



CryoLife, Inc. Management Reviewed Operating Events In Teleconference Call Following Release of Fourth Quarter and Year End 2001 Revenues and Earnings Results

January 29, 2002

ATLANTA, Jan 29, 2002 /PRNewswire-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 fourth quarter and year ended December 31, 2001 earlier today (January 29, 2002).

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 analysts and shareholders. The following are excerpts from the teleconference call:

BioGlue(R) Update

The Company has commenced aggressive marketing programs to promote the FDA approved expanded uses of BioGlue. CryoLife is contacting the more than 600 hospitals and medical centers in North America whose Internal Review Boards (IRBs) had previously approved the use of BioGlue for aortic dissections to inform them that the product is approved for vascular repair and that the Humanitarian Device Exemption (HDE) restrictions have been lifted. Additionally, contact with those medical centers that did not have IRB approvals in place for the use of BioGlue for aortic dissections has resulted in BioGlue orders. Other promotional programs include contact with vascular surgeons and emergency room physicians who perform central and peripheral vascular repair. Initial feedback from cardiovascular surgeons indicates that BioGlue is being used for, among other procedures, aneurysms, Bentall procedures, valve replacement and LVAD implants. Vascular surgeons are using the glue for abdominal aortic aneurysms, infra-inguinal bypasses, A-V access devices and carotid endarterectomies, as well as other procedures. The Company estimates the current U.S. market potential for BioGlue to be approximately \$700 million, up from earlier estimates of \$500 million. CryoLife expects January 2002 BioGlue sales to be over \$1.3 million.

SynerGraft(R) Update

Since February 2001, approximately 394 SynerGraft processed pulmonary allograft heart valves have been implanted. Of these 394 valves, only three have been removed, none of which were removed for structural failure. The histological examination of the three explanted valves showed that they were re-modeling in vivo (in the living body), as the Company had anticipated, and that the valves had normal tissue architecture.

Since January of 2001, 250 SynerGraft processed allograft vascular grafts have been and remain implanted. These vascular grafts have been used for A-V access and for peripheral reconstruction.

Approximately 15 SynerGraft vascular grafts, made from bovine ureters, have been and remain implanted in patients in Italy, both as A-V access devices and also for peripheral reconstruction. The longest implant is now about eight weeks. The implanting physician has submitted a paper on these implants to the American Association of Thoracic Surgeons. The SynerGraft vascular grafts represent the first technological advance in vascular graft technology in the last thirty to thirty-five years and address an A-V access market estimated to be in excess of \$400 million.

Approximately 31 porcine SynerGraft heart valves have been implanted in patients, 23 of which remain implanted. The first of these valves was implanted in August of 2000. The seven valves that have been explanted have shown that the valves re-modeled themselves in vivo. There was one structural failure of a SynerGraft valve. The other explants appear to have been caused by surgical technique issues. SynerGraft heart valves have been implanted in Australia, Austria, Finland, Norway, Denmark, France and the U.K.

Procurement Update

In December of 2001, CryoLife completed negotiations on a strategic alliance with AlloSource, an orthopaedic tissue processor, located in Denver, Colorado. This alliance requires CryoLife to distribute minimum quantities of AlloSource processed sports medicine allografts used in reconstruction of the knee, as well as provides CryoLife with additional tissues that will be processed and distributed using the Company's proprietary processing methods. The two organizations will also coordinate efforts to offer communities the highest quality tissue technologies in the United States. During the fourth quarter of 2001, the number of orthopaedic allografts processed by the Company increased 57% over the corresponding period in the prior year. This increase resulted primarily from the collaboration with AlloSource, as well as procurement from other organizations that previously did not send tissues to CryoLife for processing. The Company anticipates that the first quarter of 2002 will be another record quarter for orthopaedic tissue processing.

The Company also reported that cardiac procurement for the month of January 2002 was expected to increase 20% compared to January of 2001.

Inside the Numbers

BioGlue revenues were \$3.1 million and \$10.6 million for the three months and year ended December 31, 2001, up 46% and 65% respectively over the corresponding periods in 2000. The primary factors driving the growth in BioGlue revenues were the Premarket Approval (PMA) of BioGlue for use in open surgical repair of large vessels, as well as increased growth of revenues in international markets. Initial shipments of BioGlue under the PMA approval began mid-December 2001. In December, CryoLife received orders from 51 new BioGlue customers. Of those customers, over one third have already re-ordered product. In 2001, approximately 66% of BioGlue revenues were generated domestically, with the 4th quarter reorder rate at approximately 80%. The remainder of 2001 BioGlue revenues, or approximately 34%, were generated internationally; these revenues were up 41% in the 4th quarter of 2001 as compared to the corresponding period in the prior year.

Cardiac revenues were \$6.3 million and \$28.6 million for the three months and year ended December 31, 2001, down 5% and 4% over the corresponding periods in 2000. The decrease in revenues in the fourth quarter came on a 1% increase in unit shipments. Revenues from SynerGraft treated human allograft heart valves represented 27% of total cardiac revenues during the 4th quarter. The increase in units did not result in an increase in revenues because a greater portion of revenues resulting from SynerGraft treated tissues came from non-valved conduit and patch material, which have lower average processing prices than allograft heart valves.

The Company's cardiac procurement, for the period of time from which 4th quarter revenues generally have resulted, was actually up 4% over the corresponding period in the prior year. However, the yields on those tissues were slightly lower than historical yields due to the age distribution of the donors. Additionally, in a greater number of incidences in 2001 as compared to 2000 the Company was unable to secure the appropriate information from third parties on a timely basis to allow tissues to clear quarantine. The Company believes that had the yields been equivalent to historical yields, and had the information required to clear donors been received on a timely basis, the cardiac business would have demonstrated revenue growth during the quarter.

Vascular revenues were \$5.9 million and \$24.5 million for the three months and full year ended December 31, 2001, up 16% for the quarter and 15% for the full year. The 4th quarter revenue increase came on a 15% increase in unit shipments. Vascular revenues increased primarily due to an increase in procurement, as well as marked improvement in the number of femoral veins and arteries that were shipped to be used in A-V access procedures for dialysis patients. For the quarter, 6% of vascular revenues were generated from SynerGraft processed tissues.

Orthopaedic revenues were \$6.3 million and \$22.5 million for the three months and full year ended December 31, 2001, up 46% and 39% over the corresponding periods in 2000. The increase in orthopaedic revenues during the 4th quarter is primarily due to a 26% increase in unit shipments. The Company continues to see increases in procurement, which in turn have resulted in continuing strength in the area of non-bone tendons for ACL reconstruction surgeries and in osteochondral grafts.

Gross margins in the fourth quarter and year ended December 31, 2001 were 58%, compared to 58% and 56% for the corresponding periods in 2000. The improvement in gross margins for the year resulted from the increasing contribution of BioGlue sales to the Company's operating results and the termination of the OEM contract with Horizon Medical, Inc. on October 9, 2000.

General, administrative and marketing expenses as a percentage of revenues for the fourth quarter and year ended December 31, 2001, excluding non-recurring charges of \$684,000, were 39.1% and 37.8%, compared to 39.1% and 37.3% for the corresponding periods in 2000. The increase in expenditures in 2001 resulted primarily from expenses necessary to support the rollout of BioGlue under the PMA approval, general business growth, as well as additional expenses resulting from the expansion of the Company's corporate headquarters and manufacturing facilities.

Research and development expenses were \$1.1 million and \$4.7 million for the three and twelve months ended December 31, 2001, compared to \$1.5 million and \$5.2 million for the corresponding periods in 2000. R&D expenditures for the full year of 2001 represent approximately 5.4% of 2001 revenues. R&D spending relates principally to the Company's development of its Protein Hydrogel Technologies and its SynerGraft technologies. R&D expenses for 2001 as compared to 2000 have declined from the prior year due to the absence of an ongoing clinical trial.

Selected balance sheet items are as follows as of December 31, 2001:

* Cash and Cash Equivalents	\$33,687
* Accounts Receivable	\$13,305
* Inventory and Deferred Preservation Cost	\$30,457
* Total Assets	\$129,363
* Total Equity	\$101,439

First Quarter 2002

- * BioGlue revenues are expected to be between \$3.8 and \$4.2 million for the quarter.
- * Cardiac revenues are expected to increase between 3% and 6% for the quarter as compared to the 1st quarter of 2001.
- * Vascular revenues are expected to increase between 5% and 8% for the quarter as compared to the 1st quarter of 2001.
- * Orthopaedic revenues are expected to grow between 15% and 20% for the quarter as compared to the 1st quarter of 2001.
- * Total revenues are expected to be between \$24 and \$25 million for the quarter.
- * Gross margins for the quarter are expected to be between 58% and 59%.
- * General, administrative and marketing expenses are anticipated to be between 38% and 39% of revenues.
- * R&D expenses are expected to approximate between 5% and 5.5% of revenues in 2002.
- * Earnings per share are expected to be between \$0.15 and \$0.17 for the quarter.

2002 Full Year Guidance

The full year guidance for 2002 given in October of last year remains unchanged, with the exception of the Company's effective tax rate, which is expected to be 34% of pretax income, as opposed to the 32% guidance that was given previously. However, consistent with previous guidance, earnings per share are expected to be in the range of \$.74 to \$.80.

Regulatory Affairs Update

Lloyd's Register Quality Assurance, the Company's Notified Body, has recommended European CE mark approval for an extended list of soft tissue repairs for the Company's BioGlue surgical adhesive. In addition, while BioGlue is typically used as an adjunct to sutures, staples, electrocautery, and patches to bond, seal, and reinforce tissue, this approval would allow the use in the European Union of BioGlue by itself to seal and reinforce damaged soft tissue when other ligatures or conventional procedures are ineffective or impractical. If approved, BioGlue is expected to be indicated for the repair of the following soft tissues: cardiac, genitourinary, dural, alimentary tract (which includes esophageal, gastrointestinal, and colorectal tissues), and other abdominal soft tissues (such as pancreatic, splenic, hepatic, and biliary). BioGlue may also be used in the fixation of surgical meshes in hernia repair. Clinical data used to support the application found that BioGlue was effective or highly effective in these types of soft tissue repair in general surgery. All of these indications are in addition to presently approved vascular and pulmonary repair. The Company anticipates formal receipt of the CE certificate very shortly with distribution to begin immediately thereafter.

The Company stated that the Food and Drug Administration (FDA), the U.S. Centers for Disease Control and Prevention (CDC), and the States of Minnesota and Georgia have completed their investigations into the death of a Minnesota patient who received an orthopaedic graft from CryoLife in November. There were no citations for CryoLife from any of the four agencies. The conclusions drawn by both CDC and FDA are that the patient most likely died of an acute *Clostridium sordellii* infection; that this organism was probably on the donor tissue prior to arrival at CryoLife; that the organism, as a spore, survived the decontamination process; and that CryoLife procedures, which met or exceeded typical industry processes for aseptic handling, were properly followed. The CDC did confirm that *Clostridium sordellii* was isolated from two other tissues from the same donor. However, none of the eight other recipients of tissue from this donor has become infected with *sordellii* and all are doing well. In consideration of these conclusions and actions, CryoLife has formally closed its file on this matter.

The following regulatory submissions are planned for 2002:

In August 2002, the Company plans to submit an application for an Investigational Device Exemption (IDE) to the FDA to conduct a clinical trial for the SynerGraft Vascular Graft Model 100 for A-V access. CryoLife expects the FDA will require 400 patients with a one-year follow-up period.

In September 2002, the BioGlue surgical adhesive gel formulation for the current BioGlue indications is expected to be submitted as a supplement to its CE mark approval, followed in December 2002 by a submission to the FDA for a supplement to the Company's Premarket Approval (PMA) application. The same strategy will be followed for the foam configuration of BioGlue. The CE mark application is anticipated in December and the U.S. filing in March of 2003.

The Company anticipates filing an IDE submission to the FDA in December 2002 for the SynerGraft Heart Valve Model 700 for use as a pulmonary valve replacement in the less than 6-year-old pediatric population. As the trial progresses, the interim data will be reviewed and may provide a basis for supporting an HDE application to the FDA. This is the strategy first successfully followed by CryoLife for BioGlue for aortic dissections. The Company plans to file for CE mark approval in January 2003 for the SynerGraft Model 700 porcine heart valve to be used as an aortic valve replacement.

CryoLife plans to apply for a CE mark for the BioDisc(TM) spinal disc as early as December 2002. The Company plans to submit an IDE for BioDisc to the FDA in April of 2003.

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 first quarter and full year of 2002, and statements regarding expected cardiac procurement trends in January 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 deaths of three knee surgery patients, that future clinical SynerGraft or BioGlue test results will prove less encouraging than current results, that SynerGraft, BioGlue, CryoLife-O'Brien Heart Valve 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 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 the Company 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, if the PMA for the CryoLife-O'Brien Heart Valve is approved, that American surgeons will not accept it or utilize it in aortic valve surgeries or competing products will be deemed more effective or expedient, that pending legal proceedings against the Company 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, 2000.

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

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