UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): NOVEMBER 4, 2004

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

FLORIDA (State or Other Jurisdiction (Commission File Number) of Incorporation)

1-13165

59-2417093 (IRS Employer Identification No.)

1655 ROBERTS BOULEVARD, N.W., KENNESAW, GEORGIA 30144 (Address of principal executive office) (zip code)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (770) 419-3355

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- | | Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- | | Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR
- | | Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- | | Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

The information provided pursuant to this Item 12 is to be considered "filed" under the Securities Exchange Act of 1934 ("Exchange Act") and incorporated by reference into those filings of CryoLife, Inc. ("CryoLife") that provide for the incorporation of all reports and documents filed by CryoLife under the Exchange Act.

On November 4, 2004, CryoLife issued a press release announcing its results for the quarter ended September 30, 2004. CryoLife hereby incorporates by reference

herein the information set forth in its Press Release dated November 4, 2004, a copy of which is attached hereto as Exhibit 99.1. Except as otherwise provided in the press release, the press release speaks only as of the date of such press release and such press release shall not create any implication that the affairs of CryoLife have continued unchanged since such date.

Except for the historical information contained in this report, the statements made by CryoLife are forward-looking statements that involve risks and uncertainties. All such statements are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. CryoLife's future financial performance could differ significantly from the expectations of management and from results expressed or implied in the Press Releases. For further information on other risk factors, please refer to the "Risk Factors" contained in CryoLife's Form 10-K for the year ended December 31, 2003, CryoLife's Form S-3 (Registration No. 333-112673), as filed with the Securities and Exchange Commission ("SEC") and any subsequent SEC filings. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

- (a) Financial Statements.
- (b) Pro Forma Financial Information.
- (c) Exhibits.

Exhibit Number Description
-----99.1 Press Release dated November 4, 2004

2

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, CryoLife, Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CRYOLIFE, INC.

Date: November 4, 2004 By: /s/D. Ashley Lee

Name: D. Ashley Lee

Title: Vice President, Chief Financial Officer and Treasurer

3

EXHIBIT INDEX

Exhibit Number Description

99.1 Press Release dated November 4, 2004

[COMPANY LOGO]

FOR IMMEDIATE RELEASE

CONTACT: JOSEPH T. SCHEPERS

VICE PRESIDENT, CORPORATE COMMUNICATIONS (770) 419-3355

CRYOLIFE REPORTS THIRD QUARTER 2004 FINANCIAL RESULTS

BIOGLUE(R) SALES INCREASED 33% OVER THIRD QUARTER 2003
PROJECTS REVENUE GROWTH AND MARGIN IMPROVEMENT IN 2005
STRONG GROWTH IN ORTHOPAEDIC TISSUE REVENUES
PROGRESS WITH NEW PROTEIN HYDROGEL PRODUCTS

ATLANTA...(NOVEMBER 4, 2004)... CryoLife, Inc. (NYSE: CRY), a biomaterials and biosurgical device company, today reported financial results for the third quarter and first nine months of 2004.

Revenues for the third quarter of 2004 were \$16.1 million compared to \$15.1 million in the third quarter of 2003. The net loss in the third quarter of 2004 was \$6.0 million compared to \$4.7 million in the third quarter of 2003. The net loss in the third quarter of 2004 included a legal liability accrual of \$2.4 million. On a fully diluted basis, net loss per common share for the third quarter of 2004 was \$.26 compared to a loss of \$.24 in the same period of 2003.

Revenues for the first nine months of 2004 were \$46.5 million compared to \$46.7 million in the first nine months of 2003. The net loss in the first nine months of the year was \$16.4 million compared to a net loss of \$25.1 million in the first nine months of 2003. On a fully diluted basis, the net loss per common share was \$.72 in the first nine months of 2004 compared to a net loss of \$1.27 per common share in the same period of 2003.

In the third quarter of 2004, BioGlue(R) sales increased 33% to \$8.9 million compared to \$6.7 million in the third quarter of 2003. U.S. BioGlue sales increased 37% to \$6.9 million in the third quarter of 2004 compared to \$5.0 million in the same period in 2003. International BioGlue sales increased 21% to \$2.0 million in the third quarter of 2004 compared to \$1.7 million in the same period last year. BioGlue revenues are expected to be between \$8.6-\$9.0 million in the fourth quarter of 2004.

"We are pleased with the successful launch of the BioGlue Syringe Delivery Device in the U.S. and Europe. BioGlue sales remain on track to increase at least 25% to \$35.0-\$35.5 million in 2004 from \$27.8 million in 2003," said Steven G. Anderson, CryoLife President and Chief Executive Officer.

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Page 2 of 5

Tissue processing revenues, which include cardiac, vascular, and orthopaedic tissues, were \$7.0 million in the third quarter of 2004 compared to \$8.1 million in the third quarter of 2003. Cardiac tissue processing revenues were \$3.5 million in the third quarter of 2004 compared to \$4.5 million in the third quarter of 2004 compared to \$4.5 million in the third quarter of 2003. Vascular tissue processing revenues were \$2.6 million in the third quarter of 2004 compared to \$3.1 million in the third quarter of 2003. Orthopaedic revenues were \$843,000 in the third quarter of 2004 compared to \$467,000 in the third quarter of 2003.

"Tissue processing revenues increased in the third quarter of 2004 to \$7.0 million from \$6.1 million in the second quarter of 2004. The gross margin significantly improved again to -2\$ in the third quarter of 2004 from -25\$ in the second quarter of 2004 due to processing improvements that were implemented by the Company. Our orthopaedic business has achieved strong revenue increases in each quarter this year and revenues are expected to be \$6.0-\$8.0 million in 2005," stated Anderson.

Total tissue processing revenues are expected to be between \$6.0-\$7.0 million in the fourth quarter of 2004 and \$25.0-\$26.0 million for the full year 2004. Total tissue processing and product revenues are projected to be \$15.0-\$16.5 million in the fourth quarter and \$61.5-\$63.0 million for full year

In the third quarter 2004, general, administrative, and marketing expenses were \$12.1 million, which included an increase in the legal liability accrual of \$2.4 million, compared to \$10.6 million in the third quarter of 2003. In the third quarter of 2004, research and development expenses were \$904,000 as compared to \$823,000 in third quarter of 2003.

For the fourth quarter of 2004, the Company expects general, administrative, and marketing expenses of approximately \$9.5-\$11.0 million and approximately \$41.5-\$43.0 million for the full year 2004. The Company expects research and development expenses to be approximately \$1.0 million in the fourth quarter of 2004 and approximately \$3.7 million in 2004.

The Company expects strong revenue growth and margin improvement in 2005. Guidance for 2005 is the following: BioGlue revenues are expected to be \$40.0-\$42.0 million in 2005. Total tissue processing revenues are expected to be \$32.0-\$37.0 million in 2005. The Company expects tissue processing and product revenues of \$73.0-\$80.0 million in 2005. The Company expects its tissue processing business to have a positive gross margin in the first quarter of 2005. The combined tissue processing and product gross margin is expected to be approximately 45% to slightly more than 50%.

General, administrative, and marketing expenses are expected to be \$41.0-\$45.0 million in 2005. Research & Development is expected to be approximately \$4.0 million in 2005.

The Company's protein hydrogel research and development initiatives include the following:

The Company is developing BioDisc(TM), a spinal disc nucleus repair system, and expects to begin a human feasibility study in the U.K. with initial implants in the first half of 2005. The Company plans to file an IDE for BioDisc with the FDA in the first half of 2005.

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Page 3 of 5

The Company is developing a proprietary, bioresorbable stent based on its protein hydrogel technology, that is designed to open stenotic blood vessels and increase blood flow by providing a contiguous intravascular paving of the arterial walls. These biological stents have been implanted in animals and were found to be patent after removal. The technology is intended to be a long-term solution, which has the potential to allow the arteries to return to normal function, and may have applications in a wide array of medical conditions, such as athlerosclerosis and vulnerable plaque.

In late July, the Company announced that the 2005 Defense Appropriations Conference Report included \$1.0 million to develop BioFoam(TM) for rapid hemostasis in penetrating wounds and severe trauma on the battlefield.

The Company will hold a teleconference call and live web cast at 11:15 a.m. Eastern Standard Time, Thursday, November 4, 2004, to discuss third quarter 2004 results, followed by a question and answer session hosted by Steven G. Anderson, CryoLife President and Chief Executive Officer.

To listen to the live teleconference, please dial 973-582-2749 a few minutes prior to 11:15 a.m. No identification number is required. A replay of the teleconference will be available November 4 through November 10, and can be accessed by calling (toll free) 877-519-4471 or 973-341-3080. The identification number for the replay is 5284237. The live webcast can be accessed by going to the Investor Relations section of the CryoLife website at WWW.CRYOLIFE.COM.

ABOUT CRYOLIFE, INC.

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiovascular and vascular 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 for use in soft tissue repair and approved in Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SG Model #100 vascular graft, which is CE marked for distribution within the European Community.

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. These risks and uncertainties include that the Company's 2004 and 2005 revenues and expenses may not meet its expectations, that the Company's 2004 and 2005 BioGlue revenues may not meet its expectations, that the demand for CryoLife preserved tissues may not return to prior levels, that the orthopaedic business will not grow as expected in 2005, that the gross margins in the tissue processing business may not improve, that the Company may experience delays in filing its IDE for BioDisc, that the Company's general administrative and marketing expenses may not meet expectations due to higher than expected costs of resolving existing and future litigation, the possibility that the FDA could impose additional restrictions on the Company's operations, require a recall, or prevent the Company from processing and distributing tissues or manufacturing and distributing other products, that FDA regulation of the Company's CryoValve SG and CryoVein SG may require significant time and expense, that the protein hydrogel products under development, such as the bioresorbable stent, may not be commercially feasible, that the Company may not have sufficient borrowing or other capital availability to fund its business, that pending litigation cannot be settled on terms acceptable to the Company, that the Company may not have sufficient resources to pay punitive damages (which are not covered by insurance) or other liabilities in excess of available insurance, the possibility of severe decreases in the Company's revenues and working capital, that to the extent the Company does not have sufficient resources to pay the claims against it, it may be forced to cease operations or seek protection under applicable bankruptcy laws, changes in laws and regulations applicable to CryoLife and other risk factors detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-K filing for the year ended December 31, 2003, and the Company's other SEC filings. The Company does not undertake to update its forward-looking statements.

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

Page 4 of 5

Nine Months Ended

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

Three Months Ended

	September 30,			September 30,				
			2003				2003	
Revenues:								
Products	\$	9,151	\$	6,831		27,213		
Human tissue preservation services				8,097		19,234		
Distribution and grant		12		169		71		526
Total revenues						46,518		
Costs and expenses:								
Products		1,998		1,782		5,839		5,429
Human tissue preservation services		7,124		7,481		23,770		15,084
General, administrative, and marketing		12,127		10,575		31,968		45,706
Research and development		904		823		2,716		2,828
Interest expense		54		87		156		366
Interest income		(71)		(101)				(348)
Other (income) expense, net		(10)		(94)		27		46
Total costs and expenses				20,553		64,275		
Loss before income taxes		(6,008)		(5,456)		(17,757)		(22,381)
Income tax (benefit) expense				(761)		(1,371)		2,669
Net loss	\$	(6,008)		(4,695)		(16,386)		(25,050)
Net loss per share:								
Basic		(0.26)		(0.24)		(0.72)		(1.27)
Diluted	==== \$	(0.26)	\$	(0.24)	=== \$	(0.72)	=== \$	(1.27)
	===		===		===		===	

Basic		23,287	19,701	22,928	19,669
Diluted		23,287	19,701	22,928	19,669
Revenues from:					
Cardiovascular	\$	3,476	\$ 4,547	\$ 9,737	\$ 14,308
Vascular		2,636	3,083	7,771	10,637
Orthopaedic		843	467	1,726	897
Total cryopreservation		6,955	 8,097	 19,234	 25,842
BioGlue			6,694		
Implantable medical devices		237	137	694	335
Distribution and grant		12	 169	 71	 526
Total revenues	\$ ====	16,118	\$ 15,097	\$ 46,518	\$ 46,730
International revenues		2,346	1,951		
Domestic revenues		13,772	 13,146	 39,754	 41,222
Total revenues	\$	16,118	15,097	46,518	\$ 46,730

Page 5 of 5

CRYOLIFE, INC. Financial Highlights (In thousands)

	Unaudited September 30 2004		Audited Dec. 31, 2003		
Cash and cash equivalents and marketable securities, at market	\$	15,193	\$	11,916	
Trade receivables, net		8,938		6,377	
Other receivables, net		1,505		1,865	
Deferred preservation costs, net		8,038		8,811	
Inventories		4,829		4,450	
Total assets		78,525		75,027	
Shareholders' equity		51,620		48,338	