CryoLife, Inc. Management Reviews Operating Events in Teleconference Call Following Release of 2nd Quarter and First Half Of 2001 Revenues and Earnings Results

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ATLANTA, July 17 /PRNewswire/ -- CryoLife, Inc. (NYSE: CRY), a life- science company involved in the development and commercialization of cryopreserved and tissue-engineered implantable heart valves, vascular and orthopaedic grafts, and surgical adhesives, commented on operational events in its teleconference call following release of its revenues and earnings for the 2nd quarter and first six months ended June 30, 2001 earlier today (July 17, 2001).

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., reviewed operational information of interest to both analysts and shareholders. The following are excerpts from the teleconference call:

BioGlue(R) Update

The sales objective for BioGlue surgical adhesive for 2001 will be close to $11 million. International sales of BioGlue were bolstered by the Company's first order from the United Arab Emirates for $132,000. CryoLife was informed by the Food and Drug Administration (FDA) that its Premarket Approval (PMA) application for BioGlue use in all cardiac and vascular repair will be on the FDA's cardiovascular panel meeting agenda scheduled for September 10 or 11, 2001. The Company is hopeful that it will receive approval for its BioGlue PMA within 90 days after the panel meeting in September, although there can be no guarantee that approval will be granted. If the BioGlue PMA is approved, the Company plans to file a supplement to the PMA for a BioGlue foam or gel product, also for application in all cardiac and vascular repair. As a result, the Company does not plan to file an Investigational Device Exemption (IDE) with the FDA for pulmonary repair as it had previously indicated.

During May 2001, CryoLife exhibited its injectable spinal disc (BioDisc(TM)) based on the Company's BioGlue technology at the International Intradiscal Society Therapy Meeting in Phoenix, Arizona. A paper on the animal work for the injectable spinal disc was presented. Animal studies are expected to be completed by September 2001 following which the Company plans to file for a European CE (product certification) Mark and an IDE with the FDA during the first quarter of 2002.

SynerGraft(R) Technology Update

The SynerGraft technology centers around the removal of antigens from human and/or animal tissues leaving a collagen matrix that has the potential to then be repopulated with the recipient's own cells.

CryoLife now has a total of 15 porcine tissue-engineered SynerGraft heart valves implanted throughout the world. There have been six implanted in Australia with two explants that were previously discussed. There have been nine SynerGraft heart valves implanted in Europe, two of which were subsequently explanted for non-valve related reasons. The Company conducted post-operative histologies on the valves and confirmed that both of the explants had been repopulated with the recipient's own cells in vivo and that all of the explants showed minimal, if any, calcification.

Since February 2000, the Company has had over 320 allograft CryoValve(R) SG implants by 63 surgeons in the U.S. Two of these valves have been removed for non-valve related reasons. Neither valve was removed due to structural failure and both showed that they had remodeled with the recipients' cells. Additionally, the calcification usually observed in allograft valves was greatly reduced in these two valves. To date, only three of the 320 valves have converted to positive PRA (panel reactive antibodies) levels. In conventionally processed allograft valves, it is anticipated that 90% of the pediatric patients' PRA levels would turn positive after implant.

CryoLife was able to confirm that four major medical centers have converted all of their allograft valve business to the SynerGraft treated tissues during the last ninety days. Due to the increased demand for SynerGraft treated tissues, the local tissue bank or organ procurement organization has agreed to send significant portions of their tissues to CryoLife to meet the increased demand.

The importance of SynerGraft technology is underscored by the fact that 33% of all cardiac allograft preservation revenues in June 2001 were from SynerGraft processed tissues.

Since January 2001, the Company had 47 allograft vascular grafts treated with the SynerGraft process implanted in patients with various stages of renal disease. None of the vascular grafts has had to be removed and only one of the vascular grafts has caused an increase in the patient's PRA levels. In conventionally preserved human vascular grafts, over 90% of these graft recipients would have had increased PRA levels. A paper on the human implants of SynerGraft treated allograft vascular grafts was given at the Vascular Access Society Meeting in London in May 2001, by John H. Matsuura, M.D. F.A.C.S., Assistant Professor of Surgery, Medical College of Georgia, Atlanta Medical Center, Atlanta, Georgia. Dr. Matsuura is a consultant to CryoLife, Inc.

In July 2001, CryoLife submitted an application for its bovine-based SynerGraft vascular graft with the European Notified Body. CryoLife hopes to receive CE Mark approval for this A-V (arteriovenous) access device within the next 60 days. This tissue also has the potential to repopulate, in vivo. The U.S. timetable for IDE submission to the FDA for the bovine ureter-based vascular graft is expected to occur in the fourth quarter of 200l.

During the teleconference call, Mr. Anderson also discussed the Company's plan to submit a Premarket Approval (PMA) application for the CryoLife-O'Brien(R) stentless porcine heart valve at the end of July. The Company has been able to bypass the standard IDE approach by using the seven-year international follow-up data on some 862 patients.

Procurement

So far this year, tissue procurement is up 4% over last year, and CryoLife expects that its allograft tissue procurement will be up 10-15% next year.

Accordingly, the Company will begin to build out additional clean room space in its present tissue processing laboratory to accommodate growth in procurement.

AuraZyme(TM) Pharmaceuticals, Inc. Update

As previously announced on March 13, 2001, CryoLife formed AuraZyme Pharmaceuticals, Inc., a wholly owned subsidiary, to foster development of its proprietary light-activated drug delivery systems for application in cancer treatment, heart attacks, stroke and blood therapies. Gerald B. Seery, President and Chief Executive Officer of AuraZyme Pharmaceuticals, Inc., provided an update during the teleconference on activities of the new subsidiary.

Initially, the new company is focusing research and development in the field of oncology. The AuraZyme technology, called A-Z-CINN represents an opportunity to create a revolutionary drug delivery solution that, if successful, can alter significantly the course of anti-cancer chemotherapy treatments. A-Z-CINN is an energy reversible linker that binds a targeting agent, such as monoclonal (derived from a single cell and cells identical to that cell) antibody, with a therapeutic, such as a chemotherapy drug to create A-Z-CINN Targeted Prodrugs (TARPs). The benefit of this technology is its ability to deliver and release a targeted payload of chemotherapy drug at a level 100 times higher than a normal systemic dose to achieve localized and immediate destruction of tumor cells. The A-Z-CINN TARPs have the potential to destroy a tumor in a single treatment.

Recently completed animal studies on mice established the potential efficacy of the technology in treating primary and metastatic cancer. Results solicited a response from clinicians at the University of California at Los Angeles Jonsson Comprehensive Care Center to initiate a pre-clinical efficacy study anticipated to begin in early fall.

AuraZyme has also prepared and filed two grant applications, one with the National Institute of Standards and Technology's Advanced Technology Program and the second with the National Cancer Institutes, Flexible System to Advance Innovative Research (FLAIR) program. A third grant application will be filed in August 2001 with the National Institutes of Health's Small Business Innovative Research (SBIR) program. AuraZyme management believes A-Z-CINN represents a first in class solution to the unmet needs of chemotherapy treatments in a single treatment. Management is currently in discussions with leading biotech companies engaged in the development of monoclonal antibodies and pharmaceutical companies that manufacture chemotherapy drugs for exploring the possibility of forming collaborations.

Forward Guidance

The following financial guidance was given during the teleconference call:

- Cardiac revenues for the full year of 2001 are expected to be down slightly or flat as compared to 2000.
- Vascular revenues for the full year of 2001 are expected to increase 15% as compared to 2000.
- Orthopaedic revenues are expected to increase at 25% plus for the remainder of the year.
- Selling, General & Administrative expenses for the full year of 2001 are expected to be between 36 1/2% - 37 1/2% of revenues.
- Research & Development expenses for the full year of 2001 are expected to be between 6% - 6 1/2% of revenues.

Founded in 1984, CryoLife, Inc., is the leader in the development and commercialization 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 approved as an adjunct for acute thoracic aortic dissections under HDE regulations in the United States 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, the world's first tissue-engineered heart valve replacement and the CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are 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 regarding future occurrences are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur when expected, if at all, and are subject to various risks and uncertainties. Such risks and uncertainties include the possibility that SynerGraft-treated tissues will not have the expected long-term functionality, repopulate with human recipient cells, reduce immune response, or remain infection free, that future clinical SynerGraft or BioGlue test results will prove less encouraging than current results, that SynerGraft, BioGlue or other regulatory submissions will not be ready when planned, that anticipated regulatory approvals will not be obtained on a timely basis, if at all, and that SynerGraft treated tissues, BioGlue or other products or services offered by the Company may not be accepted or utilized by surgeons, the possibility that the Company will be unable to find an investor in its proprietary light-activated drug delivery systems or that such systems will proved ineffective in oncology applications, and other risk factors detailed in the Company's Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended December 31, 2000.

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

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