

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): September 11, 2001

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)

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

Item 9. Regulation FD Disclosure.

On September 11, 2001, The U.S. Food and Drug Administration's (FDA) Circulatory System Devices Panel unanimously recommended to approve CryoLife Inc.'s BioGlue Surgical Adhesive as an adjunct to the use of sutures and staples in vascular and cardiac repair to achieve hemostasis. The Panel's recommendation will be reviewed by the FDA, which is ultimately responsible for market approval decisions.

In December 1999, BioGlue was made available in the U.S. under an FDA approved Humanitarian Device Exemption for use as an adjunct in the repair of acute thoracic aortic dissections, a life-threatening condition. For this indication, BioGlue has received Institutional Review Board (IRB) approval to be shipped to over 600 hospitals in the United States. Internationally, BioGlue is currently approved in 36 foreign countries for use in vascular and pulmonary repair and to provide more effective hemostasis control.

Pursuant to the rules of the Securities and Exchange Commission, the information contained in this report shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and will not be incorporated by reference into any filing of the Company under such Act or the Securities Act of 1933, as amended.

Statements made herein that look forward in time or that express management's beliefs, expectations or hopes regarding future occurrences are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur when expected, if at all, and are subject to various risks and uncertainties. Such risks and uncertainties include the possibility that the FDA may not ultimately approve BioGlue Surgical Adhesive as an adjunct to the use of sutures and staples in vascular and cardiac repair to achieve hemostasis or for the general distribution of BioGlue Surgical Adhesive and other risk factors detailed in the

Company's Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended December 31, 2000.

SIGNATURES

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

CRYOLIFE, INC.

Date: September 13, 2001

By: /s/ Steven G. Anderson

Name: Steven G. Anderson
Title: President, Chief Executive
Officer and Chairman

1395470v1