



## **CryoLife, Inc. Management Reviews Operating Events In Teleconference Call Following Release of Second Quarter and First Half of 2002 Revenues and Earnings Results**

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ATLANTA, Jul 24, 2002 /PRNewsire-FirstCall via Comtex/ -- 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 during its teleconference call following the release of its revenues and earnings results for the second quarter and first six months ended June 30, 2002 yesterday.

Steven G. Anderson, President and Chief Executive Officer, D. Ashley Lee, Vice President and Chief Financial Officer, and James D. Vander Wyk, Ph.D., Vice President, Regulatory Affairs and Quality Assurance, CryoLife, Inc. reviewed operational information of interest to both shareholders and analysts. The following are excerpts from the teleconference call:

### **BioGlue(R) Update**

The Pre Market Application (PMA) CryoLife received in December 2001, for all vascular sealing, is an expansive indication and CryoLife expects sales to continue to grow. CryoLife is on track to sell over \$20 million this year in BioGlue. BioGlue's effectiveness when compared to standard treatments was demonstrated by a paper on BioGlue recently given at the European Society for Cardiovascular Surgery meeting in Helsinki by Dr. Joseph Bavaria of the University of Pennsylvania. Dr. Bavaria, a member of CryoLife's cardiovascular medical advisory board, reported that BioGlue was 64% better at anastomotic hemostasis than the control model and that BioGlue resulted in 31% fewer pledgets, 33% fewer red blood cell units and 43% fewer frozen plasma units being used per procedure when using BioGlue instead of standard procedures.

CryoLife had been investigating the feasibility of filing PMA supplements related to a BioGlue Gel and BioGlue Foam. Due to additional ingredients required for the BioGlue Gel and BioGlue Foam from the basic BioGlue formulation, CryoLife would need to conduct lengthy clinical trials under an Investigational Device Exemption (IDE) and additional biocompatibility and shelf life testing to support a PMA. Because of the lengthy time required for BioGlue Gel and BioGlue Foam regulatory submissions, CryoLife has lowered the priority of these products.

CryoLife anticipates applying to the FDA for additional indications for the presently approved BioGlue formulation for both hernia repair and sealing dura mater, the fibrous membrane that surrounds the spinal cord and the brain. CryoLife's present data indicates that of the approximate 1,000,000 hernia procedures per year, 285,000 may be appropriate for the use of BioGlue. In addition, the market for dura mater sealant indicates that there are about 112,000 procedures that might be applicable for the use of BioGlue. If one 5ml cartridge was used in each of the appropriate procedures, the markets would be \$70 million and \$39 million, respectively. CryoLife expects to file IDE applications for hernia repair and dura mater sealing in the 2nd quarter of 2003.

The CE Mark application for European distribution of the injectable spinal disc is scheduled for the first quarter of 2003. The IDE submission to the FDA will be filed in the second quarter of 2003.

### **SynerGraft(R) Update**

Since February 2000 approximately 813 SynerGraft processed pulmonary allograft heart valves have been implanted. Of these valves, 800 remain implanted at this time. Additionally, CryoLife has implanted 648 processed SynerGraft patches for cardiac reconstruction. The histological examination of the explanted allograft heart valves showed that the valves were re-modeling in vivo (in the living body). About 48% of CryoLife's allograft valve revenue is from SynerGraft processing. SynerGraft processing for heart valves carries a 24% price premium when compared to allograft valves processed by conventional methods. Over 88% of CryoLife preserved allograft heart valves are free from structural failure at 10 years. CryoLife estimates that it provides over 70% of the cryopreserved cardiac tissues in the United States.

In addition, since January 2001 CryoLife has implanted about 394 vascular grafts processed with SynerGraft technology. About 381 of these grafts remain implanted. A key feature of these SynerGraft allograft vascular grafts is that they do not increase PRA levels in patients. Approximately 7% of CryoLife's vascular revenue is from SynerGraft processing. CryoLife estimates that it provides over 90% of the cryopreserved vascular tissues in the United States.

CryoLife received a CE mark for SynerGraft vascular grafts made from bovine ureters in August 2001. Through device follow-up CryoLife have been able to verify that 54 SynerGraft vascular grafts have been implanted as Arteriovenous (AV) access devices and for peripheral vascular reconstruction. CryoLife believes the number is higher than 54, but has been unable to verify a higher number. A recent report at the cardiovascular meeting in Helsinki, Finland by Professor Luisa Berardinelli from Italy reported more favorable clinical results compared to synthetic vascular grafts. She reported on the results of 10 AV access grafts implanted for approximately 4.5 months mean time. As a result of the clinical results of the SynerGraft bovine vascular grafts for AV access, CryoLife has moved up the priority of these grafts and will apply for an IDE in the 4th quarter of this year. CryoLife believes that it would be reasonable to expect approval of the IDE in the first quarter of 2003 and would enroll patients in the clinical trial at that time. Based on a clinical trial of two years and required administrative follow-up, CryoLife believes that it would be reasonable to expect PMA approval some time in late 2005 or early 2006. Based on market data available to CryoLife, CryoLife anticipates that the device could potentially address up to 75,000 to 80,000 of the 234,000 AV access procedures performed annually in the United States, and with an anticipated charge for the grafts of \$1200 (three times the \$400 sales price of current AV access grafts), CryoLife could potentially triple the current U.S. market of \$35 million to \$40 million for AV access procedures. Because the device is made from a bovine ureter, it does not have the supply constraint of human vascular grafts.

In a related move, CryoLife has decided to withdraw its IDE for the CryoLife-O'Brien(R) prosthetic heart valve. This strategy will help focus the Company on the SynerGraft Vascular IDE for AV Access. The CryoLife-O'Brien prosthetic heart valve will continue to be distributed internationally. The SynerGraft porcine heart valves continue to be followed and the results of the international clinical trial that has been going on are as follows: Since

August 1999, 38 SynerGraft valves have been implanted and 10 of these valves have been explanted. These valves have been implanted in both the pulmonary and the aortic position. In many cases these initial implants of the SynerGraft valves have been made in very sick patients or patients who have had problems with prior surgical implants. Seven of these 38 patients have died from various causes. We are continuing to follow the remaining 21 implanted SynerGraft valves. An analysis of some of the explanted valves shows that they also have remodeled themselves in-vivo.

#### Procurement Update

For the three and six months ending June 30, 2002, procured and processed tissues are up 29% and 34%, respectively, over last year. Orthopaedic tissues are up 62%, cardiovascular tissues are up 16% and cardiac tissues are up 23% for the first six months of 2002. CryoLife finds it particularly rewarding that orthopaedic procurement continues to increase in the face of current adverse publicity. Since the first of the year, more than 110 surgeons have participated in surgical training in CryoLife's corporate educational facility. Since June 1, 2002, more than 30 surgeons have participated in these programs.

#### Inside the Numbers

Overall revenues for the quarter were 1% below the lower end of previous guidance of between \$26 and \$27 million, most likely due to adverse publicity associated with CDC, infections and the FDA warning letter. BioGlue revenues were \$5.3 million for the quarter ended June 30, 2002, up 100% over the corresponding period in 2001. The primary factors driving the growth in BioGlue revenues were the PMA approval of BioGlue for use in vascular repair, as well as growth of revenues in international markets. Since the PMA approval of BioGlue last December, CryoLife has received orders from approximately 370 new customers, with approximately 190 of those accounts being added during the second quarter of 2002. Comparing the last 6 months sales prior to the PMA approval at our top 50 hospitals to those same hospitals since the PMA approval, the average sales at those 50 hospitals have increased approximately 46% (from \$22,800 to \$33,400). Approximately 77% of BioGlue revenues are generated domestically, with the current reorder rate over 70%. The remainder of BioGlue revenue is generated internationally, where revenue for the quarter for BioGlue was up 28% year over year.

Cardiac revenues were \$7.7 million for the quarter, up 7% over the corresponding period in 2001. The 7% increase in revenues for the 2nd quarter came on a 3% increase in units. Revenues from SynerGraft treated cardiac tissues represented 48% of total cardiac revenues for the quarter.

Vascular revenues were \$6.4 million for the quarter, up 6% over the corresponding period in 2001. The second quarter revenue increase came on an 8% increase in unit shipments.

Orthopaedic revenues were \$5.9 million for the quarter, up 7% over the corresponding period in 2001. The increase in orthopaedic revenues came on a 6% increase in unit shipments. Increases in orthopaedic procurement helped fuel the growth in orthopaedic revenues.

Gross margins in the second quarter were 59.9%, compared to 57.7% for the corresponding period in 2001. The improvement is due to the increasing contribution of BioGlue to operating results.

General, administrative and marketing expenses as a percentage of revenue for the quarter were 39.4%, compared to 37.4% for the corresponding period in 2001. The increase in expenses as a percentage of total revenues was higher than anticipated due to several factors, including higher than expected insurance premiums that went into effect in April and May of this year, costs associated with legal matters, costs associated with addressing regulatory issues, and lower than anticipated revenues. Planned increases in expenditures in 2002 resulted primarily from expenses necessary to support the rollout of BioGlue under the PMA approval, general business growth, as well as some additional expenses resulting from the expansion of our corporate headquarters and manufacturing facilities.

Research and development expenses were \$1.2 million for the quarter compared to \$1.3 million for the corresponding period in 2001. R&D expenditures currently represent approximately 4.6% of year-to-date revenues. R&D spending relates principally to the Company's development of BioGlue surgical adhesive and its focus on the SynerGraft technologies.

#### Balance Sheet Discussion

CryoLife has in excess of \$30 million in cash. CryoLife's current cash position allows it to fund both the previously announced stock buy-back and pursue both its regulatory and product development strategies. CryoLife's current ratio stands at 6 to 1 and CryoLife currently has approximately \$6.4 million in debt.

#### 2002 Third and Fourth Quarter Guidance

CryoLife anticipates total revenues for the third quarter of 2002 to be between \$26 and \$27 million, fourth quarter revenues to be between \$25 and \$26 million and 2002 full year revenues to be between \$102 million and \$104 million. Earnings per share for the third quarter of 2002 are expected to be between \$.13 and \$.14, with fourth quarter earning per share of between \$.11 and \$.13. For the full year, the Company expects earnings per share to be between \$.54 and \$.57, down from previous guidance.

Breaking down the revenue sources, CryoLife's third quarter guidance for BioGlue revenues is between \$5.3 million and \$5.7 million and for the fourth quarter guidance is in the range of \$5.7 million and \$6 million. Cardiac revenues in the third quarter are anticipated to be flat compared to the third quarter of 2001 while CryoLife anticipates cardiac revenues to increase between 6% and 10% in the 4th quarter over 2001 revenues. For the full year, CryoLife's 2002 expected revenues from cardiac tissue are expected to increase 4% to 6% over 2001 revenues, down from CryoLife's previous guidance of between 9% and 11%. Vascular revenues are expected to increase between 4% and 8% for both the third and fourth quarters of 2002 over 2001 revenues. For the full year, CryoLife anticipates vascular revenues to increase about 6% to 8%, down from its previous guidance of low double-digit percentage growth. Orthopaedic revenues for the third quarter of 2002 are expected to grow between 6% and 8% over the third quarter of 2001 and to be flat in the fourth quarter as compared to 2001. For the full year, CryoLife expects orthopaedic revenues to be about 6% to 8% above 2001, down from previous growth guidance of 20+%.

CryoLife's effective tax rate for 2002 is expected to be 34%. Gross margins for the remainder of 2002 are expected to be between 59% and 60%.

CryoLife's General, administrative and marketing expenses in 2002 are anticipated to be between 37.5% and 38.5% of revenues in the third quarter and between 42% and 43% of revenues in the fourth quarter. This takes into consideration the effects of the larger than expected increases in insurance premiums, costs associated with legal matters, as well as costs associated with complying with the FDA's recent observations. The

percentages also take into consideration the reduced revenue guidance for the remainder of the year. Research and development expenses are expected to approximate between 5% and 5.5% of revenues for the remainder of the year.

#### Regulatory Affairs Update

The Company has responded to the observations set forth in the FDA Warning Letter previously received by the Company on June 17, 2002 and expects to have a meeting with the FDA after the FDA completes its review of the Company's responses. All recommendations from all sources are being reviewed by CryoLife, which is using independent scientific expertise in its reviews and activities.

Two recommendations that have been implemented are the adoption of refrigeration protocols to extend warm ischemic time and the American Association of Tissue Banking standard for pre-processing bacterial testing that became effective July 2002.

The Company emphasized the following points:

1. It has always tested the tissue distributed by it for the presence of bacteria and fungi, using a companion sample. It has always tested for both aerobic and anaerobic bacteria, including the Clostridium species, along with the Clostridium spore form.
2. If a companion tissue exhibited growth of micro-organisms, CryoLife has always discarded the related tissue.
3. CryoLife's testing process follows treatments designed to significantly reduce bacterial bioburden that is normally found on donor tissue.
4. CryoLife only processes and releases tissues recovered from donors that are free of known infections, both bacterial and viral, as well as risks of such infections.
5. Donors must meet age and numerous other criteria.
6. The allograft soft tissues distributed by CryoLife cannot be sterilized without adverse effects on functionality and durability.
7. CryoLife has always performed annual audits of its quality system as required under FDA Good Manufacturing Practices (GMP's) and ISO9001. These audits are routinely reviewed during inspections by LRQA, CryoLife's European regulatory authorities.
8. CryoLife includes a prominent, boxed warning in its labeling describing the tissue's potential for disease transmission. In addition, CryoLife labeling also recommends that due to the nature of the tissue, the surgeon consider the use of post-operative anti-microbial regimens to reduce the potential for infections.
9. Pursuant to required FDA and ISO standards, CryoLife maintains a complaint system that relies not only on voluntarily submitted complaints and reports, but pro-actively searches out incidents from literature, observations from CryoLife personnel, case report forms from reimbursed reference hospitals, as well as media reports.
10. An analysis of CryoLife's FDA-mandated complaint file concerning reports of alleged infections associated with CryoLife tissues, both substantiated or not, over the period from January 1, 1999 to June 30, 2002 indicates that the total reported infection rate is 0.2% for orthopaedic tissues and is 0.56% for allograft heart valves. These reports include all allegations of infections in allograft recipients and do not necessarily correlate to infections caused by the implanted tissue. These rates are acknowledged by CDC and other health care professionals as very low. The rate for CryoLife valves is substantially lower than the published infection rates of 1.6% for sterile mechanical heart valves and 1.2% for sterile bioprosthetic heart valves. The reported infection rate associated with CryoLife orthopaedic allografts is 0.2%, versus 0.6 to 2.2% infection rate reported by the CDC for sterile prosthetic orthopaedic devices.

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 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 heart valve, the SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacements, 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, including statements regarding anticipated operating performance and expenditures during the third and fourth quarters and full year of 2002, statements regarding the timing of anticipated regulatory filings and approvals, and statements regarding expected procurement trends in 2002, 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 Company's dependence on cryopreservation of human tissue, 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 orthopedic tissue revenues could be adversely impacted due to the recent reports of infections and adverse media publicity, 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 or that anticipated regulatory approvals will not be obtained on a timely basis when expected, if at all, that the FDA may take actions adversely affecting the Company's operations, that allograft tissue revenues could be adversely impacted due to CDC reports, media coverage or the issuance of the FDA warning letter, that relationships with tissue procurement groups may be adversely affected, that Company initiatives are delayed pending FDA compliance, that future BioGlue performance, including the performance of gel and foam formulations, will prove less encouraging than current results, that surgeons will not continue to accept and use BioGlue, competition from other wound closure products, that markets for products and services under development may not prove as large as current estimates, that pending legal proceedings against the Company, including purported class action and product liability lawsuits, will not be resolved in its favor, 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 the Company 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, 2001.

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

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