CRYOLIFE INC Form DEFA14A May 01, 2007

# 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): May 1, 2007

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida (State or Other Jurisdiction of Incorporation) 1-13165 (Commission File Number) **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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### **Section 2 Financial Information**

#### Item 2.02 Results of Operations and Financial Condition.

On May 1, 2007, CryoLife, Inc. ("CryoLife" or the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2007. CryoLife hereby incorporates by reference herein the information set forth in its Press Release dated May 1, 2007, 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 it shall not create any implication that the affairs of CryoLife have continued unchanged since such date.

The press release includes non-GAAP financial measures, including adjusted non-GAAP net income and earnings per share, and management believes that these non-GAAP financial measures provide a better period-to-period comparison of operational performance.

The information provided pursuant to this Item 2.02 is to be considered "furnished" pursuant to Item 2.02 of Form 8-K and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be deemed incorporated by reference into any of CryoLife's reports or filings with the Securities and Exchange Commission ("SEC"), whether made before or after the date hereof, except as expressly set forth by specific reference in such report or filing.

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 release. Please refer to the last paragraph of the press release for further discussion about forward-looking statements. For further information on risk factors, please refer to "Risk Factors" contained in CryoLife's Form 10-K for the year ended December 31, 2006, as filed with the SEC, and any subsequent SEC filings. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

#### Section 9 Financial Statements and Exhibits. Item 9.01(c) Exhibits.

(a) Financial Statements. Not applicable.

(b) Pro Forma Financial Information. Not applicable.

(c) Shell Company Transactions. Not applicable.

(d) Exhibits.

Exhibit Number

Description

99.1\*

Press release dated May 1, 2007

\* This exhibit is furnished, not filed.

#### 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: May 1, 2007

By: /s/ D. Ashley Lee Name: D. Ashley Lee Title: Executive Vice President, Chief Operating Officer and Chief Financial Officer

Exhibit 99.1

# FOR IMMEDIATE RELEASE

Media Contacts:

D. Ashley Lee Executive Vice President, Chief Financial Officer and Chief Operating Officer Phone: 770-419-3355 Katie Brazel Fleishman Hillard Phone: 404-739-0150

#### CryoLife's First Quarter 2007 Revenues up 26 Percent

Earnings per diluted share of \$0.04; \$0.08 before items; Gross margins up from 55 percent in Q1 2006 to 61 percent in Q1 2007; 2007 revenue guidance raised

ATLANTA, GA... (May 1, 2007)... CryoLife, Inc. (NYSE: CRY), a biomaterials, medical device and tissue processing company, announced today that revenues for the first quarter of 2007 increased 26 percent to \$24.5 million compared to \$19.4 million in the first quarter of 2006. Net income in the first quarter of 2007 was \$1.4 million, and \$0.04 per basic and fully diluted common share, compared to a net loss of (\$1.8) million, and (\$0.08) per basic and fully diluted common share, in the first quarter of 2006.

Excluding a \$686,000 charge related to executive retirement benefits and a \$374,000 charge related to stock-based compensation, adjusted non-GAAP net income for the first quarter of 2007 was \$2.4 million, and \$0.09 per basic and \$0.08 per fully diluted common share. Excluding a \$244,000 charge related to stock-based compensation, and a \$248,000 income tax charge for the adjustment of the income tax valuation related to foreign deferred tax liabilities, the adjusted non-GAAP net loss for the first quarter of 2006 was (\$1.3) million, and (\$0.06) per basic and fully diluted common share.

Steven G. Anderson, president and chief executive officer of CryoLife, Inc., stated, "The Company's return to profitability reflects the results of last year's successful strategic review by the board of directors and management."

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BioGlue<sup>®</sup> revenues were a record \$11.2 million for the first quarter of 2007 compared to \$9.8 million in the first quarter of 2006, an increase of 14 percent. U.S. BioGlue revenues were \$8.3 million and \$7.4 million in the first quarter of 2007 and 2006, respectively. International BioGlue revenues were \$2.9 million and \$2.4 million in the first quarter of 2007 and 2006, respectively.

Tissue processing revenues in the first quarter of 2007 increased 39 percent to \$13.0 million compared to \$9.3 million in the first quarter of 2006. While some of this revenue growth was due to price increases, unit shipments of tissues also rose as the result of an increase in tissue procurement and improved processing yields.

Total product and tissue processing gross margins were 61 percent in the first quarter of 2007 compared to 55 percent in the first quarter of 2006. Tissue processing gross margins were 41 percent in the first quarter of 2007 compared to 28 percent in the first quarter of 2006. The increase in total product and tissue processing gross margins was primarily the result of price increases and an improvement in tissue processing yields.

General, administrative, and marketing expenses in the first quarter of 2007 were \$12.3 million compared to \$11.3 million in the first quarter of 2006. General, administrative, and marketing expenses in the first quarter of 2007 included a \$686,000 charge related to executive retirement benefits and a \$374,000 charge for stock-based compensation. General, administrative, and marketing expenses for the first quarter of 2006 include \$244,000 for stock-based compensation.

R&D expenses were \$1.1 million in the first quarter of 2007 compared to \$909,000 in the first quarter of 2006.

As of April 30, 2007, the Company had approximately \$10.3 million in cash, cash equivalents, marketable securities (at market), and restricted securities, of which \$1.7 million was received from the U.S. Department of Defense as advance funding for the development of protein hydrogel technology for use on the battlefield.

# 2007 Guidance

The Company expects annual product and tissue processing revenues for the full year of 2007 to be between \$92.0 million and \$96.0 million. The Company expects tissue processing revenues between \$47.5 million and \$50.5 million, and BioGlue revenues between \$43.5 million and \$44.5 million, for the full year of 2007.

The Company expects continuing improvements in its gross margins for the full year of 2007 due to more of its tissue processing revenues being generated from cardiac and vascular tissue shipments versus orthopedic tissue shipments.

The Company expects general, administrative and marketing expenses of between \$46.0 million and \$48.0 million, and research and development expenses of between \$4.0 million and \$5.0 million, for the full year of 2007.

#### Webcast and Conference Call Information

The Company will hold a teleconference call and live webcast today at 10:00 a.m. Eastern Time to discuss the financial results followed by a question and answer session hosted by Mr. Anderson.

To listen to the live teleconference, please dial 201-689-8261 a few minutes prior to 10:00 a.m. A replay of the teleconference will be available May 1 - 9, 2007 and can be accessed by calling (toll free) 877-660-6853 or 201-612-7415. The account number for the replay is 244 and the conference number is 237837.

The live webcast and replay can be accessed by going to the Investor Relations section of the CryoLife Web site at <u>www.cryolife.com</u> and selecting the heading Webcasts & Presentations.

#### About CryoLife, Inc.

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiac and vascular surgeries throughout the United States and Canada. The Company's BioGlue<sup>®</sup> Surgical Adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels. BioGlue is also CE marked in the European Community and approved in Canada and Australia for use in soft tissue repair. The Company also distributes the CryoLife-O'Brien<sup>®</sup> stentless porcine heart valve and the SG Model 100 vascular graft, which are 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 statements include those regarding anticipated revenues, expenses and gross margin improvements for 2007 and future growth and financial improvement. 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 recently announced strategic directives may not generate anticipated revenue and earnings growth, the Regeneration Technologies, Inc. ("RTI") exchange and service agreement may not result in some or all of the positive benefits anticipated, that sources of cardiovascular and vascular tissue procurement for RTI may choose not to make that tissue available to the Company or may not be able to meet the Company's tissue processing standards, or the Company may otherwise be unable to replace the orthopedic revenues that it expects to decrease as a result of the RTI agreement with cardiovascular or vascular revenues, that expected cost savings and synergies from the RTI agreement may not occur when and as anticipated, the Company's efforts to continue to increase revenue may not be effective, since their effectiveness is subject to such factors as competitive pressures and tissue availability, that the Company's efforts to develop and introduce new products outside the U.S. may be unsuccessful, that the Company's efforts to improve procurement and tissue processing yields may not continue to prove effective, 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 products and services under development, including BioDisc, may not be commercially feasible, the Company's SynerGraft products may not receive FDA approval when anticipated or at all, 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 decreases in the Company's working capital if cash flow does not improve, 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, 2006, its most recent Form 10-Q, and the Company's other SEC filings. The Company does not undertake to update its forward-looking statements.

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

		Three Months Ended March 31,			
		2007			2006
			(Unau	dited)	
Revenues:					
Human tissue preservation services	\$		961	\$	9,339
Products		11,	395		10,052
Research grants			168		58
Total revenues		24,	524		19,449
Costs and expenses:					
Human tissue preservation services		7,	632		6,763
Products		1.	948		1,923
General, administrative, and marketing		12,	335		11,312
Research and development		1,	058		909
Interest expense			153		147
Interest income			(97)		(107)
Change in valuation of derivative			(45)		56
Other expense (income), net			89		(13)
Total costs and expenses		23,	073		20,990
		1	451		(1.5.4.1)
Earnings (loss) before income taxes		1,	451		(1,541)
Income tax expense	¢	1	97	¢	239
Net income (loss)	\$	1,	354	\$	(1,780)
Effect of preferred stock		(	(243)		(243)
Net loss applicable to common shares	\$	1,	111	\$	(2,023)
Loss per common share:					
Basic	\$	(	0.04	\$	(0.08)
Diluted	\$		0.04	\$	(0.08)
Weighted average common shares outstanding:					
Basic			987		24,758
Diluted		25,	519		24,758
Revenues from:					
Vascular	\$		139	\$	4,044
Cardiovascular			973		3,573
Orthopaedic			849		1,722
Total preservation services		12,	961		9,339
BioGlue		11	163		9,757
Other implantable medical devices			232		295
Shier implaitable medical de 1000					275

Total Products	11,395	10,052
Other	168	58
Total revenues	\$ 24,524	\$ 19,449
Domestic revenues	\$ 21,402	\$ 16,642
International revenues	3,122	2,807
Total revenues	\$ 24,524	\$ 19,449

# CRYOLIFE, INC. Financial Highlights (In thousands)

	March 31, 2007 (Unaudited)	De	ecember 31, 2006
Cash and cash equivalents, marketable securities,	\$ 9,530	\$	8,669
at market, and restricted securities			
Trade receivables, net	13,908		12,553
Other receivables	1,407		1,403
Deferred preservation costs, net	20,623		19,278
Inventories	5,694		5,153
Total assets	83,416		79,865
Shareholders' equity	53,030		52,088

#### CRYOLIFE, INC. Unaudited Reconciliation of Adjusted Net Income (Loss) (In thousands, except share data)

	Three Months Ended March 31,			
		2007		2006
Net income (loss) - as reported	\$	1,354	\$	(1,780)
Adjustments to net (loss) income:				
Executive retirement benefits		686		
Stock-based compensation		374		244
Income taxes				248
Adjusted net income (loss)	\$	2,414	\$	(1,288)
Effect of preferred stock		(243)		(243)
Adjusted net income (loss) applicable to common shares	\$	2,171	\$	(1,531)
		·		
Adjusted weighted average common shares outstanding - Basic		24,987		24,758
Adjusted income (loss) per common share - Basic	\$	0.09	\$	(0.06)
Numerator for adjusted diluted income (loss) per				
common share:				
Adjusted net income (loss)		2,414		(1,288)
Less effect of preferred stock		(243)		(243)
Add back effect of preferred stock		243		
Adjust for effect of derivative (gain) loss in net				
income		(45)		
Adjusted net income (loss) applicable to common stock		2,369		(1,531)
Denominator for adjusted diluted income (loss) per				
common share:				
Basic weighted-average common shares		24,987		24,758
Adjustment for stock options		532		
Adjustment for preferred stock		2,389		
Adjusted weighted average common shares outstanding - Diluted		27,908		24,758
Adjusted income (loss) per common share - Diluted	\$	0.08	\$	(0.06)

# For additional information about the company, visit CryoLife's Web site: <u>http://www.cryolife.com</u>