain exceptions and exclusions, have guaranteed the obligations of the Amended Debt Agreement. Borrowings under the Amended Debt Agreement are secured by substantially all of the Company s real and personal property.

On October 1, 2013 Bard completed its previously announced acquisition of the outstanding shares of Medafor common stock. The Company received an initial payment of approximately $15.4 million in the fourth quarter of 2013 for its shares of Medafor common stock due to Bard s acquisition of Medafor, and received an additional payment of $530,000 in the fourth quarter of 2014 and $891,000 in the second quarter of 2015 related to the release of funds in escrow. In September 2015 the Company received a letter from Medafor s shareholder representative, indicating that net sales for the period were insufficient to trigger payment of additional contingent consideration by Bard. The final release of funds from escrow is expected to be received in October 2017 and is expected to be nominal. This subsequent payment will be recorded as an additional gain if, and when, received by the Company.

The Company is conducting its pivotal clinical trial to gain approval in the U.S. to commercialize PerClot for surgical indications. Management believes that the costs of this clinical trial will be significant in 2016. The Company began enrollment in the second quarter of 2015 but has suspended enrollment in the trial pending discussions with the FDA regarding the protocol for the clinical trial. Depending on the results of these discussions, the Company could receive Premarket Approval (PMA) from the FDA in early 2019. See also Part I, Item 1A, Risk Factors Risks Relating To Our Business Our investment in PerClot is subject to significant risks, and our ability to fully realize our investment is dependent on our ability to obtain FDA approval and to successfully commercialize PerClot in the U.S.

On April 9, 2015 Mr. Anderson retired from service as an employee of the Company and Chair of its Board of Directors. The Company made a payment of approximately $2.4 million in cash severance and compensation payments to Mr. Anderson in October 2015, six months after his retirement. Additionally, a bonus payment, estimated at target payout rates to be approximately $100,000, is expected to be made in February 2016 at the same time as annual bonus payments, if any, are made to the Company s officers.

In October 2015 the Company completed the acquisition of a portion of the business of its French distribution partner. The Company acquired in the transaction certain intangible assets, including commercial and business information, assignment of contracts, and a non-compete agreement with its former French distribution partner for a purchase price of 1.2 million Euros.

In March 2014 the Company acquired the exclusive worldwide distribution rights for ProCol from Hancock Jaffe. The agreement between CryoLife and Hancock Jaffe (the HJ Agreement) has an initial three-year term and is renewable for two one-year periods at CryoLife s option. CryoLife made inventory payments to Hancock Jaffe under the distribution arrangement of $1.7 million during 2014 and $576,000 in January 2015. The Company made additional advance payments of $1.1 million in the aggregate during the remainder of 2015. As of December 31, 2015 the Company had made a total of $3.3 million in payments to Hancock Jaffe and had received $1.3 million in inventory. Therefore, as of December 31, 2015 CryoLife had approximately $2.0 million in remaining prepayments on its Consolidated Balance Sheet for which inventory had not yet been received. During the second quarter of 2015 CryoLife notified Hancock Jaffe that it was in breach of the HJ Agreement due to, among other things, Hancock Jaffe s failure to timely ship inventory. In the fourth quarter of 2015

Table of Contents

CryoLife and Hancock Jaffe amended the HJ Agreement. This amendment included new terms which, among other changes, confirm Hancock Jaffe s breach of the HJ Agreement; accelerate and allow CryoLife to assign the purchase option; outline Hancock Jaffe s requirements to be eligible for additional advances; and modify the termination provisions. The amendment does not cure Hancock Jaffe s breach of the agreement. CryoLife is currently monitoring Hancock Jaffe s compliance with the terms of the amended HJ Agreement and determining what additional steps it can take to help ensure receipt of inventory and repayment of the additional advances. If CryoLife is unable to secure full satisfaction or repayment of the amounts owed, or sell its interest in the agreement for an amount equal to or in excess of the carrying value of the related assets, the prepayment may become impaired in future periods.

The Company acquired net operating loss carryforwards from its acquisitions of Hemosphere, Inc. and Cardiogenesis Corporation that the Company believes will reduce required cash payments for federal income taxes by approximately $1.5 million for the 2015 tax year.

As of December 31, 2015 approximately 5% of the Company s cash and cash equivalents were held in foreign jurisdictions.

Net Cash Flows from Operating Activities

Net cash provided by operating activities was $11.4 million for the twelve months ended December 31, 2015 as compared to $8.1 million for the twelve months ended December 31, 2014. The current year cash provided was primarily due to net income generated by the Company during the period, after non-cash adjustments.

The Company uses the indirect method to prepare its cash flow statement, and, accordingly, the operating cash flows are based on the Company s net income, which is then adjusted to remove non-cash items, items classified as investing and financing cash flows, and for changes in operating assets and liabilities from the prior year end. For the twelve months ended December 31, 2015 these items included a favorable $5.9 million in depreciation and amortization expense, $5.1 million in non-cash compensation, and $3.7 million in deferred income taxes.

The Company s working capital needs, or changes in operating assets and liabilities, also affected cash from operations. For the twelve months ended December 31, 2015 the increase in working capital needs of $7.9 million was primarily due to the timing difference of $3.8 million between recording receivables and the receipt of cash and $2.3 million due to increases in inventory balances and deferred preservation costs.

Net Cash Flows from Investing Activities

Net cash used in investing activities was $4.5 million for the twelve months ended December 31, 2015 as compared to $5.4 million for the twelve months ended December 31, 2014. The current year cash used was primarily due to $3.5 million in capital expenditures and $1.3 million for the fourth quarter acquisition of the French distribution business of the Company s former distribution partner.

Net Cash Flows from Financing Activities

Net cash used in financing activities was $2.8 million for the twelve months ended December 31, 2015 as compared to $7.0 million for the twelve months ended December 31, 2014. The current year cash used was primarily due to $3.4 million in cash dividends paid on the Company s common stock. The prior year cash used was primarily due to $5.6 million in purchases of treasury stock related to the Company s publicly announced stock repurchase plan.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Table of Contents

Scheduled Contractual Obligations and Future Payments

Scheduled contractual obligations and the related future payments as of December 31, 2015 are as follows (in thousands):

	Total	2016	2017	2018	2019	2020	Thereafter
Operating leases	$ 24,197	$ 3,167	$ 3,536	$ 3,524	$ 3,462	$ 3,534	$ 6,974
Purchase commitments	5,585	2,548	1,525	1,512	--	--	--
Research obligations	1,116	1,066	50	--	--	--	--
Contingent payments	1,000	--	--	--	1,000	--	--
Total contractual obligations	$ 31,898	$ 6,781	$ 5,111	$ 5,036	$ 4,462	$ 3,534	$ 6,974

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

The Company s purchase commitments include minimum purchase requirements for PerClot related to the Company s transaction with SMI. These minimum purchases are included through 2018, which assumes that the Company receives FDA approval for PerClot in early 2019. Upon FDA approval, the Company may terminate its minimum purchase requirements, per the terms of its agreements with SMI, which the Company expects to do. However, if the Company does not terminate this provision, it will have minimum purchase obligations of up to $1.75 million per year through the end of the contract term in 2025. The Company s purchase commitments includes obligations from agreements with suppliers.

The contingent payments obligation include payments that the Company will make if certain FDA regulatory approvals and other commercial milestones are achieved related to the Company s transaction with SMI for PerClot.

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

The schedule of contractual obligations above excludes (i) obligations for estimated liability claims unless they are due as a result of a settlement agreement or other contractual obligation, as no assessments have been made for specific litigation, and (ii) any estimated liability for uncertain tax positions and interest and penalties, currently estimated to be $1.2 million, as no specific assessments by any taxing authorities.

Capital Expenditures

Capital expenditures for the twelve months ended December 31, 2015 and 2014 were $3.5 million and $4.3 million, respectively. Capital expenditures in the twelve months ended December 31, 2015 were primarily related to the routine purchases of manufacturing and tissue processing equipment, including support for the Company s HeRO Graft and PerClot product lines; leasehold improvements needed to support the Company s business; CardioGenesis cardiac laser therapy laser consoles; computer software; and computer and office equipment.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The Company s interest income and interest expense are sensitive to changes in the general level of U.S. interest rates. In this regard, changes in U.S. interest rates affect the interest earned on the Company s cash and cash equivalents of $37.6 million, restricted cash and securities of $5.0 million, and interest paid on the Company s variable rate line of credit as of December 31, 2015. A 10% adverse change in interest rates as compared to the rates experienced by the Company in the twelve months ended December 31, 2015, affecting the Company s cash and cash equivalents, restricted cash, and line of credit would not have had a material impact on the Company s financial position, profitability, or cash flows.

Foreign Currency Exchange Rate Risk

The Company has balances, such as cash, accounts receivable, accounts payable, and accruals that are denominated in foreign currencies. These foreign currency denominated balances are sensitive to changes in exchange rates. In this regard,

Table of Contents

changes in exchange rates could cause a change in the U.S. Dollar equivalent of cash or funds that the Company will receive in payment for assets or that the Company would have to pay to settle liabilities. As a result, the Company could be required to record these changes as gains or losses on foreign currency translation.

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

An additional 10% adverse change in exchange rates from the exchange rates in effect on December 31, 2015 affecting the Company s balances denominated in foreign currencies would not have had a material impact on the Company s financial position or cash flows. An additional 10% adverse change in exchange rates from the weighted-average exchange rates experienced by the Company for the twelve months ended December 31, 2015 affecting the Company s revenue and expense transactions denominated in foreign currencies, would not have had a material impact on the Company s financial position, profitability, or cash flows.

Item 8. Financial Statements and Supplementary Data.

Our financial statements and supplementary data required by this item are submitted as a separate section of this annual report on Form 10-K. See Financial Statements commencing on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

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

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

assurance of achieving their objectives.

The Company s management utilizes the criteria set forth in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of its Disclosure Controls over financial reporting. Based upon the most recent Disclosure Controls evaluation conducted by management with the participation of the CEO and CFO, as of December 31, 2015, the CEO and CFO have concluded that the Company s Disclosure Controls were effective at the reasonable assurance level to satisfy their objectives and to ensure that the information required to be disclosed by the Company in its periodic reports is accumulated and communicated to management, including the CEO and CFO, as appropriate to allow timely decisions regarding disclosure and is recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission s rules and forms.

Table of Contents

During the quarter ended December 31, 2015 there were no changes in the Company s internal control over financial reporting that materially affected or that are reasonably likely to materially affect the Company s internal control over financial reporting.

The report called for by Item 308(a) of Regulation S-K is incorporated herein by reference to Management s Report on Internal Control over Financial Reporting under Sarbanes-Oxley Section 404 on page F-1 of this report.

The attestation report called for by Item 308(b) of Regulation S-K is incorporated herein by reference to Report of Independent Registered Public Accounting Firm on page F-2 of this report.

Item 9B. Other Information.

None.

Table of Contents

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The response to Item 10 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2015, with the exception of information concerning executive officers, which is included in Part I, Item 4A, Executive Officers of the Registrant of this Form 10-K.

Item 11. Executive Compensation.

The response to Item 11 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2015.

Item 12. Security Ownership of Certain Beneficial Owners and Management, and Related Stockholder Matters.

The response to Item 12 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2015.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The response to Item 13 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2015.

Item 14. Principal Accounting Fees and Services.

The response to Item 14 is incorporated herein by reference to the information to be set forth in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the Commission within 120 days after December 31, 2015.

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following are filed as part of this report:

(a) 1. Financial Statements.

Consolidated Financial Statements begin on page F-1.

2. Financial Statement Schedules.

All financial statement schedules are omitted, as the required information is immaterial, not applicable, or the information is presented in the consolidated financial statements or related notes.

3. Exhibits

The information required by this Item is set forth on the exhibit index that follows the signature page of this Annual Report on Form 10-K.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CRYOLIFE, INC.

February 16, 2016 By /s/ J. PATRICK MACKIN
J. Patrick Mackin
President, Chief Executive Officer, and
Chairman of the Board of Directors

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ J. PATRICK MACKIN **J. Patrick Mackin**	President, Chief Executive Officer, and Chairman of the Board of Directors (Principal Executive Officer)	February 16, 2016
/s/ D. ASHLEY LEE **D. Ashley Lee**	Executive Vice President, Chief Operating Officer, and Chief Financial Officer (Principal Financial Officer)	February 16, 2016
/s/ AMY D. HORTON **Amy D. Horton**	Chief Accounting Officer (Principal Accounting Officer)	February 16, 2016
/s/ THOMAS F. ACKERMAN **Thomas F. Ackerman**	Director	February 16, 2016
/s/ JAMES S. BENSON **James S. Benson**	Director	February 16, 2016
/s/ DANIEL J. BEVEVINO **Daniel J. Bevevino**	Director	February 16, 2016

/s/ RONALD C. ELKINS, M.D.	Director	February 16, 2016
Ronald C. Elkins, M.D.		
/s/ RONALD D. MCCALL	Director	February 16, 2016
Ronald D. McCall		
/s/ HARVEY MORGAN	Director	February 16, 2016
Harvey Morgan		
/s/ JON W. SALVESON	Director	February 16, 2016
Jon W. Salveson		

Table of Contents

Exhibit Number	Description
2.1+	Series A Preferred Stock Purchase Agreement Among CryoLife, Inc., The Cleveland Clinic Foundation, and ValveXchange, Inc. dated July 6, 2011. (Incorporated herein by reference to Exhibit 2.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.)
2.2	Agreement and Plan of Merger, dated May 14, 2012, by and among CryoLife, Inc., CL Crown, Inc., Hemosphere, Inc. and a Stockholder Representative. (Incorporated herein by reference to Exhibit 2.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.)
2.3	Agreement and Plan of Merger, dated as of December 22, 2015, by and among CryoLife, Inc., On-X Life Technologies Holdings, Inc., Cast Acquisition Corporation, Fortis Advisors LLC and each of the security holders who becomes a party thereto. (Incorporated herein by reference to Exhibit 2.1 to the Registrant s Current Report on Form 8-K filed January 25, 2016.)
3.1	Amended and Restated Articles of Incorporation of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed November 23, 2015.)
3.2	Amended and Restated By-Laws of CryoLife, Inc. (Incorporated herein by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed November 23, 2015.)
4.1	Form of Certificate for the Company s Common Stock. (Incorporated herein by reference to Exhibit 4.2 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1997.)
4.2	First Amended and Restated Rights Agreement, dated as of November 2, 2005, between CryoLife, Inc. and American Stock Transfer & Trust Company. (Incorporated herein by reference to Exhibit 4.1 to Registrant s Current Report on Form 8-K filed November 3, 2005.)
4.3	Registration Rights Agreement, dated as of January 20, 2016, by and between CryoLife, Inc. and the Investors party thereto. (Incorporated herein by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 25, 2016.)
4.4	Form of Indenture for Senior Debt Securities (Incorporated herein by reference to Exhibit 4.7 to the Registrant s Registration Statement on Form S-3 filed August 5, 2015 (No. 333-206119).)
4.5	Form of Subordinated Indenture for Subordinated Debt Securities (Incorporated herein by reference to Exhibit 4.9 to the Registrant s Registration Statement on Form S-3 filed August 5, 2015 (No. 333-206119).)
10.1	CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2007.)
10.1(a)	First Amendment, dated July 24, 2012, to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.1(b)	CryoLife, Inc. Equity and Cash Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to Registrant s Quarterly Report on Form 10-Q filed July 28, 2015.)
10.2	CryoLife, Inc. 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Appendix 1 to the Registrant s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.3	

	Form of 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.7 to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.3(a)	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2002 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed August 7, 2006.)
10.3(b)	Form of Restricted Stock Award Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended May 2, 2007.)

Table of Contents

Exhibit Number	Description
10.4	Form of Incentive Stock Option Grant Agreement under the 1998 Long-Term Incentive Plan. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended May 2, 2007.)
10.5	Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.9 to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.5(a)	First Amendment, dated as of May 28, 2014, to the Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)
10.5(b)	Second Amendment, dated as of September 3, 2014, to the Employment Agreement, dated as of October 23, 2012, by and between the Company and Steven G. Anderson. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed September 9, 2014.)
10.5(c)	Form of Change of Control Agreement (entered into with respect to Jeffrey W. Burris, David M. Fronk, and Scott B. Capps). (Incorporated herein by reference to Exhibit 10.9(a) to the Registrant s Annual Report on 10-K for the fiscal year ended December 31, 2012.)
10.5(d)	Change of Control Agreement, by and between the Company and D. Ashley Lee, dated October 24, 2008. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed October 28, 2008.)
10.5(e)	Compensation Arrangement between CryoLife and David M. Fronk dated April 24, 2015. (Incorporated herein by reference to Item 5.02 to Registrant s Current Report on Form 8-K filed April 27, 2015.)
10.6	Form of Secrecy and Noncompete Agreement, by and between the Company and its Officers. (Incorporated herein by reference to Exhibit 10.9 to the Registrant s Registration Statement on Form S-1 (No. 33-56388).)
10.7	Form of Key Employee Secrecy and Noncompete Agreement, by and between the Company and its Officers and Key Employees (Incorporated herein by reference to Exhibit 10.11 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.).
10.8	Separation and Release Agreement, by and between the Company and Jeffrey W. Burris. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)
10.8(a)	Separation Agreement between CryoLife and Steven G. Anderson dated April 9, 2015. (Incorporated herein by reference to Exhibit 10.1 to Registrant s Current Report on Form 8-K filed April 10, 2015.)
10.8(b)	Separation and Release Agreement between CryoLife and Bruce G. Anderson dated October 8, 2015. (Incorporated herein by reference to Exhibit 10.1 to Registrant s Quarterly Report on Form 10-Q filed October 27, 2015.)
10.8(c)	Separation and Release Agreement - Amended between CryoLife and David M. Fronk dated October 8, 2015. (Incorporated herein by reference to Exhibit 10.2 to Registrant s Quarterly Report on Form 10-Q filed October 27, 2015.)
10.9	

	CryoLife, Inc. Non-Employee Directors Stock Option Plan, as amended. (Incorporated herein by reference to Appendix 2 to the Registrant s Definitive Proxy Statement filed with the Securities and Exchange Commission on April 17, 1998.)
10.10	Lease Agreement between the Company and Amli Land Development I Limited Partnership, dated April 18, 1995. (Incorporated herein by reference to Exhibit 10.16 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007.)
10.10(a)	First Amendment to Lease Agreement, dated April 18, 1995, between the Company and Amli Land Development I Limited Partnership dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(a) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999.)

Table of Contents

Exhibit Number	Description
10.10(b)	Restatement and Amendment to Funding Agreement between the Company and Amli Land Development I Limited Partnership, dated August 6, 1999. (Incorporated herein by reference to Exhibit 10.16(b) to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)
10.10(c)	Amended and Restated Lease Agreement between the Company and P&L Barrett, L.P., dated May 10, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.)
10.10(d)	Lease, dated October 23, 2014, by and between Roberts Boulevard, LLC, as Landlord, and CryoLife, Inc., as Tenant. (Incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed October 27, 2014.)
10.11	CryoLife, Inc. 2004 Employee Stock Incentive Plan, adopted on June 29, 2004. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.)
10.11(a)	First Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated October 27, 2009. (Incorporated herein by reference to Exhibit 10.46 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2009.)
10.11(b)	Second Amendment to the CryoLife, Inc. 2004 Employee Stock Incentive Plan, dated May 24, 2011. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011.)
10.12	Form of Incentive Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)
10.13	Form of Non-Qualified Employee Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 25, 2008.)
10.14	Technology License Agreement between the Company and Colorado State University Research Foundation dated March 28, 1996. (Incorporated herein by reference to Exhibit 10.22 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007.)
10.15	Form of Section 16 Officer Stock Option Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)
10.16	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed February 27, 2006.)
10.17	Form of Incentive Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.18	Form of Non-Qualified Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.33 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)

10.19	Form of Non-Qualified Employee Stock Option Agreement and Grant pursuant to the CryoLife, Inc. 2004 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.35 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006.)
10.20	International Distribution Agreement, dated September 17, 1998, between the Company and Century Medical, Inc. (Incorporated by reference to Exhibit 10.37 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000.)

Table of Contents

Exhibit Number	Description
10.21	CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002.)
10.22	Settlement and Release Agreement, dated August 2, 2002, by and between Colorado State University Research Foundation, the Company, and Dr. E. Christopher Orton. (Incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.)
10.23	Settlement Agreement and Release, dated September 25, 2006, by and between CryoLife, Inc. and St. Paul Mercury Insurance Company. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2006.)
10.24*	Summary of Compensation Arrangements with Non-Employee Directors.
10.25	CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.)
10.26	Form of 2013 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on 10-Q for the quarter ended March 31, 2013.)
10.27	Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan entered into with each Named Executive Officer. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.)
10.28+	Distribution Agreement between the Company and Starch Medical, Inc., dated September 28, 2010. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed December 30, 2014.)
10.28(a)	First Amendment to the Distribution Agreement between the Company and Starch Medical, Inc., dated May 18, 2011. (Incorporated herein by reference to Exhibit 10.7 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.)
10.28(b)	Second Amendment to the Distribution Agreement between the Company and Starch Medical, Inc., dated September 20, 2013. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2013.)
10.29+	License Agreement between the Company and Starch Medical, Inc., dated September 28, 2010. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed December 30, 2014.)
10.29(a)	Indemnification Agreement between the Company and Starch Medical, Inc., dated May 21, 2013. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013.)
10.30	CryoLife, Inc. Executive Deferred Compensation Plan. (Incorporated herein by reference to Exhibit 10.52 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2010.)
10.31	Form of Non-Qualified Stock Option Grant Agreement pursuant to the CryoLife, Inc. 2002 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)

10.32	Form of Restricted Stock Award Agreement pursuant to the CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2011.)
10.33++	Loan and Security Agreement by and between ValveXchange, Inc., and CryoLife, Inc. dated July 6, 2011. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.)

Table of Contents

Exhibit Number	Description
10.33(a)	First Amendment to Loan and Security Agreement by and between ValveXchange, Inc., and CryoLife, Inc. dated September 6, 2011. (Incorporated herein by reference to Exhibit 10.56(a) to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2011.)
10.33(b)	Second Amendment, dated July 18, 2012, to the Loan and Security Agreement by and between ValveXchange, Inc. and CryoLife, Inc. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.34	Form of Indemnification Agreement for Non-Employee Directors and Certain Officers. (Incorporated herein by reference to Exhibit 10.1 to Registrant s Current Report on Form 8-K filed February 18, 2015.)
10.35	Form of Performance Share Agreement with Named Executive Officers. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed March 22, 2012.)
10.35(a)	First Amendment, dated July 23, 2012, to the 2012 Grant Agreement to Executive Officers pursuant to the CryoLife, Inc. 2007 Executive Incentive Plan. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.35(b)	Stock Option Grant Agreement, dated September 2, 2014, by and between CryoLife, Inc. and J. Patrick Mackin. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)
10.35(c)	Restricted Stock Award Agreement, dated September 2, 2014, by and between CryoLife, Inc. and J. Patrick Mackin. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q filed October 28, 2014.)
10.35(d)	Form of Performance Share Agreement with Named Executive Officers pursuant to the Second Amended and Restated CryoLife, Inc. 2009 Employee Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.2 to Registrant s Quarterly Report on Form 10-Q filed April 29, 2015.)
10.35(e)	Form of Amendment to Performance Share Agreement with Named Executive Officers. (Incorporated herein by reference to Exhibit 10.4 to Registrant s Quarterly Report on Form 10-Q filed July 28, 2015.)
10.36	Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 99.1 to the Registrant s Form S-8 filed June 22, 2012.)
10.36(a)	First Amendment, dated July 24, 2012, to the Amended and Restated CryoLife, Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.36(b)	Second Amended and Restated CryoLife Inc. 2009 Stock Incentive Plan. (Incorporated herein by reference to Appendix B to the Company s Definitive Proxy Statement filed April 8, 2014.)
10.37	Waiver Agreement, dated May 14, 2012, by and among CryoLife, Inc. and certain of its subsidiaries, as borrowers, and General Electric Capital Corporation, as lender and administrative agent for all lenders, under the Amended and Restated Credit Agreement between the parties, dated October 28, 2011. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.)
10.38	Final Settlement Agreement, dated June 28, 2012, by and among CryoLife, Inc. and Medafor, Inc. (Incorporated herein by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for

	the quarter ended June 30, 2012.)
10.39	Settlement Agreement, dated June 14, 2012, by and among CryoLife, Inc. and CardioFocus, Inc. (Incorporated herein by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.)
10.40	Exclusive Supply and Distribution Agreement, dated as of March 26, 2014, by and between CryoLife, Inc. and Hancock Jaffe Laboratories, Inc. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.)

Table of Contents

Exhibit Number	Description
10.41	Employment Agreement dated as of July 7, 2014, between CryoLife, Inc. and J. Patrick Mackin. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed July 11, 2014.)
10.42 *	Form of Non-Employee Directors Restricted Stock Award Agreement pursuant to the Second Amended and Restated CryoLife, Inc. 2009 Employee Stock Incentive Plan.
10.43	Commitment Letter by and among CryoLife, Inc.; Capital One, National Association; Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association, dated as of December 22, 2015. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed December 23, 2015.)
10.44	Third Amended and Restated Credit Agreement, dated as of January 20, 2016, by and among CryoLife, Inc., On-X Life Technologies Holdings, Inc., AuraZyme Pharmaceuticals, Inc., CryoLife International, Inc., On-X Life Technologies, Inc., Valve Special Purpose Co., LLC, the lenders from time to time party thereto and Healthcare Financial Solutions, LLC, as agent. (Incorporated herein by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed January 25, 2016.)
10.45	Amended and Restated Guaranty and Security Agreement, dated as of January 20, 2016, by and among CryoLife, Inc., AuraZyme Pharmaceuticals, Inc., CryoLife International, Inc., On-X Life Technologies Holdings, Inc., On-X Life Technologies, Inc., Valve Special Purpose Co., LLC and each other grantor from time to time party thereto in favor of Healthcare Financial Solutions, LLC, as Administrative Agent. (Incorporated herein by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed January 25, 2016.)
14.1	Form of Code of Conduct, as amended (Incorporated herein by reference to Exhibit 14.1 to the Registrant s Current Report on Form 8-K filed November 23, 2015.)
21.1*	Subsidiaries of CryoLife, Inc.
23.1*	Consent of Ernst & Young LLP.
31.1*	Certification by J. Patrick Mackin pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by D. Ashley Lee pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32**	Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 Of The Sarbanes-Oxley Act Of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Furnished herewith.

Indicates management contract or compensatory plan or arrangement.

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

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

Table of Contents

Management s Report on Internal Control over Financial Reporting under Sarbanes-Oxley Section 404.

The management of CryoLife, Inc. and subsidiaries (CryoLife or we) is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. CryoLife s internal control system was designed to provide reasonable assurance to CryoLife s management and Board of Directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

CryoLife management assessed the effectiveness of CryoLife s internal control over financial reporting as of December 31, 2015. In making this assessment, we used the criteria set forth in the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our assessment, we believe that, as of December 31, 2015, the company s internal control over financial reporting was effective based on those criteria.

CryoLife s independent registered public accounting firm, Ernst & Young, LLP, has issued an audit report on the effectiveness of CryoLife s internal control over financial reporting as of December 31, 2015.

CryoLife, Inc.

February 16, 2016

Table of Contents

Report of Independent Registered Public Accounting Firm on the Financial Statements

The Board of Directors and Shareholders of CryoLife, Inc.

We have audited the accompanying consolidated balance sheets of CryoLife, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive income, shareholders equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of CryoLife, Inc. and subsidiaries at December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), CryoLife, Inc. and subsidiaries internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 16, 2016 expressed an unqualified opinion thereon.

Ernst & Young LLP

Atlanta, GA

February 16, 2016

Table of Contents

Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

The Board of Directors and Shareholders of CryoLife, Inc.

We have audited CryoLife, Inc. and subsidiaries internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). CryoLife, Inc. and subsidiaries management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control over Financial Reporting under Sarbanes-Oxley Section 404. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, CryoLife, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of CryoLife, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive income, shareholders equity and cash flows for each of the three years in the period ended December 31, 2015 of CryoLife, Inc. and subsidiaries and our report dated February 16, 2016 expressed an unqualified opinion thereon.

Ernst & Young, LLP

Atlanta, Georgia

February 16, 2016

Table of Contents

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31,	
	2015	**2014**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,588	$ 33,375
Restricted securities	830	884
Receivables:		
Trade accounts, net	23,419	21,064
Other	3,253	1,799
Total receivables	**26,672**	**22,863**
Inventories	14,643	12,739
Deferred preservation costs	24,741	25,196
Deferred income taxes	--	6,210
Prepaid expenses and other	5,189	4,761
Total current assets	**109,663**	**106,028**
Property and equipment:		
Equipment and software	28,608	26,699
Furniture and fixtures	4,483	4,375
Leasehold improvements	30,902	30,660
Total property and equipment	63,993	61,734
Less accumulated depreciation and amortization	52,509	49,732
Net property and equipment	**11,484**	**12,002**
Other assets:		
Restricted cash	5,000	5,000
Goodwill	11,365	11,365
Patents, less accumulated amortization of $2,664 in 2015 and $2,497 in 2014	1,417	1,784
Trademarks and other intangibles, less accumulated amortization of $7,997 in 2015 and $6,352 in 2014	18,480	19,496
Deferred income taxes	18,188	15,659
Other	5,582	4,823
Total assets	**$ 181,179**	**$ 176,157**

Table of Contents

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31, 2015	2014
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 4,590	$ 4,497
Taxes payable	58	46
Accrued compensation	6,335	5,406
Accrued procurement fees	4,445	4,675
Accrued expenses	2,847	2,991
Other	1,330	3,012
Total current liabilities	**19,605**	**20,627**
Deferred compensation liability	1,927	1,918
Deferred rent obligations	1,735	1,649
Other	2,661	3,278
Total liabilities	**25,928**	**27,472**
Commitments and contingencies		
Shareholders equity:		
Preferred stock $0.01 par value per share, 5,000 shares authorized, no shares issued:		
Series A Junior Participating Preferred Stock, 2,000 shares auth., no shares issued	--	--
Convertible preferred stock, 460 shares auth., no shares issued	--	--
Common stock $0.01 par value per share, 75,000 shares authorized, 29,766 shares issued in 2015 and 29,229 shares issued in 2014	298	292
Additional paid-in capital	142,888	135,227
Retained earnings	23,365	22,768
Accumulated other comprehensive loss	(76)	(121)
Treasury stock at cost, 1,265 shares in 2015 and 1,101 shares in 2014	(11,224)	(9,481)
Total shareholders equity	**155,251**	**148,685**
Total liabilities and shareholders equity	**$ 181,179**	**$ 176,157**

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

(in thousands, except per share data)

	Year Ended December 31,		
	2015	**2014**	**2013**
Revenues:			
Products	$ 83,081	$ 81,883	$ 76,194
Preservation services	62,817	62,758	64,498
Other	--	--	71
Total revenues	**145,898**	**144,641**	**140,763**
Cost of products and preservation services:			
Products	18,663	17,167	15,147
Preservation services	36,516	36,183	35,230
Total cost of products and preservation services	**55,179**	**53,350**	**50,377**
Gross margin	**90,719**	**91,291**	**90,386**
Operating expenses:			
General, administrative, and marketing	74,929	73,754	68,112
Research and development	10,436	8,699	8,454
Total operating expenses	**85,365**	**82,453**	**76,566**
Operating income	**5,354**	**8,838**	**13,820**
Interest expense	(62)	175	71
Interest income	(45)	(50)	(4)
Gain on sale of Medafor investment	(891)	(530)	(12,742)
Other than temporary investment impairment	--	--	3,229
Other expense (income), net	484	540	(26)
Income before income taxes	**5,868**	**8,703**	**23,292**
Income tax expense	1,863	1,381	7,120
Net income	**$ 4,005**	**$ 7,322**	**$ 16,172**
Income per common share:			

Basic	**$ 0.14**	**$ 0.26**	**$ 0.59**
Diluted	**$ 0.14**	**$ 0.25**	**$ 0.57**
Dividends declared per common share	**$ 0.120**	**$ 0.118**	**$ 0.108**
Weighted-average common shares outstanding:			
Basic	27,744	27,379	26,885
Diluted	28,542	28,313	27,698
Net income	**$ 4,005**	**$ 7,322**	**$ 16,172**
Other comprehensive income (loss)	45	(128)	46
Comprehensive income	**$ 4,050**	**$ 7,194**	**$ 16,218**

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2015	**2014**	**2013**
Net cash flows from operating activities:			
Net income	$ 4,005	$ 7,322	$ 16,172
Adjustments to reconcile net income to net cash from operating activities:			
Gain on sale of Medafor investment	(891)	(530)	(12,742)
Depreciation and amortization	5,863	6,028	5,843
Non-cash compensation	5,089	3,436	3,240
Other than temporary investment impairment	--	--	3,229
Write-down of inventories and deferred preservation costs	1,341	680	1,693
Deferred income taxes	3,681	178	617
Other non-cash adjustments to income	268	(474)	298
Changes in operating assets and liabilities:			
Receivables	(3,809)	(4,556)	(1,637)
Inventories and deferred preservation costs	(2,262)	(1,131)	193
Prepaid expenses and other assets	(1,187)	(2,771)	(706)
Accounts payable, accrued expenses, and other liabilities	(656)	(64)	572
Net cash flows provided by operating activities	**11,442**	**8,118**	**16,772**
Net cash flows from investing activities:			
Sales and maturities of restricted securities and investments	1,157	639	--
Proceeds from sale of Medafor investment	891	530	15,421
Capital expenditures	(3,490)	(4,310)	(4,338)
Acquisition of French distribution business	(1,349)	--	--
Purchases of restricted securities and investments	(1,085)	(1,208)	(20)
Acquisition of intangible assets	(613)	(1,010)	(196)
Other	3	6	10
Net cash flows (used in) provided by investing activities	**(4,486)**	**(5,353)**	**10,877**
Net cash flows from financing activities:			
Proceeds from exercise of stock options and issuance of common stock	1,526	2,675	2,207
Cash dividends paid	(3,408)	(3,295)	(2,967)
Repurchases of common stock	--	(5,588)	(1,523)
Redemption and repurchase of stock to cover tax withholdings	(1,386)	(1,483)	(681)

Other	458	738	(87)
Net cash flows used in financing activities	**(2,810)**	**(6,953)**	**(3,051)**
Effect of exchange rate changes on cash	67	(80)	36
Increase (decrease) in cash and cash equivalents	**4,213**	**(4,268)**	**24,634**
Cash and cash equivalents, beginning of year	33,375	37,643	13,009
Cash and cash equivalents, end of year	**$ 37,588**	**$ 33,375**	**$ 37,643**

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

CRYOLIFE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands)

	Common Stock		Additional Paid In		Accumulated Other Comprehensive	Treasury Stock		Total Shareholders
	Shares	Amount	Capital	Retained Earnings	Income (Loss)	Shares	Amount	Equity
Balance at December 31, 2012	**27,486**	**$ 275**	**$ 122,414**	**$ 5,536**	**$ (39)**	**(14)**	**$ (74)**	**$ 128,112**
Net income	--	--	--	16,172	--	--	--	16,172
Other comprehensive loss	--	--	--	--	46	--	--	46
Comprehensive income								16,218
Cash dividends paid ($0.108 per share)	--	--	--	(2,967)	--	--	--	(2,967)
Equity compensation	352	3	3,465	--	--	--	--	3,468
Exercise of options	365	4	2,728	--	--	(102)	(1,000)	1,732
Employee stock purchase plan	97	1	474	--	--	--	--	475
Excess tax shortfall	--	--	(87)	--	--	--	--	(87)
Repurchase of common stock	--	--	--	--	--	(253)	(1,523)	(1,523)
Redemption and repurchase of stock to cover tax withholdings	(56)	(1)	(409)	--	--	(44)	(271)	(681)
Balance at December 31, 2013	**28,244**	**$ 282**	**$ 128,585**	**$ 18,741**	**$ 7**	**(413)**	**$ (2,868)**	**$ 144,747**
Net income	--	--	--	7,322	--	--	--	7,322
Other comprehensive income	--	--	--	--	(128)	--	--	(128)
Comprehensive income								7,194
Cash dividends paid ($0.118 per share)	--	--	--	(3,295)	--	--	--	(3,295)
Equity compensation	642	6	3,691	--	--	--	--	3,697

Exercise of options	297	3	2,150	--	--	(18)	(191)	1,962
Employee stock purchase plan	111	1	712	--	--	--	--	713
Excess tax benefit	--	--	738	--	--	--	--	738
Repurchase of common stock	--	--	--	--	--	(585)	(5,588)	(5,588)
Redemption and repurchase of stock to cover tax withholdings	(65)	--	(649)	--	--	(85)	(834)	(1,483)
Balance at December 31, 2014	**29,229**	**$ 292**	**$ 135,227**	**$ 22,768**	**$ (121)**	**(1,101)**	**$ (9,481)**	**$ 148,685**
Net income	--	--	--	4,005	--	--	--	4,005
Other comprehensive loss	--	--	--	--	45	--	--	45
Comprehensive income								4,050
Cash dividends paid ($0.120 per share)	--	--	--	(3,408)	--	--	--	(3,408)
Equity compensation	271	3	5,323	--	--	--	--	5,326
Exercise of options	248	2	1,837	--	--	(93)	(1,002)	837
Employee stock purchase plan	78	1	688	--	--	--	--	689
Excess tax benefit	--	--	458	--	--	--	--	458
Redemption and repurchase of stock to cover tax withholdings	(60)	--	(645)	--	--	(71)	(741)	(1,386)
Balance at December 31, 2015	**29,766**	**$ 298**	**$ 142,888**	**$ 23,365**	**$ (76)**	**(1,265)**	**$ (11,224)**	**$ 155,251**

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

CRYOLIFE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Nature of Business

CryoLife, Inc. (CryoLife, the Company, we, or us), incorporated in 1984 in Florida, is a leader in medical device manufacturing and distribution and in the processing and distribution of implantable human tissues for use in cardiac and vascular surgeries. 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 internationally for Starch Medical, Inc. (SMI). CryoLife s CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used for the treatment of coronary artery disease in patients with severe angina. CryoLife is the exclusive distributor of ProCol® Vascular Bioprosthesis (ProCol) for Hancock Jaffe Laboratories, Inc. (Hancock Jaffe). CryoLife marketed the Hemodialysis Reliable Outflow Graft (HeRO® Graft) through February 3, 2016. Both HeRO Graft and ProCol are solutions for end-stage renal disease (ESRD) in certain hemodialysis patients. CryoLife is the exclusive distributor of PhotoFix™ for Genesee Biomedical, Inc. (GBI). PhotoFix is a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. The cardiac and vascular human tissues distributed by CryoLife include the CryoValve® SG pulmonary heart valve (CryoValve SGPV) and the CryoPatch® SG pulmonary cardiac patch tissue (CryoPatch SG), both of which are processed using CryoLife s proprietary SynerGraft® technology.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant inter-company accounts and transactions have been eliminated in consolidation.

Translation of Foreign Currencies

The Company s revenues and expenses transacted in foreign currencies are translated as they occur at exchange rates in effect at the time of each transaction. Realized gains and losses on foreign currency transactions are recorded as a component of other (income) expense, net on the Company s Consolidated Statements of Operations and Comprehensive Income. Assets and liabilities of the Company denominated in foreign currencies are translated at the exchange rate in effect as of the balance sheet date and are recorded as a separate component of accumulated other comprehensive income (loss) in the shareholders equity section of the Company s Consolidated Balance Sheets.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. Estimates and assumptions are used when accounting for investments, allowance for doubtful accounts, deferred preservation costs, acquired assets or businesses, long-lived tangible and intangible assets, deferred income taxes, commitments and contingencies (including product and tissue processing liability claims, claims incurred but not reported, and amounts recoverable from insurance companies), stock-based compensation, certain accrued liabilities (including accrued procurement fees, income taxes, and financial instruments), contingent consideration

liability, and other items as appropriate.

Revenue Recognition

Revenues for products, including: BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy handpieces and accessories, HeRO Grafts, ProCol, PhotoFix, and other medical devices, are recognized at the time the product is shipped, at which time title passes to the customer, and there are no further performance obligations. The Company recognizes revenues for preservation services when services are completed and tissue is shipped to the customer. Revenues from research grants are recognized in the period the associated costs are incurred. Revenues from upfront licensing agreements are recognized ratably over the period the Company expects to fulfill its obligations.

Table of Contents

Revenues from the sale of laser consoles are considered multiple element arrangements, and such revenues are allocated to the elements of the sale. The Company allocates revenues based primarily on the revenue these individual elements would generate if sold separately. Revenues from domestic laser consoles sales are typically recognized when the laser is installed at a customer site and all materials for the laser console s use are delivered. Revenues from the sales of laser consoles to international distributors are evaluated individually based on the terms of the sale and collectability to determine when revenue has been earned and can be recognized.

Shipping and Handling Charges

Fees charged to customers for shipping and handling of products and tissues are included in product revenues and preservation services revenues, respectively. The costs for shipping and handling of products and tissues are included as a component of cost of products and cost of preservation services, respectively.

Advertising Costs

The costs to develop, produce, and communicate the Company s advertising are expensed as incurred and are classified as general, administrative, and marketing expenses. The Company records the cost to print or copy certain sales materials as a prepaid expense and amortizes these costs as an advertising expense over the period they are expected to be used, typically six months to one year. The total amount of advertising expense included in the Company s Consolidated Statements of Operations and Comprehensive Income was $521,000, $821,000, and $880,000 for the years ended December 31, 2015, 2014, and 2013, respectively.

Stock-Based Compensation

The Company has stock option and stock incentive plans for employees and non-employee Directors that provide for grants of restricted stock awards (RSA s), performance stock awards (PSA s), restricted stock units (RSU s), performance stock units (PSU s), and options to purchase shares of CryoLife common stock at exercise prices generally equal to the fair values of such stock at the dates of grant. The Company also maintains a shareholder approved Employee Stock Purchase Plan (the ESPP) for the benefit of its employees. The ESPP allows eligible employees the right to purchase common stock on a regular basis at the lower of 85% of the market price at the beginning or end of each offering period. The RSAs, PSAs, RSUs, PSUs, and stock options granted by the Company typically vest over a one to three-year period. The stock options granted by the Company typically expire within seven years of the grant date.

The Company values its RSAs, PSAs, RSUs, and PSUs based on the stock price on the date of grant. The Company expenses the related compensation cost of RSAs, PSAs, and RSUs using the straight-line method over the vesting period. The Company expenses the related compensation cost of PSUs based on the number of shares expected to be issued if achievement of the performance component is probable using a straight-line method over each vesting tranche of the award. The amount of compensation costs expensed related to PSUs is adjusted as needed if the Company deems that achievement of the performance component is no longer probable, or if the Company s expectation of the number of shares to be issued changes. The Company uses a Black-Scholes model to value its stock option grants and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of the Company s ESPP options is also determined using a Black-Scholes model and is expensed over the vesting period.

The fair value of stock options and ESPP options is determined on the grant date using assumptions for the expected term, volatility, dividend yield, and the risk-free interest rate. The expected term is primarily based on the contractual term of the option and Company data related to historic exercise and post-vesting forfeiture patterns, which is adjusted

based on management s expectations of future results. The Company s anticipated volatility level is primarily based on the historic volatility of the Company s common stock, adjusted to remove the effects of certain periods of unusual volatility not expected to recur, and adjusted based on management s expectations of future volatility, for the life of the option or option group. The Company s model included a zero dividend yield assumption in the periods prior to the Company s initiation of a quarterly dividend in the third quarter of 2012. The risk-free interest rate is based on recent U.S. Treasury note auction results with a similar life to that of the option. The Company s model does not include a discount for post-vesting restrictions, as the Company has not issued awards with such restrictions.

The period expense for the Company s stock compensation is determined based on the valuations discussed above and, at that time, an estimated forfeiture rate is used to reduce the expense recorded. The Company s estimate of pre-vesting forfeitures is primarily based on the recent historical experience of the Company and is later adjusted to reflect actual forfeitures.

Table of Contents

Income Per Common Share

Income per common share is computed using the two class method, which requires the Company to include unvested RSAs and PSAs that contain non-forfeitable rights to dividends (whether paid or unpaid) as participating securities in the income per common share calculation.

Under the two class method, net income is allocated to the weighted-average number of common shares outstanding during the period and the weighted-average participating securities outstanding during the period. The portion of net income that is allocated to the participating securities is excluded from basic and dilutive net income per common share. Diluted net income per share is computed using the weighted-average number of common shares outstanding plus the dilutive effects of outstanding stock options and awards and other dilutive instruments as appropriate.

Dividends

The Company s Board of Directors approved the initiation of a quarterly cash dividend of $0.025 per share of common stock outstanding in the third quarter of 2012. The Board of Directors increased this dividend to $0.0275 per share in the second quarter of 2013, and to $0.03 per share in the second quarter of 2014. Cash dividends have been paid every three months since their initiation in September 2012 through December 2015. In December 2015 the Board of Directors undertook a review of the Company s dividend policy and determined that it would be in the best interest of the shareholders to discontinue dividend payments for the foreseeable future. The Company does not anticipate paying out any further quarterly dividends after December 31, 2015.

Financial Instruments

The Company s financial instruments include cash equivalents, marketable securities, restricted securities, accounts receivable, notes receivable, accounts payable, debt obligations, and contingent consideration. The Company typically values financial assets and liabilities such as receivables, accounts payable, and debt obligations at their carrying values, which approximate fair value due to their generally short-term duration. Other financial instruments are recorded as discussed in the sections below.

Fair Value Measurements

The Company records certain financial instruments at fair value, including: cash equivalents, certain marketable securities, certain restricted securities, contingent consideration, and derivative instruments. The Company may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis; although as of December 31, 2015 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

The Company also measures certain non-financial assets at fair value on a non-recurring basis. These non-recurring valuations include evaluating assets such as cost method investments, long-lived assets, and non-amortizing intangible assets for impairment; allocating value to assets in an acquired asset group; and applying accounting for business combinations. The Company uses the fair value measurement framework to value these assets and reports these fair values in the periods in which they are recorded or written down.

The fair value measurement framework includes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;

Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data; and

Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available. The determination of fair value and the assessment of a measurement s placement within the hierarchy requires judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Level 3 valuations may require the use of various cost, market, or income valuation methodologies applied to unobservable management estimates and assumptions. Management s assumptions could vary depending on the asset or liability valued and the valuation method used. Such assumptions could include: estimates of prices, earnings, costs, actions of market participants, market factors, or the weighting of various valuation methods. The Company may also engage external advisors to assist in determining fair value, as appropriate.

Table of Contents

Although the Company believes that the recorded fair value of its financial instruments is appropriate, these fair values may not be indicative of net realizable value or reflective of future fair values.

Cash and Cash Equivalents

Cash equivalents consist primarily of highly liquid investments with maturity dates of three months or less at the time of acquisition. The carrying value of cash equivalents approximates fair value.

Cash Flow Supplemental Disclosures

Supplemental disclosures of cash flow information for the years ended December 31 (in thousands):

	2015	2014	2013
Cash paid during the year for:			
Interest	$ 1	$ 34	$ 3
Income taxes	145	3,450	5,693

Marketable Securities and Other Investments

The Company typically invests its excess cash for short-term periods in large, well-capitalized financial institutions, and the Company s policy excludes investment in any securities rated less than investment-grade by national rating services, unless specifically approved by the Board of Directors. The Company sometimes makes longer term strategic investments in medical device companies, and these investments must be approved by the Board of Directors.

The Company determines the classification of its investments as trading, available-for-sale, or held-to-maturity at the time of purchase and reevaluates such designations quarterly. Trading securities are securities that are acquired principally for the purpose of generating a profit from short-term fluctuations in price. Debt securities are classified as held-to-maturity when the Company has the intent and ability to hold the securities to maturity. Any securities not designated as trading or held-to-maturity are considered available-for-sale. The Company typically states its investments at their fair values; however, for held-to-maturity securities or when current fair value information is not readily available, investments are recorded using the cost method. The cost of securities sold is based on the specific identification method.

Under the fair value method, the Company adjusts each investment to its market price and records the unrealized gains or losses in other (income) expense, net for trading securities, or accumulated other comprehensive income (loss), for available-for-sale securities. Interest, dividends, realized gains and losses, and declines in value judged to be other than temporary are included in other (income) expense, net. Under the cost method, investments are recorded at cost, with subsequent dividends received recognized as income. Cost method investments are reviewed for impairment if factors indicate that a decrease in the value of the investment has occurred.

Accounts and Notes Receivable and Allowance for Doubtful Accounts

The Company s accounts receivable are primarily from hospitals and distributors that either use or distribute the Company s products and tissues. The Company assesses the likelihood of collection based on a number of factors, including past transaction history and the credit worthiness of the customer, as well as the increased risks related to international customers and large distributors. The Company s accounts receivable balances were reported net of

allowance for doubtful accounts of $232,000 and $317,000 as of December 31, 2015 and 2014, respectively.

The Company may lend money from time-to-time through a note receivable, which may be made in conjunction with a longer term strategic investment in a medical device company, as approved by the Board of Directors. The Company assesses the likelihood of collection of its notes receivable based on a number of factors, including past transaction history, credit worthiness, and the liquidity position of the recipient as well as the expected value of any collateral. The Company s notes receivable balance was zero as of December 31, 2015 and 2014, respectively. See Note 7 for further discussion of the Company s note receivable from ValveXchange, Inc. (ValveXchange).

Table of Contents

Inventories

Inventories are comprised of BioGlue; BioFoam; PerClot; CardioGenesis cardiac laser therapy laser consoles, handpieces, and accessories; HeRO Grafts; ProCol; PhotoFix; other medical devices; supplies; and raw materials. Inventories are valued at the lower of cost or market on a first-in, first-out basis. Upon shipment, revenue is recognized and the related inventory costs are expensed as cost of products. Cost of products also includes, as applicable, lower of cost or market write-downs and impairments for products not deemed to be recoverable and, as incurred, idle facility expense, excessive spoilage, extra freight, and rehandling costs.

Inventory costs for manufactured products consist primarily of direct labor and materials (including salary and fringe benefits, raw materials, and supplies) and indirect costs (including allocations of costs from departments that support manufacturing activities and facility allocations). The allocation of fixed production overhead costs is based on actual production levels, to the extent that they are within the range of the facility s normal capacity. Inventory costs for products purchased for resale or manufactured under contract consist primarily of the purchase cost, freight-in charges, and indirect costs as appropriate.

The Company regularly evaluates its inventory to determine if the costs are appropriately recorded at the lower of cost or market value. The Company also evaluates its inventory for costs not deemed to be recoverable, including inventory not expected to ship prior to its expiration. Lower of cost or market value write-downs are recorded if the book value exceeds the estimated market value of the inventory, based on recent sales prices at the time of the evaluation. Impairment write-downs are recorded based on the book value of inventory deemed to be impaired. Actual results may differ from these estimates. Write-downs of inventory are expensed as cost of products, and these write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if the Company s estimates change.

The Company recorded write-downs to its inventory totaling $858,000, $140,000, and $1.2 million for the years ended December 31, 2015, 2014, and 2013, respectively. The 2015 write-down is primarily related to $764,000 of PerClot largely due to the write-down of PerClot Topical inventory following the Company s cessation of marketing, sales, and distribution of that product in the U.S. in accordance with the U.S. District Court for the District of Delaware (the District Court s) order. See Note 8 for further discussion of the Company s lawsuit with Medafor, Inc. (Medafor). The 2013 write-down includes $684,000 in additional contractual costs and inventory impairment costs, primarily related to a BioGlue accessory product, and $483,000 in additional costs for CardioGenesis cardiac laser therapy handpieces that were made obsolete by the Company s decision to exclusively distribute the new handpiece design, which was approved by the U.S. Food and Drug Administration (FDA) in June 2013.

Deferred Preservation Costs

Deferred preservation costs includes costs of cardiac and vascular tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status. By federal law, human tissues cannot be bought or sold; therefore, the tissues the Company preserves are not held as inventory. The costs the Company incurs to procure and process cardiac and vascular tissues are instead accumulated and deferred. Deferred preservation costs are stated at the lower of cost or market value on a first-in, first-out basis and are deferred until revenue is recognized. Upon shipment of tissue to an implanting facility, revenue is recognized and the related deferred preservation costs are expensed as cost of preservation services. Cost of preservation services also includes, as applicable, lower of cost or market write-downs and impairments for tissues not deemed to be recoverable, and includes, as incurred, idle facility expense, excessive spoilage, extra freight, and rehandling costs.

The calculation of deferred preservation costs involves judgment and complexity and uses the same principles as inventory costing. Donated human tissue is procured from deceased human donors by organ and tissue procurement organizations (OTPOs), which consign the tissue to the Company for processing, preservation, and distribution. Deferred preservation costs consist primarily of the procurement fees charged by the OTPOs, direct labor and materials (including salary and fringe benefits, laboratory supplies and expenses, and freight-in charges), and indirect costs (including allocations of costs from support departments and facility allocations). Fixed production overhead costs are allocated based on actual tissue processing levels, to the extent that they are within the range of the facility s normal capacity.

These costs are then allocated among the tissues processed during the period based on cost drivers, such as the number of donors or number of tissues processed. The Company applies a yield estimate to all tissues in process and in quarantine to estimate the portion of tissues that will ultimately become implantable. Management estimates quarantine yields based on its experience and reevaluates these estimates periodically. Actual yields could differ significantly from the Company s estimates, which could result in a change in tissues available for shipment, and could increase or decrease the balance of deferred preservation costs. These changes could result in additional cost of preservation services expense or could increase per tissue preservation costs, which would impact gross margins on tissue preservation services in future periods.

Table of Contents

The Company regularly evaluates its deferred preservation costs to determine if the costs are appropriately recorded at the lower of cost or market value. The Company also evaluates its deferred preservation costs for costs not deemed to be recoverable, including tissues not expected to ship prior to the expiration date of their packaging. Lower of cost or market value write-downs are recorded if the tissue processing costs incurred exceed the estimated market value of the tissue services, based on recent average service fees at the time of the evaluation. Impairment write-downs are recorded based on the book value of tissues deemed to be impaired. Actual results may differ from these estimates. Write-downs of deferred preservation costs are expensed as cost of preservation services, and these write-downs are permanent impairments that create a new cost basis, which cannot be restored to its previous levels if the Company s estimates change.

The Company recorded write-downs to its deferred preservation costs totaling $483,000, $540,000, and $448,000 for the years ended December 31, 2015, 2014, and 2013, respectively.

Property and Equipment

Property and equipment is stated at cost. Depreciation is provided over the estimated useful lives of the assets, generally three to ten years, on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the remaining lease term at the time the assets are capitalized or the estimated useful lives of the assets, whichever is shorter.

Depreciation expense for the years ended December 31 is as follows (in thousands):

	2015	2014	2013
Depreciation expense	$ 3,728	$ 4,001	$ 3,837

Goodwill and Other Intangible Assets

The Company s intangible assets consist of goodwill, patents, trademarks, and other intangible assets, as discussed in Note 10. These assets include intangible assets from the acquisition of Hemosphere, Inc. (Hemosphere) in 2012 and the acquisition of Cardiogenesis Corporation (Cardiogenesis) in 2011.

The Company amortizes its definite lived intangible assets over their expected useful lives using the straight-line method, which the Company believes approximates the period of economic benefits of the related assets. The Company s indefinite lived intangible assets do not amortize, but are instead subject to periodic impairment testing as discussed in Impairments of Long-Lived Assets and Non-Amortizing Intangible Assets below.

Impairments of Long-Lived Assets and Non-Amortizing Intangible Assets

The Company assesses the potential impairment of its long-lived assets to be held and used whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include, but are not limited to, the following:

Significant underperformance relative to expected historical or projected future operating results;

Significant negative industry or economic trends;

Significant decline in the Company s stock price for a sustained period; or

Significant decline in the Company s market capitalization relative to net book value.

If CryoLife determines that an impairment review is necessary, the Company will evaluate its assets or asset groups by comparing their carrying values to the sum of the undiscounted future cash flows expected to result from their use and eventual disposition. If the carrying values exceed the future cash flows, then the asset or asset group is considered impaired, and the Company will write down the value of the asset or asset group. For the years ended December 31, 2015, 2014, and 2013 the Company did not experience any factors that indicated that an impairment review of its long-lived assets was warranted.

CryoLife evaluates its goodwill and other non-amortizing intangible assets for impairment on an annual basis as of October 31 and, if necessary, during interim periods if factors indicate that an impairment review is warranted. As of

Table of Contents

October 31, 2015 the Company s non-amortizing intangible assets consisted of goodwill, acquired procurement contracts and agreements, trademarks, and other acquired technology. The Company performed an analysis of its non-amortizing intangible assets as of October 31, 2015 and 2014, and determined that the fair value of the assets and the fair value of the reporting unit exceeded their associated carrying values and were, therefore, not impaired. Management will continue to evaluate the recoverability of these non-amortizing intangible assets.

Accrued Procurement Fees

Donated tissue is procured from deceased human donors by OTPOs, which consign the tissue to the Company for processing, preservation, and distribution. The Company reimburses the OTPOs for their costs to recover the tissue and includes these costs as part of deferred preservation costs, as discussed above. The Company accrues estimated procurement fees due to the OTPOs at the time tissues are received based on contractual agreements between the Company and the OTPOs.

Leases

The Company has operating lease obligations resulting from the lease of land and buildings that comprise the Company s corporate headquarters and manufacturing facilities; leases related to additional manufacturing, office, and warehouse space; leases on Company vehicles; and leases on a variety of office equipment, as discussed in Note 13. Certain of the Company s leases contain escalation clauses, rent concessions, and renewal options for additional periods. Rent expense is computed on the straight-line method over the lease term and the related liability is recorded as deferred rent obligations on the Company s Consolidated Balance Sheets.

Liability Claims

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

The Company engages external advisors to assist it in estimating its liability and any related recoverable under the Company s insurance policies as of each balance sheet date. The Company uses a frequency-severity approach to estimate its unreported product and tissue processing liability claims, whereby projected losses are calculated by multiplying the estimated number of claims by the estimated average cost per claim. The estimated claims are determined based on the reported claim development method and the Bornhuetter-Ferguson method using a blend of the Company s historical claim experience and industry data. The estimated cost per claim is calculated using a lognormal claims model blending the Company s historical average cost per claim with industry claims data. The Company uses a number of assumptions in order to estimate the unreported loss liability including: the future claim reporting time lag, the frequency of reported claims, the average cost per claim, and the maximum liability per claim. The Company believes that the assumptions it uses provide a reasonable basis for its calculation. However, the accuracy of the estimates is limited by various factors, including, but not limited to, Company specific conditions, uncertainties surrounding the assumptions used, and the scarcity of industry data directly relevant to the Company s business activities. Due to these factors, actual results may differ significantly from the Company s assumptions and from the amounts accrued.

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

Legal Contingencies

The Company accrues losses from a legal contingency when the loss is both probable and reasonably estimable. The accuracy of the Company s estimates of losses for legal contingencies is limited by uncertainties surrounding litigation. Therefore, actual results may differ significantly from the amounts accrued, if any. The Company accrues for legal contingencies as a component of accrued expenses and/or other long-term liabilities. Gains from legal contingencies are recorded when the contingency is resolved.

Table of Contents

Legal Fees

The Company expenses the costs of legal services, including legal services related to product and tissue processing liability claims and legal contingencies, as they are incurred. Reimbursement of legal fees by an insurance company or other third-party is recorded as a reduction to legal expense.

Uncertain Tax Positions

The Company periodically assesses its uncertain tax positions and recognizes tax benefits if they are more-likely-than-not to be upheld upon review by the appropriate taxing authority. The Company measures the tax benefit by determining the maximum amount that has a greater than 50 percent likelihood of ultimately being realized. The Company reverses previously accrued liabilities for uncertain tax positions when audits are concluded, statutes expire, administrative practices dictate that a liability is no longer warranted, or in other circumstances as deemed necessary. These assessments can be complex and the Company often obtains assistance from external advisors to make these assessments. The Company recognizes interest and penalties related to uncertain tax positions in other (income) expense, net on its Consolidated Statements of Operations and Comprehensive Income. See Note 11 for further discussion of the Company s liabilities for uncertain tax positions.

Deferred Income Taxes

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and tax return purposes. The Company periodically assesses the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially affect its determination of the recoverability of its deferred tax assets. Management provides a valuation allowance against its deferred tax assets when, as a result of this analysis, management believes it is more likely than not that some portion or all of its deferred tax assets will not be realized.

Assessing the recoverability of deferred tax assets involves judgment and complexity. Estimates and judgments used in the determination of the need for a valuation allowance and in calculating the amount of a needed valuation allowance include, but are not limited to, the following:

Projected future operating results;

Anticipated future state tax apportionment;

Timing and amounts of anticipated future taxable income;

Timing of the anticipated reversal of book/tax temporary differences;

Evaluation of statutory limits regarding usage of certain tax assets; and

Evaluation of the statutory periods over which certain tax assets can be utilized.

Significant changes in the factors above, or other factors, could affect the Company s ability to use its deferred tax assets. Such changes could have a material, adverse impact on the Company s profitability, financial position, and cash flows. The Company will continue to assess the recoverability of its deferred tax assets, as necessary, when the Company experiences changes that could materially affect its prior determination of the recoverability of its deferred tax assets.

The Company believes that the realizability of its acquired net operating loss carryforwards will be limited in future periods due to a change in control of its former subsidiaries Hemosphere and Cardiogenesis, as mandated by Section 382 of the Internal Revenue Code of 1986, as amended. The Company believes that its acquisitions of these companies each constituted a change in control, and that prior to the Company s acquisition, Hemosphere had experienced other equity ownership changes that should be considered a change in control. The deferred tax assets recorded on the Company s Consolidated Balance Sheets exclude amounts that it expects will not be realizable due to these changes in control. A portion of the acquired net operating loss carryforwards is related to state income taxes for which management believes it is more likely than not that these deferred tax assets will not be realized. Therefore, the Company recorded a valuation allowance against these state net operating loss carryforwards.

Table of Contents

Valuation of Acquired Assets or Businesses

As part of its corporate strategy, the Company is seeking to identify and capitalize upon acquisition opportunities of complementary product lines and companies. The Company evaluates and accounts for acquired patents, licenses, distribution rights, and other tangible or intangible assets as the purchase of an asset or asset group or as a business combination, as appropriate. The determination of whether the purchase of a group of assets should be accounted for as an asset group or as a business combination requires significant judgment based on the weight of available evidence.

For the purchase of an asset group, the Company allocates the cost of the asset group, including transaction costs, to the individual assets purchased based on their relative estimated fair values. In-process research and development acquired as part of an asset group is expensed upon acquisition. The Company accounts for business combinations using the acquisition method. Under this method, the allocation of the purchase price is based on the fair value of the tangible and identifiable intangible assets acquired and the liabilities assumed as of the date of the acquisition. The excess of the purchase price over the estimated fair value of the tangible net assets and identifiable intangible assets is recorded as goodwill. Transaction costs related to business combinations are expensed as incurred. In-process research and development acquired as part of a business combination is accounted for as an indefinite-lived intangible asset until the related research and development project gains regulatory approval or is discontinued.

The Company typically engages external advisors to assist it in determining the fair value of acquired asset groups or business combinations, using valuation methodologies such as: the excess earnings, the discounted cash flow, or the relief from royalty methods. The determination of fair value in accordance with the fair value measurement framework requires significant judgments and estimates, including, but not limited to: timing of product life cycles, estimates of future revenues, estimates of profitability for new or acquired products, cost estimates for new or changed manufacturing processes, estimates of the cost or timing of obtaining regulatory approvals, estimates of the success of competitive products, and discount rates. Management, in consultation with its advisor(s), makes these estimates based on its prior experiences and industry knowledge. Management believes that its estimates are reasonable, but actual results could differ significantly from the Company s estimates. A significant change in management s estimates used to value acquired asset groups or business combinations could result in future write-downs of tangible or intangible assets acquired by the Company and, therefore, could materially impact the Company s financial position and profitability. If the value of the liabilities assumed by the Company, including contingent liabilities, is determined to be significantly different from the amounts previously recorded in purchase accounting, the Company may need to record additional expenses or write-downs in future periods, which could materially impact the Company s financial position and profitability.

Derivative Instruments

The Company determines the fair value of its stand-alone and embedded derivative instruments at issuance and records any resulting asset or liability on the Company s Consolidated Balance Sheets. Changes in the fair value of the derivative instruments are recognized in other (income) expense on the Company s Consolidated Statements of Operations and Comprehensive Income.

New Accounting Pronouncements

In May 2014 the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers,* which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes the most current revenue recognition guidance. The core principle of the revenue model is that an entity recognizes revenue to depict the transfer of promised goods or services to

customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. On July 9, 2015, the FASB approved the deferral of the effective date of ASU 2014-09 by one year. The new standard is effective for annual and interim reporting periods beginning after December 15, 2017, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2014-09 to have a material impact on its financial position, results of operations, or cash flows.

In July 2015 FASB issued ASU No. 2015-11, Inventory *Simplifying the Measurement of Inventory,* which requires that inventory be measured at the lower of cost and net realizable value. Prior to the issuance of the new guidance, inventory was measured at the lower of cost or market. Replacing the concept of market with the single measurement of net realizable value is intended to create efficiencies for preparers. Inventory measured using the last-in, first-out (LIFO) method and the retail inventory method are not impacted by the new guidance. The ASU becomes effective for fiscal years beginning after December 15, 2016, including interim periods with those fiscal years and early application is permitted. The Company is evaluating the effect that ASU 2015-11 will have on its consolidated financial statements and related disclosures, but does not expect the adoption of ASU 2015-11 to have a material impact on its financial position, results of operations, or cash flows.

Table of Contents

In November 2015 the FASB issued ASU 2015-17, *Income Taxes (Topic 740) Related to the Balance Sheet Classification of Deferred Taxes,* which requires entities to present deferred tax assets (DTA s) and deferred tax liabilities (DTL s) as noncurrent in a classified balance sheet. The ASU simplifies the current guidance (ASC 740-10-45-4), which requires entities to separately present DTAs and DTLs as current and noncurrent in a classified balance sheet. ASU 2015-17 is effective for annual reporting periods beginning on or after December 15, 2016 and interim periods within those annual periods. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. The Company elected to early adopt ASU 2015-17 prospectively as of December 31, 2015. Accordingly, deferred tax assets in the amount of $5.3 million, which would have been classified as a current asset, have been classified as a non-current asset on the Company s Consolidated Balance Sheet as of December 31, 2015.

2. Financial Instruments

A summary of financial instruments measured at fair value is as follows (in thousands):

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

December 31, 2014	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 18,213	$ --	$ --	$ 18,213
Restricted securities:				
Money market funds	884	--	--	884
Total assets	$ 19,097	$ --	$ --	$ 19,097

The Company used prices quoted from its investment management companies to determine the Level 1 valuation of its investments in money market funds.

3. Cash Equivalents and Restricted Cash and Securities

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

December 31, 2015	**Cost Basis**	**Unrealized Holding Gains (Losses)**	**Estimated Market Value**
Cash equivalents:			
Money market funds	$ 549	$ --	$ 549

Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	830	--	830

Table of Contents

December 31, 2014	Cost Basis	Unrealized Holding Gains (Losses)	Estimated Market Value
Cash equivalents:			
Money market funds	$ 18,213	$ --	$ 18,213
Restricted cash and securities:			
Cash	5,000	--	5,000
Money market funds	884	--	884

As of December 31, 2015 and 2014 $830,000 and $884,000, respectively, of the Company s money market funds were designated as short-term restricted securities due to a contractual commitment to hold the securities as pledged collateral relating primarily to international tax obligations. As of December 31, 2015 and 2014 $5.0 million of the Company s cash was designated as long-term restricted cash due to a financial covenant requirement under the Company s credit agreement with General Electric Capital Corporation (GE Capital) as discussed in Note 12. This restriction lapses upon expiration of the credit agreement with GE Capital on September 26, 2019.

There were no gross realized gains or losses on cash equivalents or restricted securities for the years ended December 31, 2015, 2014, and 2013. At December 31, 2015 and 2014 $5.0 million of the Company s restricted cash had no maturity date. At December 31, 2015 $595,000 of the Company s restricted securities had a maturity date within three months and $235,000 had a maturity date between three months and one year. At December 31, 2014 $622,000 of the Company s restricted securities had a maturity date within three months and $262,000 of the Company s restricted securities had a maturity date between three months and one year.

4. Distribution Agreements

PhotoFix Distribution Agreement

In 2014 CryoLife entered into an exclusive supply and distribution agreement with GBI to acquire the distribution rights to PhotoFix, a bovine pericardial patch stabilized using a dye-mediated photo-fixation process that requires no glutaraldehyde. PhotoFix has received FDA 510(k) clearance and is indicated for use in intracardiac repair, including ventricular repair and atrial repair, great vessel repair and suture line buttressing, and pericardial closure.

The agreement between CryoLife and GBI (the GBI Agreement) has an initial five-year term and is renewable for two one-year periods at CryoLife s option. Under the terms of the GBI Agreement, CryoLife is purchasing PhotoFix inventory for resale at an agreed upon transfer price and has the option, which became effective in March 2015, to acquire the PhotoFix product line from GBI. In January 2015 the Company received its initial shipments and launched its distribution of PhotoFix.

ProCol Distribution Agreement

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

ProCol, which is approved for sale in the U.S., is a biological graft derived from a bovine mesenteric vein that provides vascular access for ESRD hemodialysis patients. It is intended for the creation of a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft. ProCol is complementary to the Company s HeRO, which also serves patients with ESRD; however, ProCol provides vascular access for ESRD patients in an

earlier-stage of treatment protocol than the HeRO Graft.

In accordance with the terms of the HJ Agreement, CryoLife made payments to Hancock Jaffe of $1.7 million during 2014 and $576,000 in January 2015. In exchange for these payments, CryoLife obtained the right to receive a designated amount of ProCol inventory for resale, a portion of which the Company received in 2014 and 2015. Subsequent to this initial inventory purchase, CryoLife can purchase additional units from Hancock Jaffe at an agreed upon transfer price. The Company began limited distribution of ProCol in the second quarter of 2014. On September 29, 2014 Hancock Jaffe received FDA approval of the Premarket Approval (PMA) Supplement associated with its new manufacturing facility, and the Company began shipping product made in this new facility in the fourth quarter of 2014.

Table of Contents

CryoLife made additional advance payments of $1.1 million in the aggregate during the remainder of 2015. As of December 31, 2015 CryoLife had made a total of $3.3 million in payments to Hancock Jaffe and had received $1.3 million in inventory. Therefore, as of December 31, 2015 CryoLife had approximately $2.0 million in remaining prepayments on its Consolidated Balance Sheet for which inventory had not yet been received. During the second quarter of 2015 CryoLife notified Hancock Jaffe that it was in breach of the HJ Agreement due to, among other things, Hancock Jaffe s failure to timely ship inventory. In the fourth quarter of 2015 CryoLife and Hancock Jaffe amended the HJ Agreement. This amendment included new terms which, among other changes, confirm Hancock Jaffe s breach of the HJ Agreement; accelerate and allow CryoLife to assign the purchase option; outline Hancock Jaffe s requirements to be eligible for additional advances; and modify the termination provisions. The amendment does not cure Hancock Jaffe s breach of the agreement. CryoLife is currently monitoring Hancock Jaffe s compliance with the terms of the amended HJ Agreement and determining what additional steps it can take to help ensure receipt of inventory and repayment of the additional advances. If CryoLife is unable to secure full satisfaction or repayment of the amounts owed, or sell its interest in the agreement for an amount equal to or in excess of the carrying value of the related assets, the prepayment may become impaired in future periods.

5. Direct Sales in France

In June 2015 CryoLife signed a Business Transfer Agreement with its French distribution partner to facilitate an orderly transition of the Company to a direct sales model in France. In October 2015 the Company completed the acquisition of a portion of the business of its French distribution partner. The Company acquired in the transaction certain intangible assets, including commercial and business information, assignment of contracts, and a non-compete agreement with its former French distribution partner for a purchase price of 1.2 million Euros or $1.3 million. During the third quarter of 2015 the Company established a wholly owned subsidiary in France, CryoLife France SAS, and certain members of the distributor s sales team who were responsible for selling the Company s products in France became employees of the Company s newly created subsidiary.

6. Hemosphere Acquisition

Overview

On May 16, 2012 CryoLife completed its acquisition of Hemosphere, a privately held company, and its HeRO Graft product line for a total purchase price of approximately $22.0 million, net of $3.2 million cash acquired. CryoLife used cash on hand to fund the transaction and operated Hemosphere as a wholly owned subsidiary until December 31, 2014, when it was merged into the CryoLife, Inc. parent entity. The HeRO Graft is a proprietary graft-based solution for ESRD hemodialysis patients with limited access options and central venous obstruction.

Contingent Consideration

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

The fair value of the contingent consideration liability was estimated by discounting to present value the contingent payments expected to be made based on a probability-weighted scenario approach. The Company applied a risk-based estimate of the probability of achieving each scenario and then applied a cost of debt based discount rate. This fair value measurement was based on unobservable inputs, including management estimates and assumptions about future

revenues, and was, therefore, classified as Level 3 within the fair value hierarchy presented in Note 2. The Company remeasured this liability at each reporting date and recorded changes in the fair value of the contingent consideration in other (income) expense on the Company s Consolidated Statements of Operations and Comprehensive Income. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the timing and amount of Company revenue estimates. As of December 31, 2014 the Company reviewed the full year revenue performance of Hemosphere for 2014 and 2013, and reviewed its 2015 annual budgets, which were updated in the fourth quarter of 2014. As a result of this review, as of December 31, 2014 the Company believed that achievement of the minimum revenue target to trigger payment was remote, and, therefore, estimated the fair value of the contingent consideration to be zero.

Table of Contents

The Company recorded gains of zero, $1.9 million and $28,000 the years ended December 31, 2015, 2014, and 2013, respectively, on the remeasurement of the contingent consideration liability. The balance of the contingent consideration liability was zero as of December 31, 2015 and 2014.

7. ValveXchange

Preferred Stock Investment

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

During the fourth quarter of 2013 the Company reevaluated its investment in ValveXchange preferred stock for impairment. Based on this analysis, the Company believed that its investment in ValveXchange was fully impaired as of December 31, 2013, and the impairment was other than temporary. As of December 31, 2015 and December 31, 2014 the carrying value of the Company s investment in ValveXchange preferred stock was zero.

Loan Agreement

In July 2011 the Company entered into an agreement with ValveXchange, as amended, to make available to ValveXchange up to $2.0 million in debt financing through a revolving credit facility (the Loan). The Loan included various affirmative and negative covenants, including financial covenant requirements, and would have expired on July 30, 2018, unless terminated earlier. Amounts under the Loan earned interest at an 8% annual rate and were secured by substantially all of the tangible and intangible assets of ValveXchange. The Company advanced $2.0 million to ValveXchange under this loan in 2012.

During the quarter ended December 31, 2014 CryoLife became aware of various factors, including ValveXchange s inability to secure additional funding, its lack of capital to continue basic operations, and the likelihood of impending default on the Loan. In December 2014 CryoLife notified ValveXchange that it was in breach of the Loan, and in January 2015, after ValveXchange failed to cure this breach, CryoLife accelerated the amounts due under the Loan. In January 2015 ValveXchange informed CryoLife management of its intent to file for bankruptcy, which created substantial uncertainty regarding the disposition of CryoLife s claim for amounts it is owed under the Loan. Given these circumstances, CryoLife believed that its Loan became fully impaired in the fourth quarter of 2014. As a result, during the three months ended December 31, 2014 the Company recorded other non-operating expense of $2.0 million to write-down its long-term note receivable from ValveXchange. ValveXchange was dissolved in June 2015. The net carrying value of the long-term note receivable was zero as of December 31, 2015 and December 31, 2014.

8. Medafor Matters

Investment in Medafor Common Stock

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

On October 1, 2013 C.R. Bard, Inc., a developer, manufacturer, and marketer of medical technologies in the fields of vascular, urology, oncology, and surgical specialty products (Bard), and its subsidiaries completed its acquisition of all outstanding shares of Medafor common stock. The Company received an initial payment of approximately $15.4 million in the fourth quarter of 2013 for its 2.4 million shares of Medafor common stock and received additional payments of $530,000 in the fourth quarter of 2014 and $891,000 in April 2015 related to the release of transaction consideration in escrow. Based on information provided by Medafor in its September 24, 2013 Proxy Statement, Bard was required to make additional contingent milestone payments based on the achievement of certain net revenue targets measurable through June 2015.

Table of Contents

In September 2015 the Company received a letter from the representative of the former shareholders of Medafor, which stated that net sales were insufficient to trigger payment of additional contingent consideration by Bard. The final release of transaction consideration from escrow is expected to be received in October 2017 and is expected to be nominal. This subsequent payment will be recorded as an additional gain if, and when, received by the Company.

The Company recorded a gain on the sale of approximately $12.7 million in the fourth quarter of 2013, $530,000 in the fourth quarter of 2014 and $891,000 in the second quarter of 2015.

Legal Action

In April 2014 CryoLife filed a declaratory judgment lawsuit against Bard, and its subsidiaries Davol, Inc. (Davol) and Medafor (collectively, Defendants), in the District Court. CryoLife requested that the District Court declare that CryoLife s manufacture, use, offer for sale, and sale of PerClot in the U.S. does not, and would not, infringe Bard s U.S. Patent No. 6,060,461 (the 461 Patent). In addition, CryoLife requested that the District Court declare that the claims of the 461 Patent are invalid. CryoLife also requested injunctive relief and an award of attorneys fees.

The lawsuit against the Defendants followed the receipt by CryoLife of a letter from Medafor in September 2012 stating that PerClot, when introduced in the U.S., would infringe the 461 Patent when used in accordance with the method published in CryoLife s literature and with the instructions for use. CryoLife received FDA 510(k) clearance for the sale of PerClot Topical in April 2014 and began distributing PerClot Topical in August 2014. CryoLife also received investigational device exemption approval in March 2014 to begin clinical trials for PerClot in certain surgical indications.

In August 2014 Medafor filed a counterclaim against CryoLife for infringement of the 461 Patent. In September 2014 Medafor filed a motion for a preliminary injunction, asking the District Court to enjoin CryoLife s marketing and sale of PerClot in the U.S. In March 2015 the District Court ruled that CryoLife s declaratory judgment lawsuit against Medafor may proceed but dismissed Bard and Davol from the lawsuit. The District Court also granted Medafor s motion for a preliminary injunction, which prohibits CryoLife from marketing, selling, and distributing PerClot in the U.S. while the litigation proceeds. In March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot in the U.S., including PerClot Topical, in accordance with the District Court s order. In April 2015 CryoLife appealed the District Court s ruling on the preliminary injunction motion to the U.S. Court of Appeals for the Federal Circuit. CryoLife dismissed this appeal in June 2015. On November 18, 2015, the lawsuit was resolved by entry by the District Court of the Parties Joint Stipulation for Dismissal, which resulted in the dismissal with prejudice of all parties claims and counterclaims in the lawsuit, the continuation of the preliminary injunction prohibiting CryoLife from marketing, selling and distributing PerClot in the U.S. until expiration of the 461 Patent on February 8, 2019, each party bearing its own attorneys fees and costs associated with the lawsuit, and the continuation of the District Court s jurisdiction over the parties to enforce the resolution.

9. Inventories and Deferred Preservation Costs

Inventories at December 31, 2015 and 2014 are comprised of the following (in thousands):

	2015	2014
Raw materials and supplies	$ 8,590	$ 7,942
Work-in-process	633	1,006
Finished goods	5,420	3,791

Total inventories	$ 14,643	$ 12,739

Deferred preservation costs at December 31, 2015 and 2014 are comprised of the following (in thousands):

	2015	2014
Cardiac tissues	$ 11,722	$ 10,875
Vascular tissues	13,019	14,321
Total deferred preservation costs	$ 24,741	$ 25,196

Table of Contents

10. Goodwill and Other Intangible Assets

Indefinite Lived Intangible Assets

As of December 31, 2015 and 2014 the carrying values of the Company s indefinite lived intangible assets are as follows (in thousands):

	2015	2014
Goodwill	$ 11,365	$ 11,365
Procurement contracts and agreements	2,013	2,013
Trademarks	860	853

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

As of December 31, 2015 and 2014 the Company s entire goodwill balance is related to its Medical Devices segment, and there has been no change from the balance recorded as of December 31, 2013.

Definite Lived Intangible Assets

As of December 31, 2015 and 2014 gross carrying values, accumulated amortization, and approximate amortization periods of the Company s definite lived intangible assets are as follows (dollars in thousands):

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

December 31, 2014	Gross Carrying Value	Accumulated Amortization	Amortization Period
Acquired technology	$ 14,020	$ 3,815	11 16 Years
Patents	4,281	2,497	17 Years
Distribution and manufacturing rights and know-how	4,559	989	11 15 Years
Customer lists and relationships	3,370	813	13 17 Years
Non-compete agreement	381	305	10 Years
Other	461	239	1 5 Years

Amortization Expense

Amortization expense recorded in general, administrative, and marketing expenses on the Company s Consolidated Statements of Operations and Comprehensive Income for the years ended December 31 is as follows (in thousands):

	2015	2014	2013
Amortization expense	$ 2,135	$ 2,027	$ 2,006

As of December 31, 2015 scheduled amortization of intangible assets for the next five years is as follows (in thousands):

	2016	2017	2018	2019	2020	Total
Amortization expense	$ 2,456	$ 2,403	$ 2,280	$ 1,894	$ 1,722	$ 10,755

Table of Contents

11. Income Taxes

Income Tax Expense

Income before income taxes consists of the following (in thousands):

	2015	2014	2013
Domestic	$ 5,701	$ 8,350	$ 23,004
Foreign	167	353	288
Income before income taxes	$ 5,868	$ 8,703	$ 23,292

Income tax expense consists of the following (in thousands):

	2015	2014	2013
Current:			
Federal	$ 231	$ 898	$ 6,304
State	142	211	396
Foreign	160	99	96
	533	1,208	6,796
Deferred:			
Federal	1,011	127	1,142
State	319	46	(818)
	1,330	173	324
Income tax expense	$ 1,863	$ 1,381	$ 7,120

The Company s income tax expense in 2015, 2014, and 2013 included the Company s federal, state, and foreign tax obligations. The Company s effective income tax rate was approximately 32%, 16%, and 31% for the years ended December 31, 2015, 2014, and 2013, respectively. The Company s income tax rate for the twelve months ended December 31, 2015 was favorably affected by the reversal of $869,000 in uncertain tax positions, primarily related to research and development tax credits for which the statute of limitations has expired, partially offset by the expiration of certain state net operating losses and other permanent differences. The Company s income tax rate for the twelve months ended December 31, 2014 was favorably affected by the reduction in uncertain tax positions, nontaxable gains recorded as change in stock basis of subsidiary, and favorable deductions taken on the Company s 2013 federal tax return, which was filed in 2014. The Company s income tax rate for the twelve months ended December 31, 2013 was favorably affected by adjustments to valuation allowances on certain of the Company s state net operating loss carryforwards, based on revised estimates of utilization of these carryforwards, and by the 2012 research and development tax credit, which was enacted in January 2013 and, therefore, reduced the Company s tax expense during 2013.

The income tax expense amounts differ from the amounts computed by applying the U.S. federal statutory income tax rate of 34% for the years ended December 31, 2015 and 2014 and 35% for the year ended December 31, 2013 to pretax income as a result of the following (in thousands):

	2015	2014	2013
Tax expense at statutory rate	$ 1,995	$ 2,959	$ 8,152
Increase (reduction) in income taxes resulting from:			
State income taxes, net of federal benefit	499	220	183
Non-deductible entertainment expenses	184	218	207
Equity compensation	144	63	(29)
Provision to return adjustments	122	(321)	(344)
Foreign income taxes	118	69	96
Other	57	(98)	165
Non-deductible change in stock basis of subsidiary	--	(641)	--
Net change in uncertain tax positions	(869)	(781)	104
Research and development credit	(281)	(237)	(252)
Domestic production activities deduction	(87)	(153)	(402)
State valuation allowance adjustment	(19)	83	(760)
Total Income tax expense	$ 1,863	$ 1,381	$ 7,120

Table of Contents

Deferred Taxes

The Company generates deferred tax assets primarily as a result of write-downs of inventory and deferred preservation costs; accruals for product and tissue processing liability claims; investment and asset impairments; and, in prior periods, due to operating losses. The Company acquired significant deferred tax assets, primarily net operating loss carryforwards, from its acquisitions of Hemosphere and Cardiogenesis in the second quarters of 2012 and 2011, respectively.

The tax effects of temporary differences which give rise to deferred tax assets and liabilities at December 31 are as follows (in thousands):

	2015	2014
Deferred tax assets:		
Allowance for bad debts	$ 142	$ 853
Inventory and deferred preservation costs write-downs	536	873
Investment in equity securities	58	1,913
Property	2,987	2,934
Intangible assets	591	400
Accrued expenses	3,276	3,864
Loss carryforwards	12,262	14,141
Credit carryforwards	616	635
Stock compensation	2,546	2,367
Transaction Costs	1,048	--
Other	1,448	1,402
Less valuation allowance	(2,109)	(2,145)
Total deferred tax assets	23,401	27,237
Deferred tax liabilities:		
Prepaid items	(471)	(420)
Intangible assets	(4,401)	(4,652)
Other	(341)	(296)
Total deferred tax liabilities	(5,213)	(5,368)
Total net deferred tax assets	$ 18,188	$ 21,869

As of December 31, 2015 the Company maintained a total of $2.1 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of $18.2 million. As of December 31, 2014 the Company maintained a total of $2.1 million in valuation allowances against deferred tax assets, related to state net operating loss carryforwards, and a net deferred tax asset of $21.9 million.

As of December 31, 2015 the Company had approximately $9.5 million tax-effected federal net operating loss carryforwards related to the acquisitions of Cardiogenesis and Hemosphere that will begin to expire in 2017, $2.7 million of tax-effected state net operating loss carryforwards that began to expire in 2015, $445,000 in research and development tax credit carryforwards that will begin to expire in 2022, and $154,000 in credits from the state of Texas

that will fully expire by 2027.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the Company s uncertain tax position liability, excluding interest and penalties, is as follows (in thousands):

	2015	2014	2013
Beginning balance	$ 1,437	$ 2,100	$ 2,004
Increases related to current year tax positions	103	92	281
Increases related to prior year tax positions	403	--	--
Decreases related to prior year tax positions	(70)	(265)	(185)
Decreases due to the lapsing of statutes of limitations	(904)	(490)	--
Ending balance	$ 969	$ 1,437	$ 2,100

Table of Contents

A reconciliation of the beginning and ending balances of the Company s liability for interest and penalties on uncertain tax positions is as follows (in thousands):

	2015	2014	2013
Beginning balance	$ 366	$ 422	$ 489
Accrual of interest and penalties	50	91	66
Decreases related to prior year tax positions	(206)	(147)	(133)
Ending balance	$ 210	$ 366	$ 422

As of December 31, 2015 the Company s uncertain tax liability, including interest and penalties of $1.2 million, was recorded as a reduction to deferred tax assets of $104,000, and a non-current liability of $1.1 million on the Company s Consolidated Balance Sheets, all of which, except for the portion related to interest and penalties, is expected to impact the Company s tax rate when recognized. The Company believes it is reasonably possible that approximately $227,000 of its uncertain tax liability will be recognized in 2016 due to the lapsing of various federal and state statutes of limitations. As of December 31, 2014 the Company s total uncertain tax liability, including interest and penalties of $1.8 million, was recorded as a reduction of deferred tax assets of $108,000 and a non-current liability of $1.7 million on the Company s Consolidated Balance Sheets.

Other

The Company s tax years 2012 through 2014 generally remain open to examination by the major taxing jurisdictions to which the Company is subject. However, certain returns from years prior to 2012, in which net operating losses and tax credits have arisen, are still open for examination by the tax authorities.

12. Debt

GE Credit Agreement

On September 26, 2014 the Company amended and restated its credit agreement with GE Capital, extending the expiration date and amending other terms, which are discussed further below. CryoLife s second amended and restated credit agreement with GE Capital (the GE Credit Agreement) provided revolving credit for working capital, permitted acquisitions, and general corporate purposes. The GE Credit Agreement had aggregate commitments of $20.0 million for revolving loans, including swing loans, subject to a sublimit, and letters of credit, and was due to mature on September 26, 2019.

Amounts borrowed under the GE Credit Agreement were secured by substantially all of the tangible and intangible assets of CryoLife and its subsidiaries. Commitment fees were paid based on the unused portion of the facility. As of December 31, 2015 and 2014 the aggregate interest rate was 4.75%. As of December 31, 2015 and 2014 the outstanding balance of the GE Credit Agreement was zero, and the remaining availability was $20.0 million.

The GE Credit Agreement placed limitations on the amount that the Company could borrow and included various affirmative and negative covenants, including financial covenants such as a requirement that the Company (i) not exceed a defined leverage ratio and (ii) maintain minimum earnings subject to defined adjustments as of specified dates. The agreement also (i) limited the payment of cash dividends, (ii) required that, after giving effect to stock repurchases, the Company maintain liquidity, as defined within the agreement, of at least $20.0 million, (iii) limited

acquisitions or mergers except for certain permitted acquisitions, (iv) set specified limits on the amount the Company can pay to purchase or redeem CryoLife common stock pursuant to a stock repurchase program and to fund estimated tax liabilities incurred by officers, directors, and employees as a result of awards of stock or stock equivalents, and (v) included customary conditions on incurring new indebtedness. As of December 31, 2015 the Company was in compliance with the covenants of the GE Credit Agreement.

As required under the terms of the GE Credit Agreement, the Company maintained cash and cash equivalents of at least $5.0 million in accounts in which GE Capital had a first priority perfected lien. These amounts are recorded as long-term restricted cash as of December 31, 2015 and 2014 on the Company s Consolidated Balance Sheets, as they were restricted for the term of the GE Credit Agreement.

Table of Contents

Amended Debt Agreement

In connection with the closing of the On-X Life Technologies Holdings, Inc., (On-X) acquisition, discussed below in Note 20, on January 20, 2016 the Company and certain of its subsidiaries entered into the Third Amended and Restated Credit Agreement (Amended Debt Agreement) with Capital One, National Association; Healthcare Financial Solutions, LLC; Fifth Third Bank; and Citizens Bank, National Association, collectively the (Lending Parties). The Amended Debt Agreement amended and restated the GE Credit Agreement discussed above and provides the Company with a senior secured credit facility in an aggregate principal amount of $95 million, which includes a $75 million term loan and a $20 million revolving credit facility (including a $4 million letter of credit sub-facility and a $3 million swing-line sub-facility). The $75 million term loan was used to finance, in part, the acquisition of On-X.

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

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

Interest is due and payable with respect to base rate loans is payable quarterly. Interest is due and payable with respect to LIBOR loans on the last day of the applicable interest period and at least the last day of each three month interval, if the interest period is six months.

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

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

Interest

Total interest expense was a favorable $62,000 in 2015 due to the reversal of accrued interest on uncertain tax positions as discussed in Note 11 above. Total interest expense was $175,000 and $71,000 in 2014 and 2013, respectively. Interest expense includes interest on debt and uncertain tax positions in all periods.

13. Commitments and Contingencies

Leases

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

Table of Contents

The Company had deferred rent obligations of $1.7 million and $1.6 million as of December 31, 2015 and 2014, respectively, primarily related to the lease on its corporate headquarters, which expires in 2022. Total rental expense for operating leases was $3.4 million in 2015 and $3.0 million in both 2014 and 2013. The increase in rent expense in 2015 is due to a lease the Company entered into for additional office space in Kennesaw, GA.

	Operating Leases
2016	$ 3,167
2017	3,536
2018	3,524
2019	3,462
2020	3,534
Thereafter	6,974
Total minimum lease payments	$ 24,197

Liability Claims

At December 31, 2015 and 2014 the Company s unreported loss liability was $1.4 million and the related insurance recoverable amounts were $600,000. The Company accrues its estimate of unreported product and tissue processing liability claims as other long-term liabilities and records the related recoverable insurance amounts as other long-term assets. Further analysis indicated that the liability as of December 31, 2015 could be estimated to be as high as $2.6 million, after including a reasonable margin for statistical fluctuations calculated based on actuarial simulation techniques.

Employment Agreement

In July 2014 the Company s Board of Directors appointed Mr. James P. Mackin as President and Chief Executive Officer (CEO), and the Company and Mr. Mackin entered into an employment agreement, which became effective September 2, 2014. The employment agreement has an initial three-year term. Beginning on the second anniversary of the effective date, and subject to earlier termination pursuant to the agreement, the employment term will, on a daily basis, automatically extend by one day. In accordance with the agreement, on September 2, 2014, Mr. Mackin received a one-time signing bonus of $200,000, a grant of 400,000 stock options, and a performance stock award grant of 250,000 shares. The agreement also provides for a severance payment, which would become payable upon the occurrence of certain employment termination events, including termination by the Company without cause.

The employment agreement of the Company s former President, CEO, and Executive Chairman, Mr. Steven G. Anderson, conferred certain benefits on Mr. Anderson upon his retirement or termination of employment in conjunction with certain change in control events. As of December 31, 2014 the Company had $2.2 million included in its accrued expenses and other current liabilities on the Consolidated Balance Sheet, primarily related to severance payable upon Mr. Anderson s voluntary retirement. Mr. Anderson s employment agreement took effect on January 1, 2013 and would have terminated on December 31, 2016.

On April 9, 2015 Mr. Anderson retired from service as an employee of the Company and Chair of its Board of Directors, and entered into a Separation Agreement (the Agreement) with the Company. In accordance with the Agreement, in addition to the severance benefit discussed above, Mr. Anderson received an additional $400,000 in

cash; and will receive 25% of the annual bonus he would have been entitled to under his employment agreement, estimated at target payout rates to be approximately $100,000; reimbursement of a Medicare supplement policy for Mr. Anderson and his spouse for the duration of their lives; accelerated vesting of all outstanding and unvested stock options and awards; and reimbursement of attorneys fees not to exceed $20,000. The Company recorded expense of approximately $1.4 million related to the Agreement in the second quarter of 2015. The acceleration of Mr. Anderson s stock options and awards was effective as of the date of his retirement. The Company made a payment of approximately $2.4 million in cash severance and compensation payments to Mr. Anderson in October 2015, six months after his retirement. The bonus payment is expected to be made in February 2016 at the same time as annual bonus payments, if any, are made to the Company s officers.

PerClot Technology

On September 28, 2010 the Company entered into a worldwide distribution agreement (the Distribution Agreement) and a license and manufacturing agreement (the License Agreement) with SMI, for PerClot, a polysaccharide hemostatic agent used in surgery. The Distribution Agreement contains certain minimum purchase requirements and has a term of 15

Table of Contents

years. Following U.S. regulatory approval and the start of U.S. manufacturing, CryoLife may terminate the Distribution Agreement and the related requirements to purchase minimum amounts of PerClot manufactured by SMI. Upon termination of the Distribution Agreement, CryoLife would manufacture and sell PerClot pursuant to the License Agreement. The Company would pay royalties to SMI at stated rates on net revenues of products manufactured under the License Agreement.

In April 2014 CryoLife received 510(k) clearance from the FDA to market PerClot Topical in the U.S. PerClot Topical is a version of the Company s PerClot product, which was manufactured by the Company at its headquarters and labeled for use in certain topical indications. CryoLife launched PerClot Topical in August 2014. In March 2015 CryoLife ceased all marketing, sales, and distribution of PerClot, including PerClot Topical, in the U.S. in accordance with the District Court order that granted the motion of Medafor for a preliminary injunction in its patent dispute with CryoLife. See Note 8 for further discussion of the Company s lawsuit with Medafor.

The Company is conducting its pivotal clinical trial to gain approval to commercialize PerClot for surgical indications in the U.S. Management believes that the costs of this clinical trial will be significant in 2016. The Company began enrollment in the second quarter of 2015. Enrollment in the clinical trial was slower than anticipated, and the Company voluntarily suspended enrollment in the clinical trial pending discussions with the FDA to modify the IDE study protocol. These planned modifications will need to be approved by the FDA in an IDE supplement. Depending on the outcome of those discussions, the Company will determine when it anticipates resuming enrollment in the clinical trial. If the Company is able to resume enrollment in the clinical trial during 2016, the Company would expect to receive PMA from the FDA in early 2019.

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

14. Shareholders Equity

Common Stock Repurchase

In February 2013 the Company s Board of Directors authorized the purchase of up to $15.0 million of its common stock through October 31, 2014. During the year ended December 31, 2014 the Company purchased approximately 585,000 shares for an aggregate purchase price of $5.6 million. These shares were recorded, at cost, as treasury stock on the Company s Consolidated Balance Sheets. During 2015 the Company did not repurchase any common stock under a repurchase program, and no formal repurchase program was in effect during that period.

Cash Dividends

The Company initiated a quarterly cash dividend of $0.025 per share of common stock outstanding in the third quarter of 2012 and increased this dividend to $0.0275 per share in the second quarter of 2013 and $0.03 per share in the second quarter of 2014. The Company paid dividend payments from cash on hand of $3.4 million and $3.3 million for the years ended December 31, 2015 and 2014, respectively. The dividend payments were recorded as a reduction to retained earnings on the Company s Consolidated Balance Sheets. In December 2015 the Company s Board of Directors discontinued dividend payments for the foreseeable future.

Shareholder Rights Plan

The Company had a shareholder rights agreement entered into in 1995 and amended in 2005. Under the rights agreement, each share of the Company s common stock outstanding on December 11, 1995 was entitled to one Right, as defined in, and subject to, the terms of the rights agreement. A Right entitled the registered holder to purchase from the Company one one-hundredth of a share of Series A Junior Participating Preferred Stock (Series A Stock) of the Company at $33.33 per one one-hundredth of a Preferred Share, subject to adjustment. Additionally, each common share that became outstanding after December 11, 1995 was also entitled to a Right, subject to the terms and conditions of the rights agreement. The shareholder rights agreement expired on November 23, 2015.

Table of Contents

15. Employee Benefit Plans

401(k) Plan

The Company has a 401(k) savings plan (401(k) Plan) providing retirement benefits to all employees who have completed at least three months of service. The Company made matching contributions of 40% of each participant s contribution for up to 5% of each participant s salary in 2015, 2014, and 2013. Total Company contributions approximated $573,000, $553,000, and $541,000 for the years ended December 31, 2015, 2014, and 2013, respectively. Additionally, the Company may make discretionary contributions to the 401(k) Plan; however, no discretionary contributions were made in any of the past three years.

Deferred Compensation Plan

On January 1, 2011 the Company initiated a nonqualified Deferred Compensation Plan (Deferred Plan). The Deferred Plan allows certain employees of CryoLife to defer receipt of a portion of their salary and cash bonus. The Deferred Plan provides for tax-deferred growth of deferred compensation. Pursuant to the terms of the Deferred Plan, the Company agrees to return the deferred amounts plus gains and losses, based on investment fund options chosen by each respective participant, to the plan participants upon distribution. All deferred amounts and deemed earnings thereon are vested at all times. The Company has no current plans to match any contributions. Amounts owed to plan participants are unsecured obligations of the Company. CryoLife has established a rabbi trust in which it will make contributions to fund its obligations under the Deferred Plan. Pursuant to the terms of the trust, the Company will be required to make contributions each year to fully match its obligations under the Deferred Plan. The trust s funds are invested in Company Owned Life Insurance (COLI), and the Company plans to hold the policies until the deaths of the insured.

The Company s deferred compensation liabilities are recorded as a component of other current liabilities or long-term deferred compensation liabilities, as appropriate, based on anticipated distribution dates. The cash surrender value of COLI is recorded in other long-term assets. Changes in the value of participant accounts and changes in the cash surrender value of COLI are recorded as part of the Company s operating expenses and are subject to the Company s normal allocation of expenses to inventory and deferred preservation costs.

16. Stock Compensation

Overview

The Company is currently authorized to grant and has available for grant the following number of shares under the Company s stock plans as of December 31, 2015 and 2014:

Plan	Authorized Shares	Available for Grant 2015	Available for Grant 2014
1996 Discounted Employee Stock Purchase Plan, as amended	1,900,000	560,000	638,000
2009 Employee Stock Incentive Plan	7,100,000	3,361,000	3,929,000
Total	9,000,000	3,921,000	4,567,000

During 2014 the Company amended the 2009 Employee Stock Incentive Plan to increase the authorized shares under the plan by 3.0 million shares. Upon the exercise of stock options or grants of RSAs, PSAs, RSUs, or PSUs, the Company may issue the required shares out of authorized but unissued common stock or out of treasury stock, at management s discretion.

Stock Awards

In 2015 the Compensation Committee of the Company s Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee directors, RSUs to certain employees, and RSAs, PSUs, and PSAs to certain Company officers, which, counting PSUs at target levels, together totaled 405,000 shares and had an aggregate grant date market value of $4.3 million. The PSUs granted in 2015 represented the right to receive from 60% to 150% of the target number of shares of common stock. The performance component of PSU awards granted in 2015 was based on attaining specified levels of adjusted EBITDA, adjusted inventory levels, and trade accounts receivable days sales outstanding, each as defined in the PSU grant documents, for the 2015 calendar year. The PSUs granted in 2015 earned 127% of the target number of shares.

Table of Contents

In 2014 the Compensation Committee of the Company s Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee Directors, RSUs to certain employees, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 655,000 shares of common stock and had an aggregate grant date market value of $6.6 million. The PSUs granted in 2014 earned approximately 50% of the target number of shares.

In 2013 the Compensation Committee of the Company s Board of Directors authorized awards from approved stock incentive plans of RSAs to non-employee Directors, RSUs to certain employees, and RSAs and PSUs to certain Company officers, which, counting PSUs at target levels, together totaled 467,000 shares of common stock and had an aggregate market value of $3.1 million. The PSUs granted in 2012 earned approximately 115% of the target number of shares.

A summary of stock grant activity for the years ended December 31, 2015, 2014, and 2013 for RSAs, PSAs, RSUs, and PSUs, based on the target number of shares, is as follows:

RSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2012	639,000	$ 5.48
Granted	232,000	6.10
Vested	(215,000)	5.80
Forfeited	(34,000)	5.31
Unvested at December 31, 2013	622,000	5.62
Granted	232,000	9.97
Vested	(324,000)	5.55
Forfeited	(35,000)	7.22
Unvested at December 31, 2014	495,000	7.65
Granted	207,000	10.33
Vested	(278,000)	8.10
Forfeited	(110,000)	8.49
Unvested at December 31, 2015	314,000	9.31

PSAs	Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2014	250,000	$ 10.18

Granted	--	--
Vested	--	--
Forfeited	--	--
Unvested at December 31, 2015	250,000	10.18

Table of Contents

RSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2012	120,000	1.54	$ 747,000
Granted	73,000		
Vested	(54,000)		
Forfeited	(10,000)		
Outstanding at December 31, 2013	129,000	1.56	1,425,000
Granted	5,000		
Vested	(52,000)		
Forfeited	(21,000)		
Outstanding at December 31, 2014	61,000	1.21	687,000
Granted	88,000		
Vested	(36,000)		
Forfeited	(10,000)		
Outstanding at December 31, 2015	103,000	1.17	1,110,000
Vested and expected to vest	95,000	1.17	$ 1,029,000

PSUs	Shares	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2013	236,000	0.81	$ 2,612,000
Granted	185,000		
Vested	(143,000)		
Forfeited	(21,000)		
Outstanding at December 31, 2014	257,000	0.73	2,907,000
Granted	125,000		
Vested	(139,000)		
Forfeited	(108,000)		
Outstanding at December 31, 2015	135,000	0.74	1,455,000

Vested and expected to vest	128,000	0.70	$ 1,381,000

Stock Options

The Compensation Committee of the Company s Board of Directors authorized grants of stock options from approved stock incentive plans to certain Company officers and employees totaling 328,000, 562,000, and 162,000 shares in 2015, 2014, and 2013, respectively, with exercise prices equal to the stock prices on the respective grant dates.

Table of Contents

A summary of the Company s stock option activity for the years ended December 31, 2015, 2014, and 2013 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in years	Aggregate Intrinsic Value
Outstanding at December 31, 2012	2,060,000	$ 6.74	3.66	$ 1,225,000
Granted	162,000	6.12		
Exercised	(365,000)	7.48		
Forfeited	(49,000)	5.56		
Expired	(14,000)	6.69		
Outstanding at December 31, 2013	1,794,000	6.57	3.31	8,274,000
Granted	562,000	10.12		
Exercised	(297,000)	7.26		
Forfeited	(23,000)	7.97		
Expired	(15,000)	7.34		
Outstanding at December 31, 2014	2,021,000	7.43	3.54	8,021,000
Granted	328,000	10.83		
Exercised	(248,000)	7.42		
Forfeited	(112,000)	9.93		
Expired	(93,000)	12.08		
Outstanding at December 31, 2015	1,896,000	7.65	3.31	5,992,000
Vested and expected to vest	1,859,000	7.59	3.26	5,977,000
Exercisable at December 31, 2015	1,301,000	6.44	2.16	5,649,000

Other information concerning stock options for the years ended December 31 is as follows:

	2015	2014	2013
Weighted-average fair value of options granted	$ 3.82	$ 4.14	$ 2.54
Intrinsic value of options exercised	761,000	918,000	673,000

Employees purchased common stock totaling 78,000, 111,000, and 97,000 shares in 2015, 2014, and 2013, respectively, through the Company s ESPP.

Stock Compensation Expense

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

	2015		2014		2013	
	Stock Options	ESPP Options	Stock Options	ESPP Options	Stock Options	ESPP Options
Expected life of options	4.5 Years	0.5 Years	4.2 Years	0.5 Years	4.3 Years	0.5 Years
Expected stock price volatility	0.44	0.32	0.55	0.36	0.60	0.39
Dividend yield	1.12%	1.06%	1.16%	1.12%	1.91%	1.59%
Risk-free interest rate	1.41%	0.12%	1.34%	0.08%	0.70%	0.13%

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

	2015	2014	2013
RSA, PSA, RSU, and PSU expense	$ 3,955	$ 2,855	$ 2,616
Stock option and ESPP option expense	1,371	842	852
Total stock compensation expense	$ 5,326	$ 3,697	$ 3,468

Table of Contents

Included in the total stock compensation expense, as applicable in each period, were expenses related to RSAs, PSAs, RSUs, PSUs, and stock options issued in each respective year, as well as those issued in prior periods that continue to vest during the period, and compensation related to the Company s ESPP. These amounts were recorded as stock compensation expense and were subject to the Company s normal allocation of expenses to inventory costs and deferred preservation costs. The Company capitalized $237,000, $261,000 and $228,000 in the years ended December 31, 2015, 2014, and 2013, respectively, of the stock compensation expense into its inventory costs and deferred preservation costs.

As of December 31, 2015 the Company had total unrecognized compensation costs of $4.3 million related to RSAs, PSAs, RSUs, and PSUs and $1.8 million related to unvested stock options, before considering the effect of expected forfeitures. As of December 31, 2015 this expense is expected to be recognized over a weighted-average period of 2.0 years for RSUs, 1.8 years for stock options, 1.7 years for PSAs, 1.2 years for RSAs, and 0.7 years for PSUs.

17. Income Per Common Share

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

Basic income per common share	**2015**	**2014**	**2013**
Net income	$ 4,005	$ 7,322	$ 16,172
Net income allocated to participating securities	(87)	(161)	(367)
Net income allocated to common shareholders	$ 3,918	$ 7,161	$ 15,805
Basic weighted-average common shares outstanding	27,744	27,379	26,885
Basic income per common share	$ 0.14	$ 0.26	$ 0.59

Diluted income per common share	**2015**	**2014**	**2013**
Net income	$ 4,005	$ 7,322	$ 16,172
Net income allocated to participating securities	(87)	(158)	(359)
Net income allocated to common shareholders	$ 3,918	$ 7,164	$ 15,813
Basic weighted-average common shares outstanding	27,744	27,379	26,885
Effect of dilutive options and awards[a]	798	934	813
Diluted weighted-average common shares outstanding	28,542	28,313	27,698
Diluted income per common share	$ 0.14	$ 0.25	$ 0.57

[a] The Company excluded stock options from the calculation of diluted weighted-average common shares outstanding if the per share value, including the sum of (i) the exercise price of the options and (ii) the amount of the compensation cost attributed to future services and not yet recognized, was greater than the average market price of the shares, because the inclusion of these stock options would be antidilutive to income per common share. Accordingly, stock options to purchase 710,000, 335,000, and 656,000 shares for the years ended December 31, 2015, 2014, and 2013, respectively, were excluded from the calculation of diluted weighted-average common shares outstanding.

18. Transactions with Related Parties

A member of the Company s Board of Directors and a shareholder of the Company is an employee of an investment banking services company. The Company made stock repurchases of zero, $5.6 million, and $321,000 in 2015, 2014, and 2013, respectively, which includes the cost of stock and commissions of less than 1% to that investment banking services company.

A member of the Company s Board of Directors and a shareholder of the Company was the former Chief of Thoracic Surgery of a university hospital that generated product and preservation services revenues of $329,000, $273,000, and $353,000 for the Company in 2015, 2014, and 2013, respectively. Additionally, the son of this member of the Company s Board of Directors receives a retainer for performing heart and lung transplants from a medical center that generated product and preservation services revenues of $617,000, $616,000, and $345,000 for the Company in 2015, 2014, and 2013, respectively.

Table of Contents

The Company expensed $35,000, $45,000, and $47,000 in 2015, 2014, and 2013, respectively, relating to supplies for clinical trials purchased from a company whose Chief Financial Officer is a member of the Company s Board of Directors and a shareholder of the Company.

19. Segment and Geographic Information

The Company has two reportable segments organized according to its products and services: Medical Devices and Preservation Services. The Medical Devices segment includes external revenues from product sales of BioGlue, BioFoam, PerClot, CardioGenesis cardiac laser therapy, HeRO Graft, ProCol, and PhotoFix. The Preservation Services segment includes external services revenues from the preservation of cardiac and vascular tissues. There are no intersegment revenues.

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

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

	2015	2014	2013
Revenues:			
Medical devices	$ 83,081	$ 81,883	$ 76,194
Preservation services	62,817	62,758	64,498
Other[a]	--	--	71
Total revenues	145,898	144,641	140,763
Cost of products and preservation services:			
Medical devices	18,663	17,167	15,147
Preservation services	36,516	36,183	35,230
Total cost of products and preservation services	55,179	53,350	50,377
Gross margin:			
Medical devices	64,418	64,716	61,047
Preservation services	26,301	26,575	29,268
Other[a]	--	--	71
Total gross margin	$ 90,719	$ 91,291	$ 90,386

Table of Contents

Net revenues by product for the years ended December 31, 2015, 2014, and 2013 were as follows (in thousands):

	2015	2014	2013
Products:			
BioGlue and BioFoam	$ 59,332	$ 62,091	$ 58,004
PerClot	4,083	4,289	3,494
CardioGenesis cardiac laser therapy	9,419	8,225	8,965
HeRO Graft	7,546	7,131	5,731
ProCol	1,305	147	--
PhotoFix	1,396	--	--
Total products	83,081	81,883	76,194
Preservation services:			
Cardiac tissue	28,059	29,437	29,523
Vascular tissue	34,758	33,321	34,975
Total preservation services	62,817	62,758	64,498
Other[a]	--	--	71
Total revenues	$ 145,898	$ 144,641	$ 140,763

[a] For the year ended December 31, 2013 the Other designation included grant revenue.

Net revenues by geographic location attributed to countries based on the location of the customer for the years ended December 31, 2015, 2014, and 2013 were as follows (in thousands):

	2015	2014	2013
U.S.	$ 114,978	$ 110,533	$ 109,325
International	30,920	34,108	31,438
Total revenues	$ 145,898	$ 144,641	$ 140,763

At December 31, 2015 and 2014 over 95% of the long-lived assets of the Company were held in the U.S., where all of the Company s manufacturing facilities and the corporate headquarters are located. At December 31, 2015 and 2014 the Company s $11.4 million of goodwill was allocated entirely to its Medical Devices segment.

20. Subsequent Events (unaudited)

Acquisition of On-X Life Technologies

Overview

On December 22, 2015 the Company, entered into the Agreement and Plan of Merger (On-X Agreement) to acquire On-X, an Austin, Texas-based, privately held mechanical heart valve company, for approximately $130.0 million, subject to certain adjustments, consisting of approximately $91.0 million in cash and $39.0 million of CryoLife s common stock. The transaction closed on January 20, 2016 and On-X will be operated as a wholly-owned subsidiary of CryoLife.

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

Table of Contents

Accounting for the Transaction

Per the Company s preliminary analysis, the purchase price of the transaction totaled approximately $128.0 million, consisting of cash of $93.4 million and 3,703,699 shares of CryoLife common stock, with a value of $34.6 million as determined on the date of the closing. This purchase price is subject to several potential adjustments, including a working capital adjustment, which has not yet been finalized. The Company s preliminary allocation of the $128.0 million purchase price to On-X s tangible and identifiable intangible assets acquired and liabilities assumed, based on their estimated fair values as of January 20, 2016, is included in the table below. Goodwill will be recorded based on the amount by which the purchase price exceeds the fair value of the net assets acquired and is not deductible for tax purposes. The allocation of the purchase price is preliminary and differences between the preliminary and final purchase price allocation could be material. This allocation of purchase price is expected to change based on a variety of factors including, but not limited to, determination of the valuation of intangible assets acquired, the fair value of inventories acquired, the amount of current and deferred tax assets and liabilities acquired, and the amount of non-tax liabilities assumed. Goodwill from this transaction will be allocated to the Company s medical devices segment.

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

		Opening Balance Sheet
Cash and cash equivalents	$	2,472
Receivables		6,503
Inventories		13,284
Intangible assets and goodwill		96,937
Other assets		13,426
Liabilities assumed		(4,557)
Total purchase price	$	128,065

CryoLife incurred transaction and integration costs of $2.8 million for the year ended December 31, 2015. These costs were expensed as incurred and were primarily recorded as general, administrative, and marketing expenses on the Company s Consolidated Statements of Operations and Comprehensive Income.

Pro Forma Results

The Company s unaudited pro forma results of operations for the year ended December 31, 2015 and 2014 assuming the On-X acquisition had occurred as of January 1, 2014 are presented for comparative purposes below. These amounts are based on available information of the results of operations of On-X prior to the acquisition date and are not necessarily indicative of what the results of operations would have been had the acquisition been completed on January 1, 2014. The pro forma adjustments related to the acquisition of On-X are based on a preliminary purchase price allocation. Differences between the preliminary and final purchase price allocation could have an impact on the pro forma financial information presented below and that impact could be material. This unaudited pro forma information does not project operating results post acquisition.

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

	2015	2014
Total revenues	$ 179,266	$ 177,722
Net income	6,458	3,730

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

Table of Contents

Divestiture of the HeRO Graft Product Line

On February 3, 2016 the Company sold its HeRO Graft product line to Merit Medical Systems, Inc. (Merit) for $18.5 million in cash. Under terms of the agreement, Merit acquired the HeRO Graft product line, including worldwide marketing rights, customer relationships, intellectual property, inventory, and certain property and equipment. The Company will continue to manufacture the HeRO Graft for up to six months under a transition supply agreement, after which Merit will be responsible for manufacturing. The disposal of the HeRO Graft is part of a strategic shift of the Company s focus to selling its expanded portfolio of cardiac surgery products, including the On-X heart valve.

The HeRO Graft product line was included as part of the Company s Medical Devices segment. The Company is in the process of completing the accounting related to this sale, including an allocation of its medical device segment goodwill to the divested business using a relative fair value allocation method. The assets divested in this transaction did not meet the criteria to be reported as assets held for sale as of December 31, 2015. As of December 31, 2015 the Company had approximately $8.0 million in carrying value of assets, before the allocation of goodwill, associated with this divested product line on its Consolidated Balance Sheet, primarily in intangible assets and inventory.

Table of Contents

SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

(in thousands, except per share data)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
REVENUE:				
2015	$ 33,831	$ 35,526	$ 36,703	$ 39,838
2014	35,731	34,690	37,069	37,151
2013	35,536	33,520	36,250	35,457
GROSS MARGIN:				
2015	$ 19,667	$ 21,554	$ 22,982	$ 26,516
2014	22,473	22,384	23,799	22,635
2013	23,276	21,479	23,349	22,282
NET (LOSS) INCOME:				
2015	$ (274)	$ (502)	$ 2,145	$ 2,636
2014	1,059	2,161	2,326	1,776
2013	2,192	1,785	3,169	9,026*
(LOSS) INCOME PER COMMON SHARE DILUTED:				
2015	$ (0.01)	$ (0.02)	$ 0.07	$ 0.09
2014	0.04	0.08	0.08	0.06
2013	0.08	0.06	0.11	0.31*

* The fourth quarter 2013 net income and income per common share-diluted includes the favorable effect of a $12.7 million pre-tax gain on the sale of an investment in the common stock of Medafor, Inc. as a result of C.R. Bard, Inc. s acquisition of the outstanding common shares of Medafor, Inc. and the unfavorable effect of a $3.2 million other than temporary investment impairment as a result of the impairment and write-down of the Company s investment in ValveXchange preferred stock.