CryoLife Submits Corrective Action Plan to FDA

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ATLANTA, Oct. 8 /PRNewswire-FirstCall/ -- CryoLife Inc. (NYSE: CRY) has submitted its corrective action plan to the U.S. Food and Drug Administration as outlined in the September 6, 2002 Interim Agreement with the FDA. The action plan describes proposed steps to validate CryoLife's tissue processing procedures.

"We are processing tissue under the terms of the Interim Agreement and we are on schedule with the FDA," said CryoLife's Chief Financial Officer, D. Ashley Lee. "We will continue to cooperate with regulatory authorities with the goal of reaching a full resolution."

CryoLife continues to process life- and limb-saving cardiac and vascular tissues under the Interim Agreement. Heart valves were not affected by the original FDA Order and have not been subject to the Recall Order or the Interim Agreement.

More than 90,000 CryoLife processed tissues have been successfully used since 1984. CryoLife cardiac tissues are often used to help rebuild children's hearts. Unlike mechanical valves, CryoLife processed tissues do not require the use of blood thinners post-operatively. Consequently, they offer women an alternative to synthetic valves allowing them to bear children. CryoLife's cardiovascular tissues save limbs from amputation and are a preferred choice, for example, when synthetic veins fail in diabetic patients.

About CryoLife

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in surgeries throughout the United States and Canada. The Company's BioGlue(R) surgical adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels and is CE marked in the European Community and approved in Canada and Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) heart valve and the SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacement, respectively, and the CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are CE marked for distribution within the European Community.

Statements made in this press release 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. These future events may not occur as and when expected, if at all, and, together with the Company business, are subject to various risks and uncertainties. Such risks and uncertainties include the risk that the interim procedures agreed upon with the FDA will prove insufficient, that the corrective action plan submitted by CryoLife will not prove satisfactory to the FDA, CryoLife's dependence on cryopreservation of human tissue, the possibility that anticipated decreases in the Company's revenues and working capital may be severe, the possibility that SynerGraft-treated heart valves will not have the expected long-term functionality, repopulate with human recipient cells or reduce immune response, that future clinical SynerGraft or BioGlue test results will prove less encouraging than current results, the possibility that the SEC investigation could be concluded in a manner adverse to the Company, that SynerGraft, BioGlue, or other regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained when expected, if at all, that surgeons will not continue to accept and use tissues preserved by the Company or its other products such as BioGlue, competition from other wound closure products, that CryoLife will be unable to find an investor in its proprietary light activated drug delivery systems or that such systems will prove ineffective in oncology applications, that pending government and legal proceedings against CryoLife will not be resolved in its favor, that the FDA may require the recall of heart valve tissue processed by CryoLife, that CryoLife may be forced to discontinue its tissue processing business due to the FDA Order or subsequent FDA actions, the possibility of rapid technological change, uncertainties regarding products in development, uncertainties related to patents and protection of proprietary technology, changes in economic cycles, competition from other companies, changes in laws and governmental regulations applicable to CryoLife and other risk factors detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-Q filing for the quarter ended June 30, 2002, and the Company's other SEC filings.

For additional information about the company, visit CryoLife's web site: http://www.cryolife.com .

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