CryoLife, Inc. Management Reviews Operating Events in Teleconference Call Following Release of 3rd Quarter and Nine Month Revenues and Earnings Results

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ATLANTA, Oct. 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 reconstruction grafts, and surgical adhesives, commented on operational events in its teleconference call following release of its revenues and earnings for the third quarter and nine-month period ended September 30, 2001 on October 16, 2001.

Steven G. Anderson, President and Chief Executive Officer, and D. Ashley Lee, Vice President and Chief Financial Officer, CryoLife, Inc., reviewed operational information of interest to both analysts and shareholders. Following are excerpts from the teleconference call:

BioGlue(R) Update

The major event in the third quarter was the unanimous recommendation for the approval of BioGlue for vascular and cardiac repair by the Circulatory System Devices Panel of the Food and Drug Administration (FDA). Final FDA approval is expected in about 30 days. Analysts who follow CryoLife estimate the size of the market for this particular approval to be about $450 to $500 million.

CryoLife anticipates between $10.5 million and $11 million in BioGlue sales in 2001. A number of analysts are projecting BioGlue sales in 2002 at over $20 million.

The Company is currently completing the buildout of new manufacturing facilities that will provide capacity for 2 million cartridges per year. CryoLife plans to submit a Premarket Approval (PMA) supplement to the FDA for BioGlue gel in the second quarter of 2002. This will be followed by another PMA supplement for the BioGlue foam. Additionally, CryoLife anticipates filing for a CE (product certification) Mark for the foam formulation of BioGlue late in the third quarter of 2002.

Another product within the BioGlue family of products is the injectable spinal disc replacement. Animal studies completed in September of this year show outstanding results. The CE Mark application for European distribution of the injectable spinal disc is scheduled for the first quarter of 2002. The Investigational Device Exemption (IDE) submission to the FDA will be filed around mid-year 2002.

The BioGlue technology was recently featured at a Department of Defense (DOD) meeting for use as an adjunct in vascular and cardiac repair to achieve hemostasis. CryoLife is working with several Armed Forces units in developing this particular application.

SynerGraft(R) Technology

Development of CryoLife's SynerGraft technology is designed to provide surgeons with a new family of tissue-engineered products for use in a wide variety of applications.

SynerGraft technology represents a major development in tissue-engineered replacement biologic devices for repair of damaged or diseased human tissue. The technology incorporates the use of animal or human tissues that have been depopulated of host cells to provide a collagen matrix that has normal tissue architecture. This creates a replacement tissue structure similar to its human counterpart that can be repopulated with the recipient's own cells.

This technology has been successfully employed in creating a new tissue- engineered replacement heart valve made from porcine collagen tissue. The SynerGraft heart valve was awarded the CE Mark in early October 2000, allowing for commercial distribution throughout the European Union. To date, the Company has had 17 valves implanted, 12 of which remain implanted. The patient age range for these implants is 8 days old to 71 years.

In August 2001, CryoLife received CE Mark approval for its SynerGraft tissue-engineered vascular graft, created by using bovine tissue, for use as A-V (arteriovenous) access grafts and in peripheral vascular reconstruction. This graft is directed toward patients who have experienced negative reactions from synthetic grafts and as a result require replacement vascular grafts that reduce the risk of infection and provide for long-term functionality. In January 2001, the Company expanded its human vascular graft program to include SynerGraft processed human vascular tissue for domestic A-V access application, distributed under the trade name CryoVein(R)SG

The Company anticipates filing an IDE for the SynerGraft pulmonary heart valve sometime late in the second quarter of 2002 and an IDE for the SynerGraft vascular graft during the first quarter of 2002.

SynerGraft CryoValve(R)SG Update

In February of 2000, the Company began processing human heart valves utilizing its SynerGraft (SG) technology. Since then, 538 SG processed valves have been implanted, with none having to be removed due to valve failure. Only about 5% of these valves have shown an increase in PRA (panel reactive antibodies) levels in comparison to an 85% increase in PRA levels for valves processed by standard methods.

CryoLife-O'Brien(R) Heart Valve Update

During the third quarter, the Company filed a PMA for the CryoLife-O'Brien stentless porcine heart valve. The PMA was filed without a preceding IDE because of the extensive experience that the Company has had with over 4,000 human implants around the world since 1990. A review was performed of 862 patients who have had the CryoLife-O'Brien valve implanted for an average of 2.6 years. It showed that at seven years post implant, 93% of the valves were still implanted, and that at five years post implant, 96% of the valves were still implanted. Data such as this indicates that the

O'Brien stentless valve is comparable to the Medtronic Freestyle and the St. Jude Medical Toronto stentless heart valves. The Company expects to receive the PMA mid-year of 2002.

Inside the Numbers

BioGlue revenues were $2.4 million for the three months ended September 30, 2001, up 46% over the corresponding period in 2000. CryoLife is able to ship BioGlue to over 690 hospitals in the U.S. under the Humanitarian Device Exemption (HDE) for acute thoracic aortic dissection repair. Approximately 69% of BioGlue revenues are generated domestically, with the current 2001 re-order rate at approximately 82%. The remainder of BioGlue revenues, or approximately 31%, is generated internationally.

Cardiac revenues were $8.2 million for the three months, up 4% from the corresponding period in 2000. Cardiac revenues were down 9% year over year in the first quarter and down 5% in the second quarter, indicating an improvement in the third quarter as the Company anticipated. The increase came on a 4% increase in unit shipments. Revenues from SynerGraft treated allograft heart valves represented 27% of total cardiac revenues for the 3rd quarter and 30% of cardiac revenues for the month of September.

Vascular revenues were $6.2 million for the three months, up 19% over the third quarter of 2000 with 6% of vascular revenues generated from SynerGraft processed tissues. The revenue increase came on a 29% 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 for A-V access procedures. Vascular revenues increased 15% year over year for the nine-month period.

Orthopedic revenues were $5.3 million for the three months, up 34% over the corresponding period in 2000. The increase in orthopedic revenues came on a 23% increase in unit shipments. The Company continues to see strength in the area of non-bone tendons for ACL reconstructions and in the area of osteochondral grafts. Additionally, strong increases occurred in orthopedic procurement helping to fuel the growth in orthopedic revenues.

Gross margins in the third quarter were 58%, compared to 57% for the corresponding period in 2000. Gross margins for the nine-month period improved to 57.6% from 55.8% in the previous year's nine-month period. The improvement for the year is due to the increasing importance of BioGlue on the Company's operating results, the improvement in cardiac business which carries higher gross margins than other areas of CryoLife's tissue preservation business, as well as the absence of the OEM business with Horizon Medical.

4th Quarter 2001 Financial Guidance

- BioGlue revenues are expected to be approximately $3 million.
- Total revenues are expected to be between $22.5 million and $23 million.
- Research and development expenses are expected to be between 5% and 6% of revenues.
- Earnings per share are expected to be between $0.13 and $0.14 per share.

2002 Financial Guidance

BioGlue will continue to be the fastest growing portion of the Company's business in 2002. BioGlue revenues will increase to somewhere between $20 million and $23 million. The Company noted that sales levels will be directly correlated to the success of the rollout following the PMA approval for cardiac and vascular repair.

Cardiac revenues will increase somewhere between 9% and 11% for the full year. There will be two primary drivers for growth during 2002. First, the Company anticipates continuation of competitive wins on the supply side being driven primarily by the incorporation of its SynerGraft technology into the Company's cardiovascular and vascular allograft processing, and secondly from the pricing for SynerGraft processed tissues. By the end of 2002, CryoLife expects that 60% of the allograft cardiac revenues will be derived from SynerGraft processed tissues.

Vascular revenues will increase in the low double digits for the full year. The primary catalysts for growth in 2002 will be increased procurement of vascular tissues, as well as increasing acceptance of SynerGraft processed allograft femoral veins and arteries for dialysis access.

Orthopedic revenues will increase over 20% year over year. The Company believes growth will result from increased procurement of tissues, as well as the continuing growing acceptance of both non-bone tendons and preserved osteoarticular grafts. Additionally, CryoLife will begin processing tissues for areas outside of those targeted for the reconstruction of the knee.

International sales from SynerGraft porcine-based heart valves are expected to be between $1.2 million and $1.8 million for the full year. Sales related to clinical studies to be conducted throughout Europe during the year, as well as other commercial sales, will drive growth next year.

International sales from SynerGraft vascular grafts are expected to be between $800,000 and $1.1 million next year. The sales of these grafts will result from the CE Mark received earlier this year for the use of this graft for A-V dialysis access and peripheral vascular reconstruction.

The Company expects sales from CryoLife-O'Brien aortic heart valves to be between $1.2 million and $1.5 million for the full year. CryoLife anticipates that during the third quarter of 2002, it will receive a PMA approval to distribute this valve in the U.S.

Additional guidance for 2002 is as follows:

- Gross margins should improve to be between 59% and 60% of revenues.
- General, administrative and marketing expenses are expected to be between 36% and 36.5% of revenues.
- Research and Development expenses are expected to be between 5% and 6% of revenues.
- Earnings per share will be between $0.74 and $0.80 per share on 20,600,000 weighted average shares outstanding.

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 approved as an adjunct for use in 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 heart valve and the SynerGraft vascular graft, the world's first tissue-engineered heart valve and vascular replacements, and the CryoLife-O'Brien 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 revenues, R & D expenses and earnings per share in the fourth quarter of 2001, anticipated revenues, gross margins, expenses and earnings per share in 2002, sales capacity and estimated market potential for products, 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 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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