



CryoLife Reports 13% Revenue Growth for Third Quarter 2012

October 30, 2012

Increases Full Year 2012 Revenue and EPS Guidance

Updated dial-in information for the 10 a.m. teleconference is contained in the press release below

Third Quarter Highlights:

- Total revenues grew 13% year-over-year to \$33.4 million
- Product revenues grew 13% year-over-year to \$16.9 million
- Tissue processing revenues grew 12% year-over-year to \$16.4 million
 - EPS of \$0.06, or \$0.08 on a non-GAAP basis
 - Generated \$6.1 million in cash flow from operations
 - Initiated \$0.025 per share quarterly dividend

ATLANTA, Oct. 30, 2012 /PRNewswire/ -- **CryoLife, Inc.** (NYSE: CRY), a leading tissue processing and medical device company focused on cardiac and vascular surgery, announced today its results for the third quarter and first nine months of 2012. Revenues for the third quarter of 2012 increased 13 percent to a record \$33.4 million compared to \$29.7 million for the third quarter of 2011. Revenues for the first nine months of 2012 increased 11 percent to a record \$98.9 million compared to \$89.2 million for the first nine months of 2011.

Steven G. Anderson, president and chief executive officer, said, "We achieved another quarter of double-digit revenue growth which, coupled with our improving operating structure, contributed to strong cash flow generation and solid bottom line results. During the quarter we initiated a cash dividend, demonstrating the consistency of our cash flow and our commitment to increasing shareholder value. We made good progress in the integration of the Hemosphere acquisition, and we continue to see a significant opportunity to grow this business as part of CryoLife. In addition, our tissue processing segment results came in ahead of our expectations. Accordingly, we have raised our full year revenue and EPS guidance for the second time this year, with top line growth now expected to be 10 to 11 percent and EPS expected to be in the range of \$0.25 to \$0.27 cents."

Net income for the third quarter of 2012 was \$1.5 million, or \$0.06 per basic and fully diluted common share, compared to net income of \$2.0 million, or \$0.07 per basic and fully diluted common share, for the third quarter of 2011. Net income for the third quarter of 2012 included \$796,000 in business development and integration charges primarily related to the acquisition of Hemosphere and \$130,000 related to litigation expense. Excluding these charges, proforma non-GAAP earnings per share would have been \$0.08 in the third quarter of 2012. Net income for the third quarter of 2011 included \$1.1 million in costs related to business development and integration, and \$881,000 related to litigation expenses. Excluding these charges, proforma non-GAAP earnings per share would have been \$0.09 in the third quarter of 2011.

Net income for the first nine months of 2012 was \$5.9 million, or \$0.21 per basic and fully diluted common share, compared to net income of \$5.5 million, or \$0.20 per basic and \$0.19 per fully diluted common share, for the first nine months of 2011. Net income for the first nine months of 2012 included a pretax benefit of \$4.7 million related to the settlement of the litigation with Medafor, pretax charges of \$4.1 million related to the settlement of the litigation with CardioFocus, \$1.9 million in business development and integration charges primarily related to the acquisition of Hemosphere, and \$3.7 million in litigation expenses offset by \$3.4 million in reimbursement of certain litigation expenses from insurance carriers. Excluding these charges and benefits, proforma non-GAAP earnings per share would have been \$0.25 in the first nine months of 2012. Net income for the first nine months of 2011 included \$4.1 million in costs related to business development and integration, and \$1.0 million for litigation expenses net of insurance reimbursements. Excluding these charges, proforma non-GAAP earnings per share would have been \$0.30 in the first nine months of 2011.

Product segment revenues were \$16.9 million for the third quarter of 2012, up 13 percent from \$14.9 million in the third quarter of 2011. Product segment revenues were \$50.0 million for the first nine months of 2012, up 14 percent from \$43.9 million in the first nine months of 2011.

Surgical sealant and hemostat revenues, which consisted primarily of sales of BioGlue[®] and PerClot[®] in 2012, were \$13.5 million for the third quarter of 2012 compared to \$12.8 million for the third quarter of 2011, an increase of 5 percent. The increase in surgical sealant and hemostat revenues was primarily due to an increase in BioGlue shipments into international markets, largely Japan.

Surgical sealant and hemostat revenues were \$41.9 million for the first nine months of 2012 compared to \$40.6 million for the first nine months of 2011, an increase of 3 percent. The increase in surgical sealant and hemostat revenues was primarily due to an increase in BioGlue shipments into international markets, largely Japan, partially offset by the lack of HemoStase revenues in the first nine months of 2012. The Company discontinued U.S. and international sales of HemoStase at the end of the first quarter of 2011.

Revascularization technologies revenues were \$2.1 million for the third quarters of 2012 and 2011. Revascularization technologies revenues were \$6.1 million for the first nine months of 2012 compared to \$3.3 million in the first nine months of 2011. The increase in revascularization technologies is a result of the Company's acquisition of Cardiogenesis in May 2011.

HeRO[®] Graft revenues were \$1.4 million for the third quarter of 2012 and \$2.0 million for the first nine months of 2012 as a result of the Company's acquisition of Hemosphere in May 2012.

Preservation services revenues were \$16.4 million for the third quarter of 2012 compared to \$14.7 million for the third quarter of 2011, an increase of 12 percent. Cardiac preservation services revenues increased 22 percent for the third quarter of 2012 primarily due to an increase in shipments of cardiac tissues. Vascular preservation service revenues increased 3 percent for the third quarter of 2012 due to an increase in shipments of vascular tissues.

Preservation services revenues were \$48.4 million for the first nine months of 2012 compared to \$45.0 million in the first nine months of 2011, an

increase of 7 percent. Cardiac preservation services revenues increased 13 percent for the first nine months of 2012 primarily due to an increase in shipments of cardiac tissues. Vascular preservation service revenues increased 3 percent for the first nine months of 2012 due to an increase in shipments of vascular tissues.

Total gross margins were 64 percent in the third quarters of 2012 and 2011. Preservation services gross margins were 45 percent in the third quarter of 2012 and 43 percent in the third quarter of 2011. Product gross margins were 82 percent and 84 percent for the third quarters of 2012 and 2011, respectively.

Total gross margins increased to 64 percent in the first nine months of 2012, up from 63 percent in the first nine months of 2011, driven by higher gross margins from the Company's existing tissues business, an increase in the mix of higher margin products partially resulting from the acquisition of the Cardiogenesis and Hemosphere product lines. Preservation services gross margins were 45 percent and 43 percent for the first nine months of 2012 and 2011, respectively. Product gross margins were 83 percent and 84 percent for the first nine months of 2012 and 2011, respectively.

General, administrative, and marketing expenses for the third quarter of 2012 were \$16.5 million compared to \$14.7 million for the third quarter of 2011. General, administrative, and marketing expenses for the third quarter of 2012 increased compared to 2011 primarily due to an increase in marketing expenses, including costs of the Company's expanded sales staff and increases in spending on advertising, partially offset by a decrease in litigation expense. General, administrative, and marketing expenses for the third quarter of 2012 and 2011 included approximately \$796,000 and \$1.1 million, respectively, in business development and integration expenses.

General, administrative, and marketing expenses for the first nine months of 2012 were \$48.4 million compared to \$42.7 million for the first nine months of 2011. General, administrative, and marketing expenses for the first nine months of 2012 increased compared to 2011 due to the cumulative effect of the following: the settlement of the litigation with CardioFocus, an increase in marketing expenses, including costs of the Company's expanded sales staff, increases in spending on advertising, and an increase in litigation expenses, partially offset by a benefit from the settlement of the litigation with Medafor and the reimbursement of certain litigation expenses from insurance carriers. General, administrative, and marketing expenses for the first nine months of 2012 and 2011 included approximately \$1.9 million and \$4.1 million, respectively, in business development and integration expenses.

Research and development expenses were \$1.8 million and \$1.7 million for the third quarters of 2012 and 2011, respectively. Research and development expenses were \$5.2 million and \$5.1 million for the first nine months of 2012 and 2011, respectively. Research and development spending in the third quarter and first nine months of 2012 was focused on PerClot, HeRO graft, SynerGraft[®] tissues and products, BioFoam[™] Surgical Matrix, and revascularization technologies.

During the third quarter of 2012, the Company purchased 14,000 shares of the Company's common stock at an average price of \$5.44, resulting in aggregate purchases of \$74,000. During the first nine months of 2012, the Company purchased 639,000 shares of the Company's common stock at an average price of \$5.15, resulting in aggregate purchases of \$3.3 million.

As of September 30, 2012, the Company had \$13.1 million in cash, cash equivalents, and restricted cash and securities, compared to \$27.0 million at December 31, 2011. Of this \$13.1 million in cash, cash equivalents, and restricted cash and securities, \$740,000 was received from the U.S. Department of Defense as advance funding for the development of BioFoam protein hydrogel technology, and \$5.0 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 \$6.1 million for the third quarter of 2012 and \$5.8 million for the third quarter of 2011.

2012 Financial Guidance

The Company is updating its guidance for the full year of 2012. The Company expects total revenues for the full year of 2012 to be between \$131.0 million and \$133.0 million, which include revenues of approximately \$500,000 related to the use of funds received from the U.S. Department of Defense in connection with the development of BioFoam. This represents annual total revenue growth of 10 percent to 11 percent. This compares with prior full year 2012 revenue guidance of \$129.0 million to \$133.0 million, which represented growth of 8 percent to 11 percent.

The Company expects tissue processing revenues to increase in mid-single digits on a percentage basis for the full year of 2012 compared to 2011. Revenues from the Company's higher margin product segment are expected to grow between 12 percent and 15 percent for the full year of 2012. This includes expectations for BioGlue and BioFoam revenues to increase in the mid-single digits on a percentage basis in 2012 compared to 2011, and PerClot revenues to be between \$2.7 million and \$3.0 million. The Company expects revenues from revascularization technologies to be between \$8.0 million and \$8.5 million in 2012. The Company expects HeRO Graft revenues to be between \$3.2 million and \$3.6 million in 2012.

The Company expects general, administrative and marketing expenses for the full year of 2012 to be between \$65.0 million and \$66.0 million, which includes \$2.5 million of integration costs resulting from the acquisition of Hemosphere in May 2012. Research and development expenses are expected to be between \$7.0 million and \$8.0 million in 2012 as a result of the Company's investments in its U.S. clinical trial for PerClot, and other research and development activities.

The Company expects earnings per share of between \$0.25 and \$0.27 in 2012. This compares with prior full year 2012 GAAP earnings per share guidance of \$0.20 to \$0.23. The Company expects to incur an additional \$600,000 in transaction and integration charges in the fourth quarter of 2012. The Company's earnings per share guidance excludes expenses related to additional business development which cannot currently be estimated.

The Company expects the effective income tax rate for the full year of 2012 to be in the upper thirty to forty percent range.

The Company's financial guidance for the full year of fiscal 2012 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 10:00 a.m. Eastern Time to discuss the results followed by a question and answer session hosted by Mr. Anderson.

To listen to the live teleconference, please dial 412-902-6510 a few minutes prior to 10:00 a.m. A replay of the teleconference will be available

October 30 through November 6 and can be accessed by calling (toll free) 877-344-7529 or 412-317-0088. The conference number for the replay is 401868.

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

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiac and vascular surgeries throughout the U.S., certain countries in Europe, and Canada. 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 congenital heart defects. CryoLife's BioGlue[®] Surgical Adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. BioGlue is also CE marked in the European Community for use in soft tissue repair and is approved in Japan for use in the repair of aortic dissections. Additional marketing approvals for BioGlue have been granted in several other countries throughout the world. CryoLife, through its subsidiary Cardiogenesis Corporation, specializes in the treatment of coronary artery disease for severe angina using a laser console system and single use, fiber-optic handpieces to perform a surgical procedure known as Transmyocardial Revascularization (TMR). In addition, CryoLife's subsidiary Hemosphere, Inc. markets the HeRO[®] Graft, which is a solution for end-stage renal disease in certain hemodialysis patients. CryoLife distributes PerClot[®], an absorbable powder hemostat, in the European Community and other select international countries. CryoLife's BioFoam[™] Surgical Matrix is CE marked in the European Community for use as an adjunct in the sealing of abdominal parenchymal tissues (liver and spleen) when cessation of bleeding by ligation or other conventional methods is ineffective or impractical.

For additional information about CryoLife, visit CryoLife's website, 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 the opportunity to grow the aspects of our business related to the Hemosphere acquisition. These statements also include our anticipated performance and expected effective income tax rate for the full year of fiscal 2012. The risks and uncertainties impacting these statements include that market opportunities and potential growth related to any of our products, including HeRO Graft and business related to our Hemosphere acquisition, are subject to factors beyond our control, including general economic conditions, physician and patient acceptance of our products, our potential inability to maintain reimbursement approvals and maintain and expand reimbursement rates, and regulatory approval. Competing products may be introduced into the market that may materially impact sales growth for our products. We may be unsuccessful in our efforts to leverage our existing sales force and cross-sell our products, and integration efforts may be more costly and take longer than currently anticipated. Third-party intellectual property rights may limit the development and protection of intellectual property acquired from Hemosphere, which could adversely affect its value to us. Hemosphere may have liability for actions that occurred prior to our acquisition of Hemosphere, which could adversely affect us, and Hemosphere may have had undisclosed weaknesses in its internal controls, which could impact our internal control over financial reporting or adversely impact the value of the Hemosphere acquisition to us, which could have a material and adverse effect on us. Our anticipated performance and expected effective income tax rate for the full year of fiscal 2012 is subject to the general risks associated with our business, including that we are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product, including that the continued introduction into the market of products that compete with BioGlue could have an irreversible adverse impact on our sales of BioGlue, our BioGlue patent has expired in the U.S., and will expire in the rest of the world in mid-2013, our tissues and products allegedly have caused, and may in the future cause, injury to patients, and we have been, and may in the future be, exposed to tissue processing and product liability claims, including one currently outstanding product liability lawsuit, and additional regulatory scrutiny as a result, our investment in Medafor has been impaired due to Medafor's termination of our exclusive distribution agreement with Medafor and our investment could be further impaired by risks associated with Medafor's business or by Medafor's actions, which could have a material adverse impact on our financial condition and profitability, we will not fully realize the benefit of our investment in our distribution and license and manufacturing agreements with Starch Medical, Inc. unless we are able to obtain FDA approval for PerClot in the U.S., which will require an additional commitment of funds, the FDA rejected our initial IDE application for PerClot and we are working to address its concerns, but there is no guarantee that we can do so on a timely or cost efficient basis, if at all, Medafor sent us a letter stating that PerClot, when introduced in the U.S., will infringe their U.S. patent when used in accordance with the method published in our literature and with the instructions for use, and we may be unable to profitably market and sell PerClot in the U.S. if we are found to infringe the patent rights of Medafor or another third party or are unable to cost effectively defend a patent infringement lawsuit, the receipt of impaired materials or supplies that do not meet our standards or the recall of materials or supplies by our vendors or suppliers could have a material adverse impact on our revenues, financial condition, profitability, and cash flows, our sales are impacted by challenging domestic and international economic conditions and their constraining effect on hospital budgets and demand for our tissues and products could decrease in the future, which could have a material adverse impact on our business, healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse impact on us, the loss of any of our sole-source suppliers could have a material adverse impact on our revenues, financial condition, profitability, and cash flows, we may be unsuccessful in our efforts to market and sell PerClot in the U.S. and internationally, factors that have negatively impacted revascularization technologies revenues in the first nine months of 2012 may continue for the remainder of 2012, we have inherited risks and uncertainties related to Cardiogenesis' business, we may expand through acquisitions, or licenses of, or investments in, other companies or technologies, which may result in additional dilution to our stockholders and consume resources that may be necessary to sustain our business, we may not realize the anticipated benefits from acquisitions and we may find it difficult to integrate recent or potential future acquisitions of technology or business combinations, which could disrupt our business, dilute stockholder value, and adversely impact our operating results, we are subject to stringent domestic and foreign regulation which may impede the approval process of our tissues and products, hinder our development activities and manufacturing processes, and, in some cases, result in the recall or seizure of previously cleared or approved tissues and products, our tissues and products are subject to regulatory scrutiny and the FDA or other regulatory body could revoke our registration, require us to recall our tissues and products, change our processes or procedures, or take other enforcement actions, we received a Form 483 Notice of Observations from the FDA related to our processing, preservation, and distribution of human tissue and the manufacture of our medical devices, and it is possible that we may not be able to address the observations in a manner satisfactory to the FDA, we may not be successful in obtaining necessary clinical results and regulatory approvals for services and products in development, and our new services and products may not achieve market acceptance, uncertainties related to patents and other proprietary technology rights may adversely impact the value of our intellectual property or may result in our payment of significant monetary damages and/or

royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary technology rights against others, intense competition may impact our ability to operate profitably, if we are not successful in expanding our business activities in international markets, we may be unable to increase our revenues, we are dependent on the availability of sufficient quantities of tissue from human donors, key growth strategies may not generate the anticipated benefits, investments in new technologies and acquisitions of products or distribution rights may not be successful, regulatory action outside of the U.S. has affected our business in the past and may affect our business in the future, consolidation in the healthcare industry could continue to result in demands for price concessions, limits on the use of our tissues and products, and limitations on our ability to sell to certain of our significant market segments, extensive government regulations may adversely impact our ability to develop and market services and products, the success of many of our tissues and products depends upon strong relationships with physicians, our existing insurance policies may not be sufficient to cover our actual claims liability, we may be unable to obtain adequate insurance at a reasonable cost, if at all, we are not insured against all potential losses, and natural disasters or other catastrophes could adversely impact our business, financial condition, and profitability, our credit facility, which expires in October of 2014, limits our ability to pursue significant acquisitions, our ability to borrow under our credit facility may be limited, continued fluctuation of foreign currencies relative to the U.S. dollar could materially adversely impact our business, rapid technological change could cause our services and products to become obsolete, our CryoValve SGPV post-clearance study may not provide expected results, our investment in ValveXchange, Inc. has been impaired and may, in the future, become further impaired, which could have a material adverse impact on our earnings, and we are dependent on our key personnel. 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, 2011, our Form 10-Q for the quarter ended June 30, 2012 and our Form 10-Q to be filed for the quarter ended September 30, 2012. CryoLife does not undertake to update its forward-looking statements.

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CRYOLIFE, INC. AND SUBSIDIARIES

Financial Highlights

(In thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
	(Unaudited)		(Unaudited)	
Revenues:				
Preservation services	\$ 16,399	\$ 14,656	\$ 48,371	\$ 45,018
Products	16,893	14,923	50,043	43,932
Other	<u>137</u>	<u>75</u>	<u>504</u>	<u>279</u>
Total revenues	<u>33,429</u>	<u>29,654</u>	<u>98,918</u>	<u>89,229</u>
Cost of preservation services and products:				
Preservation services	9,005	8,349	26,645	25,709
Products	<u>3,114</u>	<u>2,393</u>	<u>8,300</u>	<u>7,051</u>
Total cost of preservation services and products	<u>12,119</u>	<u>10,742</u>	<u>34,945</u>	<u>32,760</u>
Gross margin	<u>21,310</u>	<u>18,912</u>	<u>63,973</u>	<u>56,469</u>
Operating expenses:				
General, administrative, and marketing	16,533	14,726	48,374	42,676
Research and development	<u>1,829</u>	<u>1,690</u>	<u>5,192</u>	<u>5,099</u>
Total operating expenses	<u>18,362</u>	<u>16,416</u>	<u>53,566</u>	<u>47,775</u>
Operating income	<u>2,948</u>	<u>2,496</u>	<u>10,407</u>	<u>8,694</u>
Interest expense	42	49	159	116
Interest income	(1)	(1)	(4)	(13)
Other expense (income), net	<u>283</u>	<u>159</u>	<u>442</u>	<u>(12)</u>
Income before income taxes	<u>2,624</u>	<u>2,289</u>	<u>9,810</u>	<u>8,603</u>
Income tax expense	<u>1,086</u>	<u>270</u>	<u>3,947</u>	<u>3,098</u>
Net income	<u>\$ 1,538</u>	<u>\$ 2,019</u>	<u>\$ 5,863</u>	<u>\$ 5,505</u>
Income per common share:				
Basic	<u>\$ 0.06</u>	<u>\$ 0.07</u>	<u>\$ 0.21</u>	<u>\$ 0.20</u>
Diluted	<u>\$ 0.06</u>	<u>\$ 0.07</u>	<u>\$ 0.21</u>	<u>\$ 0.19</u>

Reconciliation excluding items:

Income before income taxes, GAAP	\$ 2,624	\$ 2,289	\$ 9,810	\$ 8,603
Excluding:				
Benefit related to settlement of the litigation with Medafor	--	--	(4,672)	--
Charge related to settlement of the litigation with CardioFocus	--	--	4,050	--
Litigation expenses	117	975	3,724	1,793
Reimbursement of certain litigation expenses from insurance carriers	13	(94)	(3,396)	(757)
Charges for business development and integration	<u>796</u>	<u>1,125</u>	<u>1,899</u>	<u>4,066</u>
Adjusted income before income taxes, non-GAAP	3,550	4,295	11,415	13,705
Income tax expense calculated at 2012 effective tax rate of 38% for the three and nine months	<u>1,349</u>	<u>1,632</u>	<u>4,338</u>	<u>5,208</u>
Adjusted net income, non-GAAP	\$ 2,201	\$ 2,663	\$ 7,077	\$ 8,497
Adjusted net income, non-GAAP allocated to participating securities – diluted	<u>51</u>	<u>57</u>	<u>158</u>	<u>167</u>
Adjusted net income, non-GAAP applicable to common shareholders – diluted	\$ 2,150	\$ 2,606	\$ 6,919	\$ 8,330
Diluted adjusted income per common share, non-GAAP:	\$ 0.08	\$ 0.09	\$ 0.25	\$ 0.30
Diluted-weighted average common shares outstanding:	27,210	27,850	27,329	27,765

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 exclude litigation expenses and benefits, insurance reimbursements for litigation, and expenses for business development activities, including the Company's transaction and integration costs primarily associated with the acquisitions of Hemosphere and Cardiogenesis. The Company believes that this non-GAAP presentation provides useful information to investors regarding the operating expense structure of the Company's existing and recently acquired operations without regard to recently settled litigation, its ongoing efforts to acquire additional complementary products and businesses, and the transaction costs incurred in connection with recently acquired businesses. The Company does, however, expect to incur similar types of business development expenses and may incur significant litigation 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.

SOURCE CryoLife, Inc.