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 4, 2001

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)

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

Item 9. Regulation FD Disclosure.

The results of two separate medical studies featuring CryoLife's patented SynerGraft(R) technology are expected to be presented on May 5, 2001 by Ronald C. Elkins, M.D. Chief, Section of Thoracic and Cardiovascular Surgery, University of Oklahoma, Health Sciences Center, Oklahoma City, Oklahoma, a director of and a consultant to CryoLife, Inc., at the Fourth Stentless Bioprostheses (Heart Valve) International Symposium, held in San Diego, California.

Dr. Elkins is expected to review the clinical results of patients implanted with human heart valve allografts processed using CryoLife's SynerGraft tissue-engineering technology. The SynerGraft technology centers around the removal of antigens from human and animal tissues leaving a collagen matrix that has the potential to then be repopulated, in vivo, with the patient's own cells. When applied to a heart valve, this creates a replacement tissue structure similar to a native human heart valve with the potential to repopulate with the recipient's own cells. The SynerGraft tissue-engineered human heart valves, called CryoValve(R)SG, implanted in 63 patients were found to reduce immune responses associated with rejection that are signaled by PRA (panel reactive

antibodies) and often experienced by the recipients of transplanted tissues. These valves may therefore be appropriate for patients who have experienced previous immune response to allograft valve implants and for patients who may have immunodeficiencies.

In a second presentation before the same group, Dr. Elkins is expected to review animal studies on the viability of SynerGraft technology-treated sheep heart valves for cellular remodeling. The initial results indicated that the valves implanted in sheep were repopulated with the recipients' cells following implantation.

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 SynerGraft-treated heart valves will not have the expected long-term functionality, repopulate with human recipient cells or reduce immune response, that future clinical SynerGraft test results will prove less encouraging than current results, that SynerGraft regulatory submissions will not be ready when planned or that anticipated regulatory approvals will not be obtained on a timely basis, if at all, 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: May 4, 2001

By: /s/ Steven G. Anderson
---
Name: Steven G. Anderson
Title: President, Chief Executive Officer and Chairman