CryoLife Announces Filing and Certification of 10-Q; Revises Previously Announced 2002 Second Quarter Results Due to FDA Order

September 4, 2002

ATLANTA, Sep 4, 2002 /PRNewswire-FirstCall via COMTEX/ -- CryoLife, Inc. (NYSE: CRY), a life-science company involved in the development and commercialization of cryopreserved and manufactured implantable tissues and surgical adhesives, reported that today it filed its 10-Q for the quarter ended June 30, 2002. The document is certified by the Company's CEO and CFO.

CryoLife revised its previously announced 2002 second quarter results due to the U.S. Food and Drug Administration Order it received on August 13, 2002 (the "FDA Order"), which ordered non-valved cardiac, vascular and orthopedic tissue processed since October 3, 2001 by CryoLife to be retained "until it is recalled, destroyed, the safety of the tissues is confirmed, or an agreement is reached with the FDA for its proper disposition ... " CryoLife management determined that the FDA order was a type one subsequent event as defined by generally accepted auditing standards requiring adjustment to the second quarter financial statements as a result of necessary revisions to accounting estimates. In connection with the FDA Order, the Company recorded amounts to provide for the tissue recall, the write-down of deferred preservation costs, and accruals associated with litigation. As a result, revenues for the second quarter ended June 30, 2002 decreased to $23.3 million from a previously reported $25.7 million, and the net loss for the quarter increased to ($5.5) million, or ($0.28) per diluted share, from previously reported net income of $2.8 million, or $0.14 per diluted share. (All per share amounts are reported on an after tax basis).

The estimated impact of the recall, excluding the write down of deferred preservation costs, is a reduction in net income for the second quarter of $1.3 million, or $0.04 per diluted share. This impact includes a $2.4 million reduction in second quarter revenues due to credits to be issued to customers, which generated $1.3 million in gross margins, as well as estimated costs of $75,000 to conduct the recall.

The Company also recorded a pretax non-cash write-down of deferred preservation costs of $10.0 million, or $0.34 per diluted share, to reflect the estimated impairment of deferred preservation costs due to the FDA Order. Such write-down includes all non-valved cardiac, vascular and orthopedic tissues processed between October 3, 2001 and June 30, 2002. The Company also recorded pretax accruals of approximately $1.2 million, or $0.04 per diluted share, to provide for potential settlements and awards associated with outstanding litigation. Such amount represents the Company's aggregate retention levels under its product liability and directors' and officers' insurance policies, as the Company believes that it is now probable that these limits will be met as a result of the FDA Order.

Additionally, the Company anticipates that further charges are expected to be recorded in the third quarter of 2002 as a result of the FDA Order. The estimated impact of the recall is a reversal of $1.0 million in revenues recorded in July and August due to estimated returns of tissue subject to the FDA Order, which were shipped in July and August. Tissues subject to the FDA Order processed during the third quarter through August 14, 2002 approximate $3.9 million.

As of June 30, 2002, deferred preservation costs of tissues not subject to the FDA Order (i.e. tissue processed prior to October 3, 2001) were $829,000 for non-valved cardiac tissues, $7.3 million for vascular tissues, and $4.7 million for orthopedic tissues. Deferred preservation costs for allograft heart valves, which are not subject to the FDA Order, were $8.5 million as of June 30, 2002. The Company is continuing to ship these tissues. Although management believes that the demand for non-valved cardiac, vascular and orthopedic tissues processed prior to October 3, 2001 and all allograft heart valves stored by the Company will be affected by the adverse publicity surrounding the FDA Order, the Company cannot estimate the degree to which these tissues have been impaired. The Company may determine in the future that a substantial write-down of the deferred preservation costs for these tissues is necessary. Management will continue to monitor the Company's progress in satisfying the FDA's requirements and the effect of the FDA Order and the related adverse publicity on the demand for these tissues to determine if additional write-downs of deferred preservation costs are required.

As a result of the FDA Order, Bank of America, the Company's lender, has determined that a materially adverse event has occurred and that the Company is not in compliance with its Term Loan covenants. At present, the Company's lender has elected not to declare an event of default, but has reserved the right to do such under the Term Loan. Therefore, all amounts due under the Term Loan as of June 30, 2002 are reflected as a current liability on the Company's financial statements. Additionally, the Company's lender has declared that the Company is not entitled to any advances under its $10 million line of credit entered into on July 30, 2002.

On September 3, 2002, the Company announced a reduction in employee force of approximately 105 employees. The Company anticipates that severance and related costs will be approximately $625,000, which will be recorded in the third quarter of 2002. As a result of the employee reduction, management anticipates personnel costs will be reduced by approximately $360,000 per month.

The Company continues to assess the impact of the FDA Order on its operating activities. The magnitude and nature of additional charges, if any, resulting from this FDA Order cannot be estimated until the Company has had the opportunity to obtain additional information and further assess the impact of the FDA Order on its business.

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in surgeries throughout the United States and Canada. The Company's BioGlue(R) 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(R) 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 processed by CryoLife using the SynerGraft technology are distributed in the U.S. under the trade name of CryoValve(R)SG.

Forward-Looking Statements

Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur as and when expected, if at all, and, together with the Company's business, are subject to various risks and uncertainties. Such risks and uncertainties include CryoLife's dependence on cryopreservation of human tissue, the possibility that anticipated decreases in the Company's revenues and working capital may be severe, 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 the charges booked in the second quarter due to the FDA Order are based on estimates which may prove to be inaccurate, that the charges for second quarter earnings established to account for the cost of the FDA Order and probable losses related to claims and litigation are based on estimates which may prove to be inaccurate, that future clinical SynerGraft or BioGlue test results will prove less encouraging than current results, the possibility that the SEC investigation could be concluded in a manner adverse to the Company, 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 tissues preserved by the Company or its other products such as BioGlue, competition from other wound closure products, that CryoLife 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 government and legal proceedings against CryoLife will not be resolved in its favor, that the FDA may require the recall of heart valve tissue processed by CryoLife, that CryoLife may be forced to discontinue its tissue processing business due to the FDA Order or subsequent FDA actions, 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 CryoLife and other risk factors detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-Q Filing for the Quarter ended June 30, 2002.

CRYOLIFE, INC.
Unaudited Financial Highlights
(In thousands, except share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2002	2001	2002	2001
Revenues:				
Human tissue preservation services, net	$17,536	$18,765	$37,774	$37,331
Products	5,473	2,789	10,538	5,430
Distribution and grant	255	143	423	368
Total revenues	23,264	21,697	48,735	43,129
Costs and expenses:				
Human tissue preservation services	17,203	7,697	25,266	15,370
Products	1,843	1,423	4,078	2,855
General, administrative and marketing	11,447	8,120	20,925	16,279
Research and development	1,196	1,286	2,349	2,372
Interest expense	196	16	388	16
Interest income	(239)	(576)	(537)	(1,138)
Other (income) expense, net	(16)	(5)	(72)	742
Total Costs and expenses	31,630	17,961	52,397	36,496
Income (loss) before income taxes	(8,366)	3,736	(3,662)	6,633
Income tax expense	(2,844)	1,196	(1,244)	2,123
Net (loss) income	$(5,522)	$2,540	$(2,418)	$4,510
Net (loss) earnings per share:				
Basic	$(0.28)	$0.14	$(0.13)	$0.24
Diluted	$(0.28)	$0.13	$(0.13)	$0.23
Weighted average shares outstanding:				
Basic	19,538	18,780	19,318	18,761
Diluted	19,538	19,622	19,318	19,575
Revenues from:				
Cardiovascular	$7,336	$7,182	$14,644	$ 14,093
Vascular	4,641	6,017	11,658	12,429
Orthopedic	5,559	5,566	11,472	10,809
Total cryopreservation	17,536	18,765	37,774	37,331
BioGlue	5,251	2,631	10,124	5,074
Bioprosthetic valves	222	158	414	356

Distribution and grant	255	143	423	368
Total revenues	$23,264	$21,697	$48,735	$43,129

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

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