



CryoLife, Inc. Management Reviewed Third Quarter Operating Events In Teleconference Call

October 30, 2002

ATLANTA, Oct 30, 2002 /PRNewswire-FirstCall via COMTEX/ -- CryoLife, Inc. (NYSE: CRY), a leading tissue processing and medical device company, commented on operational events during its teleconference call following the release of its financial results for the third quarter and nine months ended September 30, 2002. The following provides highlights from the call:

Regulatory Affairs Update

CryoLife is cooperating fully with the FDA to reach a full resolution on all outstanding issues. At this time, CryoLife is proceeding with the validations of its processes as described in its corrective action plan, submitted early this month, in anticipation of the planned re-inspection of its facility by the FDA.

BioGlue(R) Surgical Adhesive Update

CryoLife expects to file an IDE for BioGlue's use in sealing dura mater for brain and spinal surgery during the second quarter of 2003, with a Pre-Market Approval ("PMA") expected in 2006. The Company estimates that the U.S. market for a dura mater sealant is about \$35 million annually.

CryoLife is also continuing its development of a spinal disc nucleus replacement using BioGlue. The IDE for this product is scheduled to be filed with the FDA during the second quarter of 2003, with a PMA approval anticipated in 2007. According to industry estimates the U.S. market for this product is estimated at \$158 million annually.

During the second quarter of 2003 CryoLife plans to file an IDE supplement for BioGlue's use as a fixation device for hernia mesh, with a PMA approval expected in 2006. According to industry estimates, the U.S. market for a hernia mesh fixation device is about \$57 million.

CryoLife also anticipates filing a PMA supplement for a BioGlue syringe in the first quarter of 2003. The syringe would be a single-use disposable device available about September 2003.

SynerGraft(R) Update

It is important to note that CryoLife has two categories of products within the SynerGraft family. First, there are the allografts, which are from human tissue. Second are xenografts, or tissue taken from animals and then engineered for human implantation. SynerGraft is the technology used on these tissues to depopulate the original cells and allow the new host cells to grow within the transplanted tissue, reducing the risk of rejection.

CryoLife continues to monitor the SynerGraft porcine heart valve implants. There have been a total of 38 porcine SynerGraft valves implanted, 21 of which remain implanted. Due to the effects of the FDA Order on Company operations and changes in Company focus, management has revised its new product priorities and timetables and decided not to pursue an IDE for the SynerGraft porcine heart valve in the U.S. Instead, management will focus on development of products that do not require clinical trials as lengthy and rigorous as those that are required for an artificial heart valve.

CryoLife plans to continue commercialization of the SynerGraft arterio- venous access device made from a bovine ureter. The Company estimates that more than 100 of these SynerGraft Model #100 vascular grafts have been implanted in Europe since a CE Mark was received in August 2001. Fifty-six of these implants are supported by implant cards, and 48 remain implanted. The Company is preparing an IDE for the SynerGraft Model 100 for submission to the FDA during first quarter 2003. Management believes the IDE will require about 400 patients and expects Pre-Market Approval in 2006. The total market addressed by this product in the U.S. exceeds \$70 million annually. CryoLife has also applied its proprietary SynerGraft technology to the human allograft valves and vascular tissues it preserves. Over 1,058 of the SynerGraft processed allograft valves have now been implanted in patients in the U.S., of which 870 are pulmonary valves and 188 are aortic valves. There have only been 5 explants. The Company reported that less than 1% of the implanted valves have failed because of structural failure. The longest implant of a SynerGraft allograft heart valve is 2.5 years. These valves have been shown to mitigate the increase in PRA (Panel Reactive Antibodies) levels that can be a problem in some patients with conventionally processed allograft heart valves and have also been observed to re-model themselves in vivo. CryoLife also preserves allograft vascular tissues with its proprietary SynerGraft process. To date, about 480 of these grafts have been implanted in humans, of which 10 have been removed. These grafts also mitigate the increase in PRA levels that sometimes occurs with conventionally processed human vascular grafts and have also been observed to re-model themselves in vivo. The U.S. market for a vascular access device exceeds \$70 million.

Orthopaedic Update

CryoLife plans to begin processing soft orthopedic tissue after re- inspection and approval by the FDA. CryoLife was a pioneer in the cryopreservation of soft tissues for knee reconstruction and was one of the first companies to successfully preserve and transplant menisci and patellar tendons for anterior cruciate ligament reconstruction and believes that its products will be well received upon re-entry into the market. The Company also anticipates introducing new tissues for foot and ankle, as well as shoulder reconstruction.

International Update

CryoLife Europa posted record revenues for the month of September and the third quarter. Europa BioGlue revenues for September were \$451,000, a monthly record. Europa BioGlue revenues for the quarter were \$814,000, an increase of 50% over the prior year quarter, and total revenues for the quarter were over \$1 million, a quarterly record and 22% above the same quarter last year. Total international revenues increased 11% year-over-year.

Procurement Update

CryoLife resumed processing certain life saving and limb saving vascular and non-valve conduit tissues subject to the FDA Order on September 16, 2002. The new processing is proceeding under controlled conditions provided in a September modification agreement with the FDA. Approximately

80% of the Company's pre-FDA Order cardiac procurement remains intact. The Company believes that it will have adequate vascular procurement in order to meet demand. Contingent upon passing the FDA inspection that CryoLife has requested for November, the Company plans to begin processing orthopedic tissues in December. Initially, the Company expects to recover up to 50% of its orthopedic procurement.

Inside the Numbers

CryoLife has received BioGlue orders from approximately 550 new customers since BioGlue received PMA approval in December 2001, with approximately 150 of those accounts being added during the third quarter of 2002. Approximately 78% of BioGlue revenues are generated domestically, with the current 2002 re-order rate at over 65%. The remainder of BioGlue revenues, or approximately 22%, is generated internationally, where 3rd quarter revenues were up 49% compared to revenues in the 3rd quarter of 2001.

BioGlue revenues in September 2003 were approximately \$1,750,000, a monthly record. October BioGlue revenues are on track to be slightly better than September. Gross margins for BioGlue were 81% in the third quarter.

Revenues from SynerGraft treated cardiac tissues represented 59% of total cardiac revenues for the quarter.

Gross margins in the third quarter were (96%), compared to 58% for the corresponding period in 2001. Excluding non-recurring, non-cash write-offs of \$25.8 million relating to deferred preservation costs and bioprosthetic valve inventory, gross margins would have been 58%. Gross margins in the fourth quarter of 2002 and 2003 are anticipated to be approximately the same as they have been historically.

General, administrative and marketing expenses for the quarter as a percentage of total revenues were higher than anticipated due to several factors, including higher than expected insurance premiums, costs associated with legal matters, costs associated with addressing regulatory issues, and lower than anticipated revenues. Costs associated with the FDA Order, including FDA consulting, public relations, miscellaneous legal fees, and downsizing costs, totaled approximately \$1,250,000 for the quarter, or 7.5% of total revenues.

The Company expects its cash burn rate to be approximately \$10 - \$12 million over the next two quarters and expects to be near cash flow break-even in mid 2003.

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiovascular, vascular and orthopaedic 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) vascular graft, the world's first tissue-engineered vascular replacement, which is CE marked for distribution within the European Community. The human heart valves and vascular grafts processed by CryoLife using the SynerGraft technology are distributed in the U.S. under the trade names of CryoValve(R)SG and CryoVein(R)SG, respectively.

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 to generate a material amount of additional income, that the corrective action plan submitted by CryoLife will not prove satisfactory to the FDA and that the FDA's concerns will not be adequately addressed in the fourth quarter, if at all, that even if the FDA's concerns are adequately addressed, demand for CryoLife preserved tissues may never return to prior levels and physicians and hospital risk managers may be unwilling to approve the use of Company-processed tissues, the Company may not have sufficient borrowing or other capital availability to fund its business over the long-term, the possibility that the heart valves processed by the Company may also be recalled, demand for the Company's products not subject to the FDA Order may decrease due to adverse publicity, federal or other regulators could impose additional restrictions on the Company's products, such as BioGlue, that are not subject to the FDA Order, current and future litigation may not be resolved within the limits of the Company's insurance policies or may otherwise be resolved in a matter that is materially adverse to the Company, the possibility that current severe decreases in the Company's revenues and working capital will continue, the possibility that SynerGraft-treated tissues 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, including the BioGlue related submissions currently planned for 2003, 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 for BioGlue 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 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 filings for the quarters ended June 30, 2002 and September 30, 2002, and the Company's other SEC filings.

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

CONTACT: D. Ashley Lee, Vice President, Chief Financial Officer of CryoLife, Inc., +1-770-419-3355, or Karen Kaplan of Fleishman Hillard, +1-404-739-0107, for CryoLife, Inc.