



CryoLife, Inc. Hosts Industry Analysts at its Newly Expanded Headquarters, Laboratory, and Manufacturing Facilities

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New 100,000 Square Foot Wing Designed to Accommodate Roll-Out of BioGlue(R) and SynerGraft(R) Product Lines

ATLANTA, Nov 29, 2001 /PRNewswire 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 orthopedic reconstruction grafts, and surgical adhesives, today hosted a meeting of approximately 30 prominent biotechnology and healthcare security analysts and investment advisors at the Company's 200,000 square foot headquarters, laboratories, and manufacturing facilities set on 21 acres in suburban Atlanta, Georgia.

The meeting and presentations highlighted CryoLife's new SynerGraft(R) and BioGlue(R) (PHT) technologies and featured presentations by both corporate officers and medical consultants on new product applications.

Steven G. Anderson, President and Chief Executive Officer, CryoLife, Inc., noted, "The newly added manufacturing facilities and physician's learning center complex coupled with our emphasis on developing two new distinct technologies inherent in SynerGraft and BioGlue PHT are a major part of our overall diversification strategy to improve the availability of human tissue for implant and to expand our focus into medical device markets with an unlimited availability of product supply."

SynerGraft(R) Technology Update

The Company's patented SynerGraft technology represents a major development in tissue-engineered replacement biologic devices for repair of damaged or diseased human tissues. SynerGraft 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 geometry, similar to the human counterpart, that has the potential to repopulate with the recipient's own cells. SynerGraft products presently being manufactured at CryoLife and distributed in international markets the Model # 700 pulmonary heart valve, and the Model # 100 vascular graft for dialysis access.

Anderson announced that there have been a total of 26 SynerGraft heart valves implanted in humans from August 2000 to present. Twenty-one of these valves remain implanted in patients ranging from 8 days old to 71 years. Implants have been performed at medical centers in Australia, Austria, Finland, France, Italy, Norway, and Sweden.

SynerGraft technology products currently being manufactured and cryopreserved for domestic applications include human tissue-based pulmonary heart valve and pulmonary patch tissue, as well as A-V access grafts for dialysis patients. There have been 672 SynerGraft processed cardiac allografts implanted in North America since February 2000. Three of these valves have been explanted. SynerGraft products presently distributed in international markets are porcine tissue-based aortic and pulmonary heart valves and bovine tissue-based vascular grafts.

Protein Hydrogel Technology Update

CryoLife's Protein Hydrogel technology (PHT) opens the door to an array of new materials that could be used in the surgical arena. BioGlue surgical adhesive represented the first PHT product to be commercially introduced into world markets for use in vascular, cardiac, and pulmonary surgeries to assist in achieving hemostasis. BioGlue has been used successfully in over 45,000 patients worldwide.

PHT is based on bovine protein that mirrors an array of amino acids that perform complex functions in the human body and hydrogel, a water-based biomaterial similar to human body tissue. Materials and implantable replacement devices created with PHT have the potential to provide structure, form, and function of the human body. Because of their versatility and ease of application, PHT is being developed for application in repair of denucleated intervertebral discs. Protein hydrogel (BioDisc(TM)) is injected in fluid form into the denucleated disc space that sets up as a pliable support solid to restore disc height and stability while preserving motion. BioDisc employs a unique, minimally invasive delivery system and a dual chamber applicator allowing the surgeon to inject the biomaterial into the void created by removal of the disc material. The new hydrogel disc device sets up in two minutes and achieves maximum strength in three to four minutes.

Phase I of the biomechanical study concluded that the application of PHT technology can restore a denucleated interdiscal void to normal spin function and potentially eliminate lower back pain. Phase II large animal studies confirmed results achieved in Phase I.

Regulatory Affairs/CE Mark Update

James C. Vander Wyk, Ph.D., Vice President, Regulatory Affairs and Quality Assurance, CryoLife, Inc., reported CryoLife will file for an Investigational Device Exemption (IDE) for Premarket Application (PMA) for SynerGraft Model # 700 heart valve and SynerGraft Model # 100 vascular grafts mid-2002.

Vander Wyk added, CryoLife will submit an application for an IDE to the FDA for human clinical trials on BioDisc in 2002. The commercial introduction of BioDisc would represent a major advancement in spinal disc surgical technology and offer orthopedic surgeons, and the more than 320,000 patients in the U.S. that annually undergo spinal disc repair, a potentially more efficient and cost-effective alternative to current disc repair methods. CryoLife will also apply for a CE Mark (European Certification) for BioDisc in mid 2002.

An additional CE Mark will be applied for the general surgery application of BioGlue in early 2002. BioGlue is currently CE Marked for use in cardiac, vascular, and pulmonary repair.

On September 17, 2001, CryoLife announced that the U.S. Food and Drug Administration's (FDA) Circulatory System Devices Panel unanimously recommended approving the Company's BioGlue surgical adhesive as an adjunct to the use of sutures and staples in vascular and cardiac repair to achieve hemostasis. The FDA will review the Panel's recommendation, which is ultimately responsible for market approval decisions. The Company expects the FDA decision before year-end.

Core Business Q4 2001 Financial Guidance Update

Ashley Lee, Chief Financial Officer of CryoLife, indicated that procurement trends remained strong into the fourth quarter and that total sales to date for the fourth quarter are in line with previous guidance.

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular and orthopedic 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(R) 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 revenues and estimated market potential for products and services, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially and significantly, and are subject to various risks and uncertainties. These 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, BioGlue or BioDisc test results will prove less encouraging than current results, that SynerGraft, BioGlue, CryoLife-O'Brien Heart Value, BioDisc 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, 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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