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CRYOLIFE INC
Form 8-K
September 06, 2002

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 5, 2002

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.

On September 5, 2002, CryoLife, Inc. reached an agreement with the U.S. Food and Drug Administration ("FDA") modifying the FDA's August 13, 2002 Order for Retention, Recall, and/or Destruction. The agreement permits the company to immediately resume processing and limited distribution of its life-saving and limb-saving non-valved cardiac and vascular tissues. It allows CryoLife to distribute existing and newly processed non-valved cardiac conduits and patches, saphenous veins, femoral veins and arteries, and aorto-iliac arteries for specified medically urgent uses when alternative treatments have been exhausted or are unavailable. The Company estimates that most of the covered tissue under its control is used by surgeons under the conditions permitted by the agreement. More information about the agreement is contained in CryoLife's press release dated September 6, 2002, which is incorporated by reference herein and attached

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as Exhibit 99.1. A copy of the agreement is attached hereto as Exhibit 10.38.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS.

(a) Financial Statements.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Exhibits.

| Exhibit Number ----- | Description ----- |
|-------------------------|---|
| 10.38 | September 5, 2002 Letter Agreement between CryoLife and FDA permitting limited distribution of certain tissues subject to August 13, 2002 FDA Order |
| 99.1 | September 6, 2002 Press Release regarding Letter Agreement with FDA |

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: September 6, 2002

By: /s/ D. Ashley Lee

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

EXHIBIT INDEX

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