



CryoLife, Inc. Management Reviewed Operating Events in Teleconference Call Following Release of Record First Quarter Revenues and Earnings Results

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ATLANTA, Apr 23, 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 record revenue and earnings results for the first quarter ended March 31, 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 increase in BioGlue revenues for the first quarter represents sales of 105,000 ml, compared to the sales of 76,000 ml recorded in the fourth quarter of 2001. According to field reports, BioGlue is being used in, among other procedures, abdominal aortic aneurysms, endarterectomy surgeries, sealing of suture lines, aortic dissections and aortic root replacements, repair of aortic aneurysms, gluing/sealing of organs, sealing of Dura, sealing of A-V access devices, femoral popliteal bypasses, sealing of LVAD cannulas, prosthetic valve suture lines, sealing of synthetic conduit suture lines, gunshot wounds, coronary artery anastomoses and Bentall procedures. Prior to the PMA approval by the FDA of BioGlue last December, CryoLife had approximately 600 accounts using BioGlue in the U.S. The Company estimates that it has opened approximately 170 new accounts since that approval. Approximately 61% of its BioGlue accounts have re-ordered during the first quarter of this year. The Company estimates the total U.S. market that BioGlue addresses is about \$700 million annually.

SynerGraft(R) Xenograft Valves and Vascular Grafts Update

There have been a total of 37 SynerGraft heart valves implanted in the world since August 1999. Valves have been implanted on both the right and left side of the heart. Twenty-five of these remain implanted. An analysis of the explanted valves indicated that they were repopulated with the recipient's own cells similar to the results experienced with the animal implants. Implants included both infants and adults.

There have been a total of 27 documented SynerGraft vascular grafts implanted in Europe since November 2001. However, the Company estimates closer to 100 of the SynerGraft vascular grafts have been implanted in Europe; not all have been documented with implant cards. These vascular grafts have been implanted for peripheral vascular reconstruction and A-V access devices for dialysis patients. To the Company's knowledge none have been removed.

SynerGraft Allograft Valves and Vascular Grafts Update

On the allograft side of the business, since February 2000, there have been 987 SynerGraft processed allograft heart valves implanted in people throughout North America. Of these valves, 982 remain implanted at this time. Five have been removed. Histological examination of some of these valves indicated that they did repopulate with the patient's own cells in vivo. Examinations also confirmed that the PRA (Panel Reactive Antibodies) levels were significantly reduced in the patients that were implanted with a SynerGraft processed allograft valve.

Since January of 2001, a total of 262 SynerGraft processed vascular grafts have been implanted in North America as A-V access devices for dialysis patients and for peripheral vascular reconstruction purposes. We believe that all of these grafts remain implanted at this time.

Procurement Update

The allograft preservation business is dependent upon procurement. The number of donors processed was up 43% in the first quarter of 2002 over the first quarter last year. The increase is attributed to several factors, including the Company's formation of strategic alliances with large tissue procurement groups and the addition of procurement liaison staff that have had an immediate impact in increasing procurement across the board. Based upon the significant procurement increases in the first quarter, CryoLife anticipates this will have a favorable impact on revenues in the second quarter as it takes 45 to 90 days to move tissue through the CryoLife's processing system.

April results to date indicate that it will be another record month in revenues. The Company estimates that April revenues will be about 25% ahead of revenues recorded in April 2001.

Inside the Numbers

BioGlue revenues were \$4.9 million for the quarter ended March 31, 2002, up 100% over the corresponding period in 2001. CryoLife has received orders from approximately 170 new customers since product launch in December 2001. Of those customers, approximately 35% have re-ordered the product as of the end of the first quarter. Approximately 80% of BioGlue revenues are generated domestically, with the current 2002 re-order rate over 70%. The remainder of BioGlue revenues, or approximately 20%, is generated internationally, where revenues for the quarter were up 17% year over year.

Cardiac revenues were \$7.3 million for the quarter, up 6% over the corresponding period in 2001. The 6% increase came on a 4% increase in units shipped. Revenues from the SynerGraft treated allograft heart valves represented 34% of total cardiac revenues for the quarter and 41% of cardiac revenues for the month of March.

Vascular revenues were \$7 million for the quarter, up 9% over the corresponding period in 2001. The first quarter revenue increase came on a 1% decrease in unit shipments. In the prior year quarter, there were a large number of the composite grafts shipped for peripheral vascular procedures. Although the number of units decreased in 2002, the number of procedures increased due to a fewer number of composite procedures being performed. The average selling price on the larger vascular segments are higher than on the composite grafts. Vascular revenues increased due to an increase in procurement, as well as a marked improvement in the number of femoral veins and arteries that were shipped for A-V access procedures for dialysis patients.

Orthopaedic revenues were \$5.9 million for the quarter, up 13% over the corresponding period in 2001. The increase in orthopaedic revenues came on a 9% increase in unit shipments. The Company experienced a healthy increase in orthopaedic procurement, primarily resulting from competitive gains and the Company's collaboration with AlloSource, helping fuel the growth in orthopaedic revenues.

Gross margins in the first quarter were 59.3%, compared to 57.1% for the same period in 2001. The improvement for the year is due to the increasing importance of BioGlue in the Company's operating results.

General, administrative and marketing expenses for the quarter were 37.2%, compared to 38.1% for the corresponding period in 2001.

Research and development expenses were \$1.2 million, compared to \$1.1 million for the same period in 2001. R&D expenditures currently represent approximately 4.5% of year-to-date revenues. R&D spending relates principally to the Company's development of BioGlue surgical adhesive and to the Company's focus on its SynerGraft technologies.

Selected balance sheet items (in thousands) were as follows as of March 31, 2002:

* Cash and Marketable Securities	\$ 34,180
* Trade Accounts Receivable	\$ 16,893
* Inventory and Deferred Preservation Cost	\$ 33,312
* Total Assets	\$136,700
* Total Equity	\$109,481

Full Year and Second Quarter 2002 Guidance

The Company does not expect to meet the previously announced revenue guidance for the second quarter and full year of between \$1.2 million and \$1.8 million, for SynerGraft heart valves, representing a lower than anticipated acceptance of the product. However, CryoLife management believes that its previously issued earnings guidance of between \$0.74 and \$0.80 for the entire year will not be adversely affected.

- * BioGlue revenues are expected to be between \$4.9 million and \$5.3 million for the second quarter.
- * Cardiovascular tissue processing revenues for the second quarter are expected to increase between 8% and 12% over the second quarter of 2001.
- * Vascular tissue processing revenues for the second quarter are expected to increase between 12% and 15% over the second quarter of 2001.
- * Orthopaedic tissue processing revenues for the second quarter are expected to grow between 14% and 20% over the second quarter of 2001.
- * Total revenues are expected to be between \$26 million and \$27 million for the second quarter.
- * Gross margins are expected to be between 58.5% and 59.5% for the second quarter.
- * General, administrative and marketing expenses are anticipated to be between 36.5 % and 37.5% of revenues for the second quarter.
- * R&D expenses are expected to approximate between 4.5% and 5.5% of revenues in the second quarter of 2002.
- * Earnings per share are expected to be between \$0.17 and \$0.19 for the second quarter.

Regulatory Affairs Update

In response to recent publicity that may have caused concern among tissue donors and recipients about the safety of preserved human tissue, CryoLife reiterated the benefits of the availability of human tissue for transplants, and the accomplishments of the industry in providing safe and viable solutions in the treatment of various diseases. In many cases, the only viable, life- saving alternative is the availability of preserved human tissue.

Donor screening mandated through various state and federal regulations, as well as voluntary industry practices, has greatly reduced the risk of infectious diseases such as HIV, hepatitis and syphilis. Even with the very stringent recovery procedures, clean room environments and standards for processing human tissues, the fact is that certain soft tissues cannot, at this time, be sterilized without detrimental damage to the allograft. CryoLife complies with current regulatory requirements of the Food and Drug Administration (FDA) in the handling and processing of human tissues. CryoLife is an industry leader in not only continuing to improve its own processing procedures, but also in providing extensive training for tissue bank personnel and implanting physicians.

Recent reports by the Center for Disease Control and Prevention (CDC) on infectious diseases relating to human soft tissue implants have focused greater attention on the industry by state health departments and federal agencies, such as the Food and Drug Administration (FDA). As a result of the incidents reported by the CDC, CryoLife and other tissue banking organizations have undergone investigations and inspections by both the CDC and

the FDA. Since certain human soft tissues cannot currently be sterilized without damage to the tissue, and because sterilization is not an FDA requirement, CryoLife places a prominent "boxed" statement in its Instructions for Use stating that the tissue has been aseptically processed. Further warning requires physicians to consider appropriate prophylactic treatment of the recipient. CryoLife has cooperated with the CDC staff in their information gathering process.

The FDA has conducted extensive inspections of CryoLife. The first was in December 2001 following the death in Minnesota, during which the FDA made no observations or recommendations. All samples taken tested negative for micro-organisms. The second FDA inspection at CryoLife followed a recent report of two heart valve infections. Subsequently, CryoLife received pathology data from the implanting hospitals' own laboratories that clearly demonstrated that there was no evidence of infection in either valve. As part of its recent investigation, the FDA did make a number of observations that do not encompass requirements for significant change to CryoLife practices, but involve efforts to demonstrate the practices in place are better documented and validated. CryoLife believes that implementing the technical procedures to address the observations will enhance its commitment to implant safety. The Company has already conducted several experiments reviewed by FDA personnel that it believes will demonstrate to the agency that the procedures being used by CryoLife are effective and controlled.

CryoLife continues its ongoing commitment to tissue safety by expanding its long-standing quality assurance programs, educational efforts, ongoing training for its staff and those involved in the recovery process as well as providing hands-on training for surgeons and others in the medical community. The incidence of infections occurring with implants of cryopreserved human tissue is dramatically below that experienced with other implants such as mechanical heart valves, pacemakers or synthetic tissue substitute implants.

The Company has also initiated research efforts into potential methods of sterilizing human soft tissue in a manner that would not adversely affect the collagen matrix of the allograft tissue.

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 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. 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.

Forward-Looking Statements. Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes regarding anticipated operating performance and expenditures during the first quarter and full year of 2002 and other matters 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 death of a knee surgery patient and a recent CDC report, potential loss of relationships with tissue providers, 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 when expected, if at all, 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, 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 filing for the year ended December 31, 2001.

Editors Note:

Xenograft - A tissue graft from a non-human species into a human.

In Vivo - In the living body.

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

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