

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): January 7, 2004

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 offices, including zip code)

(770) 419-3355
(Registrant's telephone number, including area code)

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

Item 5. Other Events and Regulation FD Disclosure.

On January 7, 2004, CryoLife issued a press release announcing its revenues for 2003 and an expected increase in revenues for 2004. CryoLife hereby incorporates by reference herein the information set forth in its Press Release dated January 7, 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 CryoLife#146;s Form 10-K/A for the year ended December 31, 2002, as filed with the Securities and Exchange Commission, and CryoLife#146;s subsequent filings with the Securities and Exchange Commission. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

Item 7. Financial Statements and Exhibits.

- (a) Financial Statements.
Not applicable.
- (b) Pro Forma Financial Information.
Not applicable.
- (c) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated January 7, 2004

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SIGNATURES

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

CRYOLIFE, INC.

Date: January 7, 2004

By: /s/ D.A. Lee

Name: D. Ashley Lee
Title: Vice President, Chief Financial
Officer and Treasurer

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N E W S R E L E A S E

FOR IMMEDIATE RELEASE

Contact: Joseph T. Schepers
Vice President, Corporate Communications
(770) 419-3355

CryoLife Announces Revenues for 2003, Expects Increase in 2004

BioGlue(R) sales increased 33% to \$27.8 million in 2003 compared to 2002

BioGlue(R) sales increased 39% to \$7.8 million in the 4th quarter 2003 compared to 4th quarter 2002

ATLANTA, Jan. 7 /PRNewswire-FirstCall/ — CryoLife, Inc. (NYSE: CRY), a human tissue processing and bio-surgical device company announced today that revenues for 2003 were approximately \$59.6 million and were approximately \$12.8 million for the fourth quarter of 2003. Revenues are expected to increase by approximately 12-18% to between \$66 and \$70 million for full year 2004 and are expected to be between \$14.8 and \$15.5 million for the first quarter of 2004.

BioGlue revenues were approximately \$27.8 million for the full year 2003 and approximately \$7.8 million in the fourth quarter of 2003. “BioGlue revenues increased 33% over full year 2002. We expect full year 2004 BioGlue revenues of between \$32 and \$34 million,” said Steven G. Anderson, CryoLife President and CEO. BioGlue revenues for the first quarter of 2004 are expected to be between \$7.8 and \$8.0 million.

Tissue processing revenues were approximately \$30.8 million for the full year 2003 and approximately \$4.9 million in the fourth quarter of 2003. The Company expects tissue processing revenues to increase by 10-15% to between \$33 and \$35 million in 2004 and expects tissue processing revenues of between \$7.0 and \$7.5 million in the first quarter of 2004. The Company is currently processing and distributing cardiac, vascular, and boned and non-boned orthopaedic tissue.

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Cardiac tissue processing revenues were approximately \$17.1 million for the full year 2003 and approximately \$2.8 million in the fourth quarter of 2003.

Vascular tissue processing revenues were approximately \$12.6 million for the full year 2003 and approximately \$2.0 million in the fourth quarter of 2003.

Orthopaedic tissue processing revenues were approximately \$1.1 million for the full year 2003 and approximately \$166,000 in the fourth quarter of 2003.

CryoLife has an ongoing, comprehensive program to increase the number of tissues available for distribution to patients who require reconstructive cardiac, vascular, and orthopaedic surgeries. This program includes recently implemented initiatives with tissue procurement organizations, operating a newly created, in-house pathology department, and several tissue processing improvements. While the Company expects to realize the positive impact of these initiatives beginning in the second quarter of 2004, there will be an increase in tissue processing costs in the fourth quarter of 2003 and first quarter of 2004.

The Company has now submitted responses to the observations (Form 483) noted by the FDA in October 2003. The submissions include the completed validation report for its anti-microbial solution. On November 3, 2003 CryoLife submitted a 510K premarket notification to the FDA for decellularized, SG processed heart valves. The initial FDA review period is ninety days from this submission date.

The company has not completed the preparation of its 2003 financial statements and additional definitive information with respect to 2003 is not yet available. This press release should not be read to confirm the accuracy of the company’s prior guidance with respect to 2003.

Selling, general, and administrative expenses are expected to be approximately \$42-\$46 million in 2004, while research and development expenses are expected to be approximately \$4 million in 2004. For the first quarter of 2004, the Company expects selling, general, and administrative expenses of approximately \$10 to \$11 million, and expects research and development expenses to be approximately \$1 million. Estimated selling, general, and administrative expenses are based on estimated expenses and reserves for product liability and securities litigation, and actual expenses and reserves may differ significantly from management’s current estimates.

As of December 31, 2003, the Company had approximately \$11 million in cash, cash equivalents, and marketable securities. Additionally, the Company expects to receive tax refunds of approximately \$2.4 million during 2004.

During 2003, the Company resolved, or reached agreements in principle to resolve, 20 product liability cases and currently has 5 lawsuits pending related to the 2002-2003 insurance policy year. Through September 30, 2003, CryoLife recorded pre-tax accruals of \$12.5 million for the uninsured portion of estimated potential legal fees and settlement costs related to the Company’s product liability lawsuits and potential claims that have been incurred, but not reported, which includes 9 claims that were made since the end of the 2002-2003 policy year. The Company is evaluating this accrual to determine if it should be increased or decreased.

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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 for use in soft tissue repair and approved in Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) 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 revenues may not meet its expectations, that gross margins may not improve in 2004, that SG&A expenses may be higher than projected, that demand for CryoLife preserved tissues may not return to prior levels, the possibility that the FDA could impose additional restrictions on the Company's processing and distribution of tissues, require a recall, or prevent the Company from processing and distributing tissues, that the Company's 510k application for SG processed heart valves may require significant time and expense and may not be cleared on a timely basis or at all, that FDA regulation of the Company's CryoValve SG and CryoVein SG may require significant time and expense, that the Company may not have sufficient borrowing or other capital availability to fund its business, that present and future litigation may be resolved only by substantial payments by the Company in excess of available insurance coverage and amounts to be set aside for products liability cases by CryoLife since the outcomes of products liability securities class action and derivative cases are inherently uncertain, 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 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, 2002, 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 Web site: <http://www.cryolife.com>

Contact: Joseph T. Schepers

Vice President, Corporate Communications

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