
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K/A

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
Date of Report (Date of earliest event reported): February 17, 2015**

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida
(State or Other Jurisdiction
of Incorporation)

1-13165
(Commission File Number)

59-2417093
(IRS Employer
Identification No.)

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

(Address of principal executive office) (zip code)

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Section 2 Financial Information

Item 2.02 Results of Operations and Financial Condition.

On February 17, 2015, CryoLife, Inc. (“CryoLife” or the “Company”) issued a press release announcing its financial results for the year and quarter ended December 31, 2014. On February 17, 2015, the Company filed a Current Report on Form 8-K to disclose the issuance of the aforementioned press release, but failed to attach the press release to the Form 8-K. This amendment to such Form 8-K is filed to attach copies of (i) the February 17, 2015 press release and (ii) the transcript of the live conference call and webcast that was held by the Company on February 17, 2015 (referred to herein as the “earnings call”).

CryoLife hereby incorporates by reference herein the information set forth in its press release dated February 17, 2015, a copy of which is attached hereto as Exhibit 99.1. CryoLife also hereby incorporates by reference herein the statements made by the Company during the earnings call as set forth in the earnings call transcript, a copy of which is attached hereto as Exhibit 99.2. Except as otherwise provided in the press release, the press release speaks only as of the date of such press release, and it shall not create any implication that the affairs of CryoLife have continued unchanged since such date. Likewise, except as otherwise provided by the Company during the earnings call, the statements made by the Company during the earnings call were made as of the date of such earnings call and do not create any implication that the affairs of CryoLife have continued unchanged since such date.

The press release and earnings call transcript include earnings per share guidance that excludes expenses related to potential future business development. The Company has excluded expenses related to potential future business development from its earnings per share guidance because the Company maintains an active business development program that is subject to changes and is currently unable to predict the level of activity during the remainder of fiscal 2015, if any.

The information provided pursuant to this Item 2.02 is to be considered “furnished” pursuant to Item 2.02 of Form 8-K and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be deemed incorporated by reference into any of CryoLife’s reports or filings with the Securities and Exchange Commission, whether made before or after the date hereof, except as expressly set forth by specific reference in such report or filing.

Except for the historical information contained in this report, the statements made by CryoLife are forward-looking statements that involve risks and uncertainties. All such statements are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. CryoLife’s future financial performance could differ significantly from the expectations of management and from results expressed or implied in the press release or during the earnings call. Please refer to (i) the last paragraph of the text portion of the press release and (ii) the first page of the earnings call transcript for further discussion about forward-looking statements. For further information on risk factors, please refer to “Risk Factors” contained in CryoLife’s Form

10-K filed for the year ended December 31, 2014 and its subsequent filings with the Securities and Exchange Commission, as well as in the press release attached as Exhibit 99.1 hereto. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

Section 9 Financial Statements and Exhibits.

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements.

Not applicable.

(b) Pro Forma Financial Information

Not applicable.

(c) Shell Company Transactions.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1*	Press release dated February 17, 2015
99.2*	Transcript of Earnings Call held on February 17, 2015

* This exhibit is furnished, not filed.

SIGNATURES

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

CRYOLIFE, INC.

Date: February 23, 2015

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

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EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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NEWS RELEASE

FOR IMMEDIATE RELEASE

Contacts:

CryoLife

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Executive Vice President, Chief Financial Officer and
Chief Operating Officer

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**CryoLife Fourth Quarter Revenues Increase 5 Percent to
\$37.2 Million; Full Year Revenues Increase 3 Percent to \$144.6 Million**

Financial and Recent Highlights:

- **Product revenues grew 12 percent for the quarter and 7 percent for the full year**
- **BioGlue® revenues grew 11 percent for the quarter and 7 percent for the full year**
- **HeRO® revenues grew 10 percent for the quarter and 24 percent for the full year**
- **PerClot® revenues grew 52 percent for the quarter and 23 percent for the full year**
- **Tissue processing revenues decreased 4 percent for the quarter and 3 percent for the full year**
- **Launched ProCol® and PhotoFix™**
- **On track to begin enrollment in PerClot IDE clinical trial in the first quarter of 2015**

ATLANTA, GA – (February 17, 2015) – CryoLife, Inc. (NYSE: CRY), a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced today its results for the fourth quarter and full year of 2014. Revenues for the fourth quarter of 2014 increased 5 percent to \$37.2 million compared to \$35.5 million for the fourth quarter of 2013. Revenues for the full year of 2014 increased 3 percent to \$144.6 million compared to \$140.8 million for the full year of 2013.

Pat Mackin, President and Chief Executive Officer, said, “CryoLife had a solid fourth quarter, with double-digit revenue growth for our key medical device products, partially offset by a decline in tissue processing revenues. During the quarter we launched ProCol, followed by the launch of PhotoFix in January, adding two new key products that further leverage our sales force and strong customer relationships. We also made good progress with our pipeline initiatives and remain positioned to begin enrollment in the PerClot IDE clinical trial during the first quarter of 2015. Outside of the U.S., we remain on track with our regulatory efforts to expand the indication for BioGlue in Japan later in 2015. Altogether, this puts us in a good position in the long-term to significantly expand our higher margin medical device revenues, which continue to represent a larger mix of our overall business.”

Mr. Mackin continued, “In 2015 we are investing in several strategic initiatives to enhance the long-term growth and margin expansion potential of our business. This includes the PerClot IDE trial, enhanced quality and regulatory controls for our tissue processing business, and plans to transition to a direct sales organization in one of our European territories. We also have ongoing litigation regarding PerClot that we believe is important to protect our investments in the IDE trial and future market opportunities. While these initiatives will impact our revenue growth and profitability in 2015, we believe they strongly position the Company for improved performance beginning in 2016.”

Net income for the fourth quarter of 2014 was \$1.8 million, or \$0.06 per basic and per fully diluted common share, compared to net income of \$9.0 million, or \$0.33 per basic and \$0.31 per fully diluted common share, for the fourth quarter of 2013. Excluding certain items as shown in the schedules below, proforma non-GAAP fully diluted earnings per share was \$0.04 in the fourth quarter of 2014, compared to \$0.07 in the fourth quarter of 2013.

Net income for the full year of 2014 was \$7.3 million, or \$0.26 per basic and \$0.25 per fully diluted common share, compared to net income of \$16.2 million, or \$0.59 per basic and \$0.57 per fully diluted common share, for the full year of 2013. Excluding certain items as shown in the schedules below, proforma non-GAAP fully diluted earnings per share was \$0.18 for the full year of 2014, compared to \$0.33 in 2013.

Product revenues were \$21.7 million for the fourth quarter of 2014, up 12 percent from \$19.4 million in the fourth quarter of 2013. Product revenues were \$81.9 million for the full year of 2014, up 7 percent from \$76.2 million in the full year of 2013.

Surgical sealant and hemostat revenues, which consisted primarily of sales of BioGlue and PerClot, were \$17.6 million for the fourth quarter of 2014 compared to \$15.6 million for the fourth quarter of 2013, an increase of 13 percent. Surgical sealant and hemostat revenues were \$66.4 million for the full year of 2014 compared to \$61.5 million for the full year of 2013, an increase of 8 percent. The increase in surgical sealant and hemostat revenues for the fourth quarter and full year of 2014 was due to an increase in BioGlue unit shipments into both domestic and international markets, and to a lesser extent, an increase in BioGlue average sales prices and an increase in PerClot unit shipments.

HeRO Graft revenues were \$1.8 million for the fourth quarter of 2014 compared to \$1.7 million in the fourth quarter of 2013, an increase of 10 percent. HeRO Graft revenues were \$7.1 million for the full year of 2014 compared to \$5.7 million for the full year of 2013, an increase of 24 percent.

CardioGenesis cardiac laser therapy revenues were \$2.2 million for the fourth quarter of 2014 compared to \$2.1 million for the fourth quarter of 2013. Cardiac laser therapy revenues were \$8.2 million for the full year of 2014 compared to \$9.0 million for the full year of 2013. The increase in cardiac laser therapy revenues for the fourth quarter of 2014 was primarily due to an increase in handpiece shipments, partially offset by a decrease in laser console shipments, while the decrease in the full year of 2014 was primarily due to a decrease in laser console and handpiece shipments.

Preservation services revenues were \$15.5 million for the fourth quarter of 2014 compared to \$16.1 million for the fourth quarter of 2013, a decrease of 4 percent. Cardiac preservation service revenues for the fourth quarter of 2014 were flat compared to the fourth quarter of 2013 and included

a decrease in unit shipments, offset by an increase in average service fees. Vascular preservation services revenues decreased 7 percent for the fourth quarter of 2014 compared to the fourth quarter of 2013 due to decreases in unit shipments of vascular tissues, partially offset by an increase in average service fees.

Preservation services revenues were \$62.8 million for the full year of 2014 compared to \$64.5 million for the full year of 2013, a decrease of 3 percent. Cardiac preservation service revenues in the full year of 2014 were flat compared to the full year of 2013 and included a decrease in unit shipments of cardiac grafts, offset by an increase in average service fees. Vascular preservation services revenues decreased 5 percent for the full year of 2014 compared to the full year of 2013 due to a decrease in unit shipments of vascular grafts, partially offset by an increase in average service fees.

Total gross margins were 61 percent in the fourth quarter of 2014 compared to 63 percent in the fourth quarter of 2013. Product gross margins were 77 percent for the fourth quarters of 2014 and 2013. Preservation services gross margins were 39 percent and 46 percent in the fourth quarters of 2014 and 2013, respectively.

Total gross margins were 63 percent and 64 percent in the full year of 2014 and 2013, respectively. Product gross margins were 79 percent and 80 percent for the full year of 2014 and 2013, respectively. Preservation services gross margins were 42 percent and 45 percent in the full year of 2014 and 2013, respectively. The decrease in preservation services gross margin was primarily related to lower processing throughput of tissues, increased compliance and personnel costs, and an increase in the cost of materials for tissues shipped during the fourth quarter and full year of 2014.

General, administrative, and marketing expenses for the fourth quarters of 2014 and 2013 were \$18.6 million and \$16.7 million, respectively. General, administrative, and marketing expenses for the full year of 2014 and 2013 were \$73.8 million and \$68.1 million, respectively. General, administrative, and marketing expenses for the fourth quarter and full year of 2014 included approximately \$565,000 and \$2.0 million, respectively, in pretax compensation charges related to personnel changes.

Research and development expenses were \$2.1 million and \$2.5 million for the fourth quarters of 2014 and 2013, respectively. Research and development expenses were \$8.7 million and \$8.5 million for the full year of 2014 and 2013, respectively. Research and development spending in 2014 was focused on PerClot, tissue processing, and BioGlue and BioFoam®.

For the full year of 2014, the Company purchased 585,000 shares of its common stock under the repurchase program that expired in October 2014 at an average price of \$9.55 per share, resulting in aggregate purchases of \$5.6 million.

As of December 31, 2014, the Company had \$39.3 million in cash, cash equivalents, and restricted cash and securities, compared to \$43.0 million at December 31, 2013. Of this \$39.3 million in cash, cash equivalents, and restricted cash and securities, \$5.9 million was designated as restricted cash and securities, primarily due to a financial covenant requirement under the Company's credit agreement. The Company's net cash flows provided by operations were \$4.8 million for the fourth quarter of 2014 compared to \$5.5 million for the fourth quarter of 2013. The Company's net cash

flows provided by operations were \$8.1 million for the full year of 2014 compared to \$16.8 million for the full year of 2013.

The Company's initial 2015 financial guidance is summarized below.

2015 Financial Guidance Summary	
Total revenues	\$151 million - \$153 million 4% - 6% increase
Product revenues	Mid-single digits % increase
Tissue processing revenues	Low-single digits % increase
Gross margins	Approximately 60%
R&D expenses	\$13.0 million - \$14.0 million
Earnings (loss) per share	\$(0.03) – breakeven

Earnings per share guidance does not include expenses related to future business development activities, which cannot currently be estimated.

The Company's financial guidance for the full year of fiscal 2015 is subject to the risks described below in the last paragraph of this press release, prior to the financial tables.

Webcast and Conference Call Information

The Company will hold a teleconference call and live webcast today at 8:00 a.m. Eastern Time to discuss the results followed by a question and answer session hosted by Mr. Mackin.

To listen to the live teleconference, please dial 201-689-8261 a few minutes prior to 8:00 a.m. A replay of the teleconference will be available February 17 through February 24 and can be accessed by calling (toll free) 877-660-6853 or 201-612-7415. The conference number for the replay is 13600732.

The live webcast and replay can be accessed by going to the Investor Relations section of the CryoLife Web site at www.cryolife.com and selecting the heading Webcasts & Presentations.

About CryoLife, Inc.

CryoLife, Inc. is a leader in medical device manufacturing and distribution and in the processing and distribution of implantable living human tissues for use in cardiac and vascular surgeries. It operates throughout the U.S. and internationally. CryoLife manufactures and distributes BioGlue® Surgical Adhesive, an FDA-approved adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. BioGlue is also CE marked in Europe for use in soft tissue repair and has received additional marketing approvals in several other countries throughout the world. CryoLife's BioFoam® Surgical Matrix is CE marked in Europe for use as an adjunct to hemostasis in cardiovascular surgery and on abdominal parenchymal tissues (liver and spleen) when control of bleeding by ligature or conventional methods is ineffective or impractical. CryoLife distributes

PerClot®, a powdered hemostat, in Europe and other select international countries. CryoLife has received FDA 510(k) clearance for PerClot Topical, which is being marketed in the U.S. primarily for use in ENT applications, and is conducting a pivotal clinical trial in the U.S. for potential FDA approval of the surgical version of PerClot. CryoLife's CardioGenesis cardiac laser therapy product line, which includes a laser console system and single-use, fiber-optic handpieces, is used in the treatment of coronary artery disease for severe angina, to perform a surgical procedure known as Transmyocardial Revascularization (TMR). CryoLife markets the HeRO® Graft, which is a solution for end-stage renal disease in certain hemodialysis patients. CryoLife distributes ProCol®, a natural biological graft derived from a bovine mesenteric vein that provides vascular access for end-stage renal disease hemodialysis patients, which is approved for sale in the U.S. CryoLife also distributes PhotoFix™ Decellularized Bovine Pericardium, a proven, clinically effective tissue substitute that has undergone a dye-mediated photo-oxidation fixation process, is biocompatible without toxicity, and is derived from bovine pericardium, a material known for reliable consistency and strength with handling characteristics similar to autologous pericardium. CryoLife's CryoValve® SG pulmonary heart valve, processed using CryoLife's proprietary SynerGraft® technology, has FDA 510(k) clearance for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic pulmonary valves. CryoLife's CryoPatch® SG pulmonary cardiac patch has FDA 510(k) clearance for the repair or reconstruction of the right ventricular outflow tract (RVOT), which is a surgery commonly performed in children with congenital heart defects.

For additional information about the company, visit CryoLife's website:
<http://www.cryolife.com>.

Statements made in this press release and during the accompanying earnings webcast that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 that may cause actual results to differ materially from current expectations. These statements include those regarding: our 2015 strategic initiatives, and the potential timing and benefits of such initiatives, including the PerClot IDE clinical trial, enhanced quality and regulatory controls for our tissue processing business, and plans to transition to a direct sales organization in a major European market; our plans and expectations related to ProCol, PhotoFix, PerClot Topical and our other products, including the benefits of such products; our expectations with respect to the PerClot IDE clinical trial and the expansion of the indication for BioGlue in Japan; our beliefs regarding the PerClot litigation; the potential timing of FDA approval of the surgical version of PerClot; our expectations related to the FDA's re-inspection of our quality systems and processes; our plans and strategies, including opportunities related to the growth of tissue processing gross margins and the development of a strategic 5-year plan; and our anticipated performance for fiscal 2015 and fiscal 2016. The risks and uncertainties affecting these statements include that: the success of efforts related to any of our product lines and tissues is subject to many significant risks and factors beyond our control, including general economic conditions, physician and patient acceptance of our products and tissues, our potential inability to maintain reimbursement approvals and maintain and expand reimbursement rates, and regulatory approvals; competing products may be introduced into the market that may materially affect sales growth for our products; our anticipated performance for fiscal 2015 and fiscal 2016 is subject to the general risks associated with our business, which, in addition to those discussed above, include that we are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product, including the risk that BioGlue may be the subject of adverse developments with regard to its safety, efficacy, or reimbursement practices; competitors have obtained FDA approval for indications in which BioGlue has been used off-label and for which we cannot market BioGlue; we may not receive expanded approval for BioGlue in Japan in the timeframe anticipated or at all, which could materially adversely affect our ability to realize our marketing strategies to grow revenues in the Asia-Pacific region and overall; we

have taken certain corrective actions and have proposed to the FDA other corrective actions in response to the Forms 483 and a Warning Letter received from the FDA related to the manufacture of medical devices and our processing, preservation, and distribution of human tissue; however, the FDA may determine that our corrective actions have not adequately addressed the issues raised in the Forms 483 or Warning Letter; if we have failed to adequately address the concerns raised by the FDA, we could be subject to additional regulatory action by the FDA, including recalls, injunctions, or legal action, and further actions required to be taken in response to such actions could adversely affect the availability of our products and tissues and our cost structure; the FDA has indicated that it is considering regulating our CryoValve SG pulmonary valve tissue as a class III medical device, and its advisory committee panel has voted in favor of such classification, which could ultimately negatively impact revenues from and negatively impact the profitability of our cardiac tissues ; there is no guarantee that the FDA will approve the surgical version of PerClot for distribution in the U.S. in accordance with our expected timeframe, or at all; clinical trials are subject to a number of risks, including unanticipated reactions or results, delays, and cost overages, and we may ultimately be unsuccessful in our clinical trials; there is no guarantee that we will be able to attain the levels of revenue and profitability that we anticipate for the surgical version of PerClot and/or PerClot Topical; our litigation against C.R. Bard, Inc. and certain of its subsidiaries will be expensive, and it may continue for longer and be costlier than we anticipate; legal costs and the timing of their incurrence are difficult to predict with any degree of certainty, we may incur costs associated with the action earlier or later than we anticipate, and there is no guarantee that we will ultimately prevail at the preliminary injunction and/or trial stages of the litigation; if we do not prevail in such action, or if C.R. Bard obtains an injunction, we may be prohibited from selling PerClot in the U.S., or we may have to pay substantial royalties or damages when we sell PerClot in the U.S.; our ability to fully realize our investment in our agreements with Starch Medical, Inc. is dependent on our ability to sell PerClot in the U.S. for a reasonable rate of return, which may be materially negatively impacted by any royalty that we might be required to pay; we may experience currently unforeseen difficulties related to our ability to successfully market and distribute ProCol and PhotoFix; our beliefs regarding the market opportunities for ProCol and PhotoFix may be incorrect, and even if correct, there is no guarantee that we will successfully grow ProCol and PhotoFix sales or fully realize the potential benefits of any clinical advantages of these products; integration efforts with respect to newly acquired products may be more costly and take longer than expected; we may receive impaired materials or supplies that do not meet our standards; the recall of materials or supplies by our vendors or our inability to obtain necessary materials and supplies due to vendor supply disruptions, our inability to secure supply contracts, or insufficient supplier diversification could have a material, adverse effect on our business; our sales are affected by challenging domestic and international economic conditions and their constraining effects on hospital budgets; healthcare policy changes may have a material, adverse effect on our business; key growth strategies may not generate the benefits we anticipate; we may not be successful in obtaining necessary clinical results and regulatory approvals for services and products in development; uncertainties related to patents and protection of proprietary technology may adversely affect the value of our intellectual property or may result in our payment of significant monetary damages and/or royalty payments, negatively affecting our ability to sell current or future products, or prohibiting us from enforcing our patent and other proprietary technology rights against others; we are dependent on the availability of sufficient quantities of tissue from human donors; consolidation in the healthcare industry could continue to result in demands for price concessions, limits on the use of our products and tissues, and limitations on our ability to sell to certain of our significant market segments; the success of many of our products and tissues depends upon strong relationships with physicians; our existing insurance policies may not be sufficient, and we may be unable to obtain insurance in the future; our credit facility limits our ability to pursue significant acquisitions and increase our cash dividend, and also may limit our ability to borrow; continued fluctuation of foreign currencies relative to the U.S. dollar could materially, adversely affect our business; rapid technological change could cause our products and services to become obsolete; we are dependent on key personnel; our expectations regarding earnings per share for 2015 include anticipated 2015 expenses for research and development; if research and development expenses are higher than expected, our actual 2015 earnings per share would be lower than projected; to the extent that we engage in significant litigation or acquisition activities (including litigation against C.R. Bard) and/or if our litigation expenses associated with the litigation against C.R. Bard exceed the

amount currently included in our guidance projections, our 2015 expenses and earnings per share could be significantly negatively affected. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2013 and our Form 10-K for the year ended December 31, 2014, which we intend to file shortly, and our subsequent filings with the SEC. CryoLife does not undertake to update its forward-looking statements.

CRYOLIFE, INC. AND SUBSIDIARIES
Financial Highlights
(In thousands, except per share data)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2014	2013	2014	2013
Revenues:				
Products	\$ 21,673	\$ 19,370	\$ 81,883	\$ 76,194
Preservation services	15,478	16,087	62,758	64,498
Other	--	--	--	71
Total revenues	37,151	35,457	144,641	140,763
Cost of products and preservation services:				
Products	5,068	4,417	17,167	15,147
Preservation services	9,448	8,758	36,183	35,230
Total cost of products and preservation services	14,516	13,175	53,350	50,377
Gross margin	22,635	22,282	91,291	90,386
Operating expenses:				
General, administrative, and marketing	18,638	16,671	73,754	68,112
Research and development	2,092	2,478	8,699	8,454
Total operating expenses	20,730	19,149	82,453	76,566
Operating income	1,905	3,133	8,838	13,820
Interest expense	65	(88)	175	71
Interest income	(1)	(1)	(50)	(4)
Gain on sale of Medafor investment	(530)	(12,742)	(530)	(12,742)
Other than temporary investment impairment	--	3,229	--	3,229
Other expense (income), net	746	(146)	540	(26)
Income before income taxes	1,625	12,881	8,703	23,292
Income tax (benefit) expense	(151)	3,855	1,381	7,120
Net income	\$ 1,776	\$ 9,026	\$ 7,322	\$ 16,172
Income per common share:				
Basic	\$ 0.06	\$ 0.33	\$ 0.26	\$ 0.59
Diluted	\$ 0.06	\$ 0.31	\$ 0.25	\$ 0.57
Dividends declared per common share	\$ 0.030	\$ 0.028	\$ 0.118	\$ 0.108
Weighted-average common shares outstanding:				
Basic	27,273	27,097	27,379	26,885
Diluted	28,238	28,208	28,313	27,698

CRYOLIFE, INC. AND SUBSIDIARIES
Financial Highlights
(In thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
Products:				
BioGlue and BioFoam	\$ 16,346	\$ 14,766	\$ 62,091	\$ 58,004
PerClot	1,232	808	4,289	3,494
CardioGenesis cardiac laser therapy	2,151	2,128	8,225	8,965
HeRO Graft	1,827	1,668	7,131	5,731
ProCol	117	—	147	—
Total products	21,673	19,370	81,883	76,194
Preservation services:				
Cardiac tissue	7,456	7,488	29,437	29,523
Vascular tissue	8,022	8,599	33,321	34,975
Total preservation services	15,478	16,087	62,758	64,498
Other	—	—	—	71
Total revenues	\$ 37,151	\$ 35,457	\$ 144,641	\$ 140,763
Revenues:				
U.S.	\$ 27,931	\$ 27,773	\$ 110,533	\$ 109,325
International	9,220	7,684	34,108	31,438
Total revenues	\$ 37,151	\$ 35,457	\$ 144,641	\$ 140,763

	December 31, 2014	December 31, 2013
Cash, cash equivalents, and restricted cash and securities	\$ 39,259	\$ 42,993
Total current assets	106,028	106,327
Total assets	176,157	174,683
Total current liabilities	20,627	20,722
Total liabilities	27,472	29,936
Shareholders' equity	148,685	144,747

CRYOLIFE, INC. AND SUBSIDIARIES
Reconciliation of
Non-GAAP Adjusted Net Income and Adjusted Income per Common Share – Diluted
(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	2013	2014	2013
GAAP:				
Income before income taxes	\$ 1,625	\$ 12,881	\$ 8,703	\$ 23,292
Income tax (benefit) 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
Reconciliation excluding items:				
Income before income taxes, GAAP	\$ 1,625	\$ 12,881	\$ 8,703	\$ 23,292
Excluding:				
Allowance for uncollectable notes receivable	2,000	--	2,000	--
Other than temporary investment impairment	--	3,229	--	3,229
Gain on contingent consideration	(1,392)	(74)	(1,884)	(28)
Gain on sale of Medafor investment	(530)	(12,742)	(530)	(12,742)
Expenses for business development and integration	9	54	27	1,125
Adjusted income before income taxes, non-GAAP	1,712	3,348	8,316	14,876
Income tax expense calculated at an effective tax rate of 37% for the three and twelve months	633	1,239	3,077	5,504
Adjusted net income, non-GAAP	\$ 1,079	\$ 2,109	\$ 5,239	\$ 9,372
Adjusted net income, non-GAAP allocated to participating securities – diluted	29	46	115	192
Adjusted net income, non-GAAP applicable to common shareholders – diluted	\$ 1,050	\$ 2,063	\$ 5,124	\$ 9,180
Diluted adjusted income per common share, non-GAAP:	\$ 0.04	\$ 0.07	\$ 0.18	\$ 0.33
Diluted-weighted average common shares outstanding:	28,238	28,208	28,313	27,698

Investors should consider this non-GAAP information in addition to, and not as a substitute for, financial measures prepared in accordance with U.S. GAAP. In addition, this non-GAAP financial information may not be the same as similar measures presented by other companies. Non-GAAP adjusted net income and adjusted income per common share excludes the allowance for uncollectable notes receivable and other than temporary investment impairment related to ValveXchange, the gain on the contingent consideration related to the acquisition of Hemosphere, the gain on sale of Medafor investment, and expenses for business development activities, including the Company's transaction and integration costs, primarily associated with the acquisition of Hemosphere. The above non-GAAP items have been calculated using an effective tax rate of 37% for all periods. The Company believes that this non-GAAP presentation provides useful information to investors regarding unusual non-operating transactions and the operating expense structure of the Company's existing and recently acquired operations, without regard its ongoing efforts to acquire additional complementary products and businesses and the transaction expenses incurred in connection with recently acquired businesses. The Company does, however, expect to incur similar types of business development expenses in the future, and this non-GAAP financial information should not be viewed as a promise or indication that these types of expenses will not recur.

February 17, 2015 Earnings Call Transcript

Feb. 17, 2015 8:00 AM ET

Executives

D. Ashley Lee - EVP, COO, CFO and Treasurer
James P. Mackin - President and CEO

Analysts

Thomas J. Gunderson - Piper Jaffrey
Jeffrey Cohen - Ladenburg Thalmann

Operator

Greetings, and welcome to CryoLife Fourth Quarter and Year End 2014 Financial Conference Call. At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. [Operator Instructions] As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host Ashley Lee, Chief Financial Officer. Thank you, you may begin.

[D. Ashley Lee](#) - EVP, COO, CFO and Treasurer

Hi, good morning. This is Ashley Lee. Before we begin, I'd like to make the following statements to comply with the Safe Harbor requirements of the Private Securities Litigation Reform Act of 1995. Comments made in this call that look forward in time involve risk and uncertainties and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements include statements made as to the company or management's intentions, hopes, beliefs, expectations or predictions of the future, including the guidance for 2015 that I will provide in a moment.

Additional information concerning risk and uncertainties that may impact these forward-looking statements is contained from time-to-time in the company's SEC filings, including the Risk Factor section of our 10-K for the year ended December 31, 2013, our 10-Qs for 2014, the 10-K for 2014, which we expect to file shortly and in the press release that was issued this morning.

Now, I'll turn the call over to Pat.

[James P. Mackin](#) - President and CEO

Thanks, Ashley, and good morning. Thank you for joining the call today. On this call this morning we will cover several items, I'll provide a high level summary of the fourth quarter and full year results. I'll review the key takeaways from my first hundred days on the job with CryoLife, and I will provide an update on our key initiatives for 2015. Following my comments, Ashley Lee, our CFO, will provide a detail review of our fourth quarter and full year 2014 results and 2015 guidance. We will then open the lines for a Q&A session.

We are pleased with our fourth quarter and full year results reported earlier this morning. Total revenues increased 5% in the fourth quarter to \$37.2 million; for the full year revenues increased 3% to \$144.6 million.

The positive trend in the fourth quarter was driven by a 12% increase in product revenues, including strong performance from BioGlue up 11% for the quarter; for HeRO up 10% for the quarter; and for PerClot up 52% for the quarter.

Our tissue processing revenues decreased 4% in the quarter, primarily due to the implementation of new and enhanced quality systems that reduced our production volumes of key tissue products. Ashley will provide further details about our Q4 and full year financial results during his remarks.

Exhibit 99.2

I joined CryoLife in September of last year, with a goal of leveraging my 20 years of experience in the cardiac and vascular markets to enhance the CryoLife business and strategy. During my first hundred days on the job, I dedicated a significant portion of my time to thoroughly learning and evaluating the state of the company, to better understand what we're doing well, where our biggest opportunities lie, and what we can do better.

This includes, field drives with 12 of our sales representatives, visiting more than 75 physician customers in the operating rooms and major medical meetings, attending investor conferences and meeting one-on-one with our top 50 employees of the company. Coming out of this evaluation, I was pleased with the positive feedback that I received from our customers on our team and our product portfolio.

Having been in this space for 20 years, I was still surprised to learn just how unique our tissue products are in the minds of our surgeons and the access it provides our sales force. My time spent with our sales representatives confirmed the high quality relationships and deep experience of our team.

I was also impressed with the engagement and quality interactions I had with top employees and the senior leadership team. Overall, I now have a better understanding of the company, my colleagues and the opportunities and challenges that face the business.

We are now working to develop a five year strategic plan that will move CryoLife toward becoming a growth company. In the meantime, we continue to execute on the key initiatives that I laid out on our Q3 conference call, with several opportunities for growth and value creation over the next few years.

The four key areas are, number one, improving our quality systems and resolving the FDA warning letter. Number two, building momentum for our three new product launches, which are ProCol, PhotoFix and PerClot Topical.

Number three, increasing our global production and distribution footprint; and number four, expanding indications of key products, particularly with the PerClot Surgical IDE clinical trial in the US, and BioGlue in Japan.

First, I will begin with an update on the quality systems, which has been my number one priority since I started with the company. I have personally led weekly top leadership meetings focused on addressing all issues raised by the FDA. In addition, expert consultants that are assisting us as we improve our quality systems and processes have augmented those efforts.

We've also made personnel changes to ensure that we have the right leadership in place to drive the necessary improvements in our quality systems. I am pleased to report that we made excellent progress and believe these changes put us in an improved position for the FDA's re-inspection which we expect to occur in the near future.

While we are pleased that we are making meaningful progress with our quality systems, the investments in our systems and processes are having a negative impact on our tissue processing business.

First, they are decreasing our production capacity as we implement these procedures, and second, they are decreasing our gross margins in the near and mid-term. We are identifying efficiency opportunities to return our margins to historical levels, and are working on other programs that should further enhance our margins.

However, we do not expect to realize these positive benefits from these initiatives until late in 2015 due to the delay of the cost going through the P&L that cycle through our inventory.

Second, on the new product front, the initial feedback is been excellent. We launched ProCol during the fourth quarter and achieved over a hundred thousand of revenue. For those who may not be aware, ProCol is complementary to the HeRO Graft and its treatment continuum of end-stage renal disease, after a failure of a synthetic graft.

There is one player in this market segment with a bovine carotid artery product. We believe that our ProCol product, which is comprised of bovine mesenteric vein that is processed using a proprietary method, offers a significant advantage over this competitive product.

Exhibit 99.2

Recent clinical trials have demonstrated that ProCol has higher patency rates at 2 years. ProCol was at 73% two year patency, while the competitor was at 64%. ProCol is a proven and effective technology, and we expect continued surgeon adoption and sales growth in the coming quarters.

In January, we launched the PhotoFix Bovine Pericardial Patch in the US and our team has already achieved key wins in the pediatric market, as well receiving favorable surgeon feedback.

We continue to believe that PhotoFix has the potential to become the product of choice for pediatric cardiac surgeons in the \$30 million plus market for biological patches used in cardiac and vascular surgical procedures.

Surgeon feedback during my site visits and at the FDS meeting have been extremely positive, as surgeons were excited about the availability of PhotoFix for their patients. Our teams are working to gain approval for PhotoFix in EU countries, and we are in the process of evaluating the pathway to use PhotoFix in the US for carotid endarterectomy procedures.

Our third recent new product is PerClot Topical, which we launched in late Q3. During the fourth quarter, we had significant trialing of the product and are currently working our way through the value analysis committees at the hospitals. The initial feedback on the product has been positive, and we continue to believe it is an excellent product for use in conjunction with FESS procedures. We are still early in the launch of PerClot Topical and continue to evaluate potential distribution options beyond the CryoLife sales force to better target ENT physicians.

Our third key initiative is our global product and distribution footprint. As we enter 2015, we plan to begin the process of the transitioning a major country in Europe from a distributor to a direct sales model.

As Ashley will outline, this will have a near term impact on our 2015 international revenue as our distributor works down their inventory before we launch direct operations in Q4. However, once we are direct, we will benefit from the transition to direct sales, pricing and margins with greater control over the sales strategy, initiatives for the team and further product launch synergies.

At this time, we have not identified or committed to transition any additional markets, but it is something we will consider on a case-by-case basis in the future if we believe there was a strategic benefit.

The fourth initiative of our strategy is expanding indications for products in our portfolio. Our biggest opportunity for mid-term growth is the expansion of the US indication for PerClot into general surgery, cardiac surgery and neurology surgery. We've already received approval from the FDA for our trial and plan on enrolling our first patient in the IDE in the first quarter of 2015. Given this first enrollment, it would position us for potential US FDA approval of PerClot surgical in the second half of 2017.

Our patent infringement lawsuit against C.R. Bard, which we discussed in the Q3 call, is continuing. A hearing on Bard's motion for a preliminary injunction to place in late January and we are currently awaiting our ruling on that motion. We remain confident about our legal position, both with respect to the preliminary injunction motion and the broader case.

Another indication expansion opportunity is BioGlue in Japan. The current indication for BioGlue in Japan is for aortic dissections, while the new indication expansion would broaden the use of BioGlue into all aortic, cardiac and large vessel procedures, essentially doubling the market opportunity. We are continuing to work through our distributor partner with MHLW in Japan and exploring approval in the first half of this year.

I will now turn the call over to Ashley for a detailed review of the fourth quarter, for full year results and 2015 financial guidance.

[D. Ashley Lee](#) - EVP, COO, CFO and Treasurer

Thanks, Pat. This morning we reported our results for the fourth quarter and full year of 2014. The following factors influenced our fourth quarter and full year performance.

Exhibit 99.2

Total company revenues increased 5% to \$37.2 million for the fourth quarter driven by 12% year-over-year revenue growth from our higher margin product segment. Our fourth quarter international revenues were \$9.2 million, up 20% compared to the fourth quarter of 2013.

For the full year, international revenues were \$34.1 million, an increase of 8% year-over-year. International revenues accounted for 25% of our business in the fourth quarter and 24% for the full year. The increase in international revenues was driven by strong sales of BioGlue, PerClot and HeRO.

Our domestic revenues increased 1% for the fourth quarter of 2014 and full year of 2014 compared to the prior year periods. The full year increases were driven primarily by an increase in BioGlue and HeRO revenues, partially offset by a decrease in tissue processing revenues.

Worldwide BioGlue revenues in the fourth quarter were up 11% year-over-year. International BioGlue revenues were up 19%, on an 18% increase in volume. Domestic BioGlue revenues were up 5%, on a 2% increase in volume. For the full year, 44% of our BioGlue revenues were generated in international markets, up from 43% in 2013.

HeRO Graft revenues increased 10% to \$1.8 million in the fourth quarter of 2014, compared to \$1.7 million in the fourth quarter of 2013. The increase was primarily driven by increased adoption of the HeRO Graft in international markets where we are still in the early stages of the product rollout.

PerClot revenues increased 52% for the fourth quarter of 2014 compared to the fourth quarter of 2013. The increase was due to continued growth in European markets where revenues increased 21% and the opening of new markets in South America and Asia Pacific. The quarter included a nominal amount of revenue from the US, where we launched PerClot Topical just before Labor Day.

Revenues from our TMR product line increased 1% for the fourth quarter of 2014 compared to 2013, which resulted primarily from a 17% increase in hand piece volume mostly offset by a decrease in laser console sales.

Tissue processing revenues were down 4% for the quarter compared to the prior year, while our tissue processing gross margin also decreased year-over-year for the fourth quarter. Tissue processing revenues were down due to the processing changes resulting from our efforts to enhance our quality systems. These changes have resulted in a temporary decrease in processing capacity and reduced availability of certain high demand tissues.

The net result is that our revenues decreased due to the lack of availability, and our costs have increased, which is reflected in our lower tissue processing margins in the fourth quarter of 2014 as compared to the fourth quarter of 2013. However, we have not seen any significant change in customer demand for our tissue products.

General, administrative, and marketing expenses were \$18.6 million for the quarter and \$73.8 million for the full year, up from \$16.7 million and \$68.1 million for the comparable periods in the prior year. The fourth quarter and full year increases were primarily due to the cost associated with executive management changes and our patent infringement lawsuit with Bard.

During the fourth quarter, we wrote-off our \$2 million note receivable from ValveXchange which was mostly offset by a reversal of a \$1.4 million liability for contingent consideration related to our Hemosphere acquisition, which we no longer expect to have to pay, and a gain of \$530,000 related to the sale of our investment in Medafor. All of these items are reflected in other income and expenses.

The carrying value of the investment in ValveXchange, the note receivable from ValveXchange and the contingent consideration payable to Hemosphere are now all zero.

We had a tax benefit for the fourth quarter of 2014, and our effective tax rate for the full year was 16%. The tax rate for the fourth quarter and full year benefited from reductions in uncertain tax positions, non-taxable gains related to the reversal of the contingent consideration liability, favorable deductions taken on the company's 2013 tax return and R&D tax credits recorded in the fourth quarter.

Exhibit 99.2

As of December 31, 2014, we had \$39.3 million in cash, cash equivalents and restricted cash and securities. We had several large outlays of cash during the year. These included \$5.6 million for share repurchases, \$3.3 million for dividends, \$2.1 million for PerClot inventory purchases pursuant to minimum purchase requirements, \$2.1 million related to business development activities, in particular for ProCol, and \$1 million for development milestone payments for PerClot. Despite these uses of cash, our balance sheet remains very strong. We continue to carry no debt and expect to continue to generate operating cash flow.

Now for our initial guidance for 2015. There were several items affecting 2015 guidance that are transient in nature and we believe will not recur in 2016, positioning the company for improved top and bottom line growth after 2015. I'll discuss each of these items in detail as I talk about the 2015 guidance.

We expect total revenues to be between \$151 million and \$153 million. This represents annual total revenue growth of 4% to 6%. We expect revenues from our higher margin product segment to increase in the mid-single digits on a percentage basis for the full year of 2015. This guidance includes the anticipated effects of the following factors.

One, we estimate that FX will adversely affect our top line in our product segment by approximately \$1 million. Two, as Pat mentioned, we plan to move to a direct sales model in a major European market beginning in October, which we believe will adversely affect our top line by approximately \$2 million in the first three quarters of 2015.

In 2014, we generated approximately \$2.8 million in sales to our distributor in this market. As our distributor sells down their existing inventory, we expect to have no sales in 2015 in that country until we go direct in October. However, for 2016 we expect that our new direct sales force will generate significantly more end-user revenue in 2016 than we did from our distributor model in 2014.

We expect tissue processing revenues to grow low single digits on a percentage basis for the full year of 2015 compared to 2014. This reflects continued customer demand for our tissue products, offset by lower processing capacity as we implement and refine new quality programs and processes.

We expect our gross margins in 2015 to be around 60% compared with 63% in 2014. There are a couple of factors contributing to the margin decrease for 2015. First, the cost associated with improving our quality systems, including consulting fees and process changes, have temporarily resulted in decreased capacity and other inefficiencies in our tissue processing operations.

As a result, we expect the gross margins in our tissue processing operations to be in the upper 30% range versus the mid 40% range historically. However, we've already identified many opportunities for improvement and expect that, barring any unforeseen issues, tissue processing gross margins could return to historical levels in 2016.

Second, recall that we have recently launched three new products. Both ProCol and PhotoFix, which we are currently distributing, have gross margins in the 50% range. However, we have the right to purchase both of these product lines in the next couple of years and bring the manufacturing to Atlanta. If and when we do so, we expect the gross margins on both of those businesses to be in the 70 plus percent range.

Additionally, we recently launched PerClot Topical here in the US. Unlike PerClot that we distribute in international markets which we source from our partner, PerClot Topical is manufactured by CryoLife in Atlanta. At low levels of production, our gross margins are close to zero.

However, once we receive PMA approval for the surgical version of PerClot in the US, we have the right to begin manufacturing all PerClot both US and international in our facilities in Atlanta, and we expect very attractive gross margins once we directly distribute these products. Considering all of that, we expect gross margins on our product business will be in the mid 70% range for the year.

We expect our G&A expenses to be affected by few items in 2015. We've included a significant amount in legal fees related to our patent case with Bard. If we are able to conclude the case in 2015, a significant amount of legal fees won't be recurring in 2016 and depending upon the timing of any resolution, the actual amount incurred in 2015 could change materially from our estimates.

Exhibit 99.2

Also, we have the cost of additional sales reps related to our direct sales strategy in a major European market beginning in October 2015. We think the annual cost of carrying this direct sales force is just over \$1 million on an annual basis. But I've talked a little already about the positive impact that we expect from going direct to have on our business beginning in 2016.

We expect research and development expenses to be between \$13 million and \$14 million in 2015, primarily reflecting our investment in our US clinical trial for PerClot which we estimate to be around \$5 million in 2015. Depending upon the rate of enrollment in the trial, a substantial portion of that \$5 million would not be repeated in 2016, although you should not assume that we won't be investing in another trial or other development activities in 2016.

The net effect of tissue processing, European distribution elimination, lower margin new products, litigation expenses, and in the PerClot IDE trial is that we expect earnings for the full year of 2015 to be anywhere from a loss of \$0.03 to breakeven. It is important to note that our guidance is not reflective of any activities related to business development, which are difficult to predict.

That concludes my comments, and now I'll turn it back over to Pat.

[James P. Mackin](#) - President and CEO

Thanks, Ashley. We will now open up the lines to take questions for the call.

Question-and-Answer Session

Operator

Thank you. [Operator Instructions] Thank you. Our first question comes from the line of Tom Gunderson with Piper Jaffrey. Please proceed with your question.

[Thomas J. Gunderson](#) - Piper Jaffrey

Hi. Good morning, guys. So, I was going to ask about gross margin, but you went through that in great detail, so I appreciate that. On the legal fees, sometimes I know you don't do it on a GAAP basis, but sometimes on the investment side we look at extraordinary legal fees as a one time. Can you put a dollar figure on that as far as incremental that you are expecting in 2015 for the Bard patent suit?

[James P. Mackin](#) - President and CEO

Yes. Hey Tom, this is Pat. Just a couple of things. One on the just a straight, pure straight cost year-over-year, the differences from last, because obviously that suit has been going on. The difference is about \$1.5 million from 2014 to 2015.

Obviously, as Ashley commented in his remarks, we're waiting for the feedback on this preliminary injunction hearing that happened on January 23rd. If we – we felt like we did very well. We'll wait to hear what the judge says.

But our goal is to come up with a reasonable settlement. We feel like we have strong case, but I don't think taking this thing all the way to the mat is the smart economic decision for either company.

[Thomas J. Gunderson](#) - Piper Jaffrey

Got it. Thanks. And then on the R&D front, it's a healthy increase in R&D, are you doing anything other than starting the PMA trial, which is obviously a big deal. But is there anything else in that R&D that starts to set us up for future growth of new products?

[James P. Mackin](#) - President and CEO

Exhibit 99.2

Yes. There are a couple of things, and clearly the PerClot trial is the big, is actually coming, it's about \$5 million investment this year and that's a big part of the jump. There are some other things that are embedded that we've talked about publicly that's more a background work.

So for example in one of my comments, we've got the new product PhotoFix which we're being, seeing really good progress as we launch that in pediatric surgery and adult surgery. But we think there is a big opportunity in carotid endarterectomies, and we'll be doing some animal clinical work which is necessary for the 510(k) extension.

The other thing is on the neuro front, we mentioned neuro in many of our investor presentations, where 15% of our revenue in Europe is in neurosurgery. We know we have a very strong product in that arena, some – already some very good data published on that. And we're going to be working with KOL physicians who have been using this product around the world, but also looking at doing some animal work to prepare for a potential IDE down the road.

So those are two things that are kind of – they are smaller, but they are clearly increases from last year where we really didn't spend any money on either of the carotid patch for endarterectomy or for animal trials in the neuro surgery space.

[Thomas J. Gunderson](#) - Piper Jaffrey

Got it. Thanks. And then my last question, Pat, is on your number one focus, and that is on the FDA. Last we talked was beginning of December, that's two and half months ago, almost three. Is there any granularity, any color you can give us on the discussions that have been going on with the FDA in the last three months?

[James P. Mackin](#) - President and CEO

Yes. I can give you some historical perspective from prior jobs. I mean, the fact of the matter is you really don't have good visibility to when they are going to come. And the discussions, we've had a couple of discussions as I mentioned on my last call, I met with a district officer September 29th. We had – I think we've had one phone call with them since, and it's really kind of up to them when they come back.

I can tell you that they – one of the things they told us is they would not let the re-inspection, which we're expecting kind of anytime now, to lapse more than a year from the previous inspection and just to remind people the last time they were in was kind of February 20th to March 20th. So I think - we're planning on a re-inspection here in the next 30 days.

I would also say just from a progress standpoint, I mentioned this in my comments, but this has really been a massive effort for the company. Myself personally, the entire executive team, we've had, and this is one of the reasons you're seeing the cost on the tissue jumping on us is the kind of the total overhaul of the quality systems. We've seen massive improvements and our CAPAs have been reduced by 65%; our backlog complaints have been reduced by 65%; our NCRs have been reduced by 65%.

So we made great progress. We're obviously waiting for the FDA to come in and we're going to continue to work extremely hard to prepare for that. But ultimately they are the ones who decide when they come back.

[Thomas J. Gunderson](#) - Piper Jaffrey

Got it. That's it from me. Thanks.

[James P. Mackin](#) - President and CEO

Thanks, Tom.

Operator

Exhibit 99.2

[Operator Instructions] Our next question comes from the line of Jeffrey Cohen with Ladenburg Thalmann. Please proceed with your question.

[Jeffrey Cohen](#) - Ladenburg Thalmann

Good morning, Pat and Ashley. How are you?

[James P. Mackin](#) - President and CEO

Good morning, Jeff.

[D. Ashley Lee](#) - EVP, COO, CFO and Treasurer

Good morning, Jeff.

[Jeffrey Cohen](#) - Ladenburg Thalmann

Could you talk a little bit about the transition with a specific European country that you are talking about? So what you had said was that \$2 million of their inventory would be pared down and that you would be offset and direct during this third quarter. Could you talk also about the size of the team that you have anticipated for direct sales?

[James P. Mackin](#) - President and CEO

Yes. So I think you guys have all experienced this before with other companies that have gone direct. And typically what you see is, if you look at last year actually we did roughly \$2.8 million in a specific country through using a distributor, and our plans are to go direct. But before you could actually benefit from the direct revenues you basically have to burn down the existing inventory that your distribution holds, and that's a very common practice.

Unfortunately we had a little more inventory than we would have liked, and we're not going to be able to go live until October 1st, but when we do go live October 1st, if you go to – kind of jump forward, as Ashley said, we get a real big pop on the revenue and the margin side. The team that we're taking about is in the five people range. We've already been in discussions, and it's a very amicable transition.

So I think that things are progressing well, and it's a real opportunity for the company. We've seen other markets when we've gone direct, not only do you get the bump from distributor revenue and distributor margins to direct revenues and direct margins, but you also see just an added bump in the productivity and the focus in the other things we could bring through those channels. And it's a significant country in Europe, and I think strategically for the company it's a very good move for the long-term.

I think last thing I would say is, if you look over a 5 year period, it is a significant improvement in revenue, profit, cash flow, kind of on every metric with a very strong IRR.

[Jeffrey Cohen](#) - Ladenburg Thalmann

Okay. Got it. And Ashley you made a little bit of commentary as far as FX effect, talking about that \$1 million top line effect for 2015, did you see any effect during the fourth quarter of 2014?

[D. Ashley Lee](#) - EVP, COO, CFO and Treasurer

We did. We actually had about a couple hundred thousand dollar negative effect on the top line related to FX.

[Jeffrey Cohen](#) - Ladenburg Thalmann

Exhibit 99.2

Okay. All right. Just comment on any measures in place to mitigate any of the effect on 2015 and or 2016?

[D. Ashley Lee](#) - EVP, COO, CFO and Treasurer

No, we don't specifically hedge to protect our top line. We kind of have a natural hedge and the fact that that we have 25 people on the ground over in Europe. And so the expenses that we pay, which are predominantly in pounds and euro, kind of give us a natural hedge to our bottom line. But again, we don't do anything specifically to hedge our top line exposure.

[Jeffrey Cohen](#) - Ladenburg Thalmann

Okay. And lastly, if I thought you could discuss a little bit about acquisitions in some of the products that you're seeing out there that the company may have interest in?

[James P. Mackin](#) - President and CEO

I've commented Jeffrey, as we met – we've been publicly making comments about the kind of the fourth strategic vector of M&A. One of the things this company has done very well is the financial discipline. Ashley commented earlier that we're sitting around \$39 million of cash, no debt and we expect a kind of transient issue in 2015 to move back to see a pretty good profitability going forward.

Given all that, we are well poised to acquire and as I've said, we have these two really nice chassis; we have a cardiac surgery sale organization in entire business and a vascular surgery business. There are a number of opportunities.

Every time I go to a new investor meeting or a new physician meeting, I am coming back with more and more opportunities, and in each one of those categories, and I am not – what I am not referring to at least in the early days of what we're looking at, this is not something where we're going to do a deal and have to – with no revenue, no profit, and we're going to have to invest a bunch of money and then three years later you guys may see something. I am talking about buying existing businesses, with existing revenue, existing profit and existing people that would be very synergistic with the company.

And again, I think there is a tremendous amount of opportunities out there. More than I actually thought there would be. Because as I – I've been in the cardiology field for 20 years, but I've been on cardiac surgery for probably 12, and I've been on a vascular surgery for probably 8 to 10. I've been kind of blown away by the amount of opportunities kind of which we fit with us that are in our kind of real house from an acquisition stand point. It's very exciting and again, I think that I can't really get more specific than that for obvious reasons. But we're very excited about that fourth vector of M&A.

[Jeffrey Cohen](#) - Ladenburg Thalmann

Appreciate it. Thanks for the color. That's it from me.

Operator

Thank you. It appears we have no further questions at this time. I would now like to turn the floor back over to management for closing comments.

[James P. Mackin](#) - President and CEO

Well, I appreciate everybody dialing in this morning. And we are – we try to put together our plan for 2015 that recognizes some of the challenges and opportunities that we talked about in the transcript. And a lot of these kind of headwinds in 2015 are very transient. And if I go back to the list, on the – on going direct in one of the European countries, we're going to take a little bit of hit on the revenue line in 2015, but in 2016 its going to come back stronger than ever with a direct strategic operation there, which is going to be good for us in the short term and then back to the M&A question, if we do any deals on that front it's just going to accelerate that.

Exhibit 99.2

The tissue COGS, we're disappointed where the tissue COGS, I'll be honest, and we – but we've said at the very beginning that quality is number one here, and we've had to put some cost in here and as those costs flow through the P&L you're going to see them in the margins.

But what I can tell you that is that once we get out of this FDA, which I am hoping to do very quickly here, as they will back into the next 30 to 40 days, I am going to be shifting all of our efforts to this tissue cost and tissue supply. Our goal is to get our tissue cost back to where they were or even better by the end of this year.

The other thing is there is huge demand for this tissue, folks. We have millions of dollars on backorder. So it's not like there is some, the revenue short fall on the tissue side is a lack of customer demand, it's actually the opposite. We've got more demand than we can handle and we need to do a better job of accessing that.

Ashley commented on the new product margin. We're very excited about ProCol and PhotoFix, and those margins are not where our normal product margins are; those are in the 50s because of the distributed products versus where we are in the 70s on our direct products. But we have the ability to take out both of those relationships and go direct, if you will, and manufacture those ourselves and take the margins up to our historical levels in the next 24 months.

We talked about the Bard litigation. We obviously feel good about that case and we'll see what the judge says, and we'll work to come up with a good solution there. But that's a transient item. And the PerClot trial is a huge opportunity for the country – for the company and it's a \$5 million investment this year, and it tails off in Q1 of next year and then kind of goes away. I just spent the weekend with a bunch of cardiac surgeons, and they were kind of blown away by the products.

So, lots of opportunities here, but we're trying to be transparent and realistic about 2015 and kind of its all out there for you, and we're very excited about where we'd be kind of this time next year. So, we appreciate you calling in and look forward to keeping you updated throughout the year. Thanks very much.

Operator

Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.