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): February 6, 2004

CRYOLIFE, INC.

(Exact name of registrant as specified in its charter)

Florida

(State or other jurisdiction of incorporation)

1-13165 59-2417093

(Commission File Number) (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 February 6, 2004, CryoLife issued a press release announcing an update on its 510K premarket notification for CryoValve SG decellularized human heart valves. CryoLife hereby incorporates by reference herein the information set forth in its Press Release dated February 6, 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's Form 10-K, as amended, for the year ended December 31, 2002, as filed with the Securities and Exchange Commission, and CryoLife'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.

Exhibit Number Description

99.1 Press Release dated February 6, 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: February 9, 2004 By: /s/ D. A. Lee

Name: D. Ashley Lee

Title: Vice President, Chief Financial

Officer and Treasurer

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EXHIBIT INDEX

Exhibit Number Description

99.1 Press Release dated February 6, 2004

[COMPANY LOGO]

FOR IMMEDIATE RELEASE

CONTACT: JOSEPH T. SCHEPERS

VICE PRESIDENT, CORPORATE COMMUNICATIONS

(770) 419-3355

CRYOLIFE PROVIDES UPDATE ON 510K PREMARKET NOTIFICATION FOR CRYOVALVE SG DECELLULARIZED HUMAN HEART VALVES

ATLANTA, GA...(February 6, 2004)...CryoLife, Inc. (NYSE: CRY), a human tissue processing and bio-surgical device company, announced today that the Food and Drug Administration ("FDA") has requested additional information be provided to support the 510k premarket notification for the CryoValve SG decellularized human heart valves. The Company plans to work with the FDA to review and address their requirements.

Since February 2003 the Company has been processing tissues without the decellularized SG technology. Revenues from CryoValve SG processed heart valves were not included in the Company's financial guidance for 2004; therefore, the Company's previously announced projection of 12 percent to 18 percent revenue growth remains unchanged.

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(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.

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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 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 over the longer term the Company may not have sufficient capital availability to fund its business, 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.