CryoLife, Inc. Says Product Diversification Strategy Paying Off

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LAS VEGAS, March 22 /PRNewswire/ -- Steven G. Anderson, President and Chief Executive Officer of CryoLife, Inc. (NYSE: CRY), told a group of investors today that the Company's growth strategy centered on product diversification continues to be successful.

In remarks prepared for delivery at 3 p.m. (PST) during the Banc of America Securities Annual Healthcare Conference being held here, Anderson said, "Our core business revenues for January and February 2000 are on a record-breaking pace. Heart valve processing revenues are up 14% over the same two months in 1999. Vascular processing revenues for the current two months are up 18%, and orthopaedic tissue processing revenues are up 74% as compared to prior periods last year."

The presentation to more than 400 national and international investors in attendance addressed the Company's growth strategy, business elements, and year-to-date revenue results through the end of February. Anderson also said he was comfortable with consensus analyst estimates of $0.11, for the Company's first quarter ending March 31, 2000.

Turning to BioGlue(R), CryoLife's protein-based surgical adhesive that positions CryoLife in the worldwide multi-billion dollar surgical repair and wound closure markets, Anderson reported that BioGlue revenues were up 1459% over the same period last year, reaching $557,000 in the first two months of 2000. BioGlue was commercially introduced in early 1998 when it was awarded the European CE (product certification) mark allowing distribution throughout the European Community for vascular sealing.

"BioGlue is currently being distributed in 35 countries worldwide. The combined market potential for vascular and pulmonary applications in these markets is estimated to be in excess of $500 million," Anderson said.

Domestically, the Food and Drug Administration (FDA), in December of 1999, approved the Company's application for a Humanitarian Device Exemption (HDE) allowing the use of BioGlue as an adjunct in the repair of acute thoracic aortic dissections, a life-threatening condition. Since that FDA approval, the use of BioGlue under the HDE has received approval by 107 Institutional Review Boards (IRBs) for 146 hospitals in the U.S. The Company has targeted 200 hospitals for IRB approval for the year. CryoLife, Inc. has subsequently submitted to the FDA a supplement to its original IDE for an expanded clinical study of BioGlue for use in all vascular repair. The Company is awaiting a reply from the FDA for the supplement's approval.

Addressing new product development, Anderson noted, "CryoLife is in the process of creating a family of tissue-engineered orthopaedic, vascular, and cardiovascular living implantable biologic devices. These new living biologic devices incorporate the use of animal tissue structures that have the potential to become repopulated with recipient cells. The most advanced of these living biological device projects is the SynerGraft(R) heart valve replacement project."

In August of 1999, the first two SynerGraft heart valves were implanted in two patients in Brisbane, Australia, by Dr. Mark O'Brien, a clinical consultant to CryoLife. Neither of these patients has exhibited any type of rejection and both valves were functioning normally six months after implant. Two additional SynerGraft heart valves have been implanted by Dr. O'Brien within the last two weeks. Dr. O'Brien expects his initial clinical study to include a total of ten to twelve SynerGraft implants. CryoLife intends to file an IDE for human testing of the SynerGraft valve in the U.S. during the first half of 2000.

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 Union and approved in Canada for use in vascular and pulmonary sealing and repair. The Company also manufactures CryoLife-O'Brien(R) and CryoLife-Ross(R) stentless porcine heart valves, which are distributed within the European Community.

Statements made in this press release which look forward in time are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include predictions regarding the pace of core business revenues, estimates of first quarter 2000 earnings, estimates of worldwide market potential for BioGlue for vascular and pulmonary applications, the ability of SynerGraft valves to become repopulated with recipient cells, the size of the initial SynerGraft clinical study, and the timing of the filing of an IDE with the FDA for human testing of SynerGraft. These statements involve risks and uncertainties and are based on current expectations and management's estimates; actual results may differ materially. Those risks and uncertainties that could impact these statements include the possibility that the number of Ross procedures being performed will not increase and that revenues from pulmonary allograft valves will not continue at the rate set from January 1, 2000 through March 10, 2000, the possibility that the implanted SynerGraft valve will not repopulate with the cells of the recipient, the risk that the SynerGraft valve will otherwise not perform as expected and will therefore not become an acceptable alternative to currently available implantable valves, the risk that the foregoing or other factors will discourage future implants of SynerGraft valves, the possibility that surgeons may choose not to utilize BioGlue surgical adhesive, the possibility that BioGlue surgical adhesive could have currently unforeseen side effects which could render it undesirable for use in vascular and pulmonary applications, and the risk that BioGlue surgical adhesive could possibly be found not to be effective in reducing bleeding in humans. Additional risks and uncertainties that could affect the forward-looking statements contained herein include 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, 1998.

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

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