CRYOLIFE INC
Form 8-K
February 01, 2013

UNITED STATES
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): January 30, 2013

CRYOLIFE, INC.
(Exact name of registrant as specified in its charter)

Florida	1-13165	59-2417093
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1655 Roberts Boulevard, N.W., Kennesaw, Georgia 30144
(Address of principal executive office) (zip code)

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

q Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 8 Other Events

Item 8.01 Other Events.

On January 30, 2013, CryoLife, Inc. (the "Company") received a warning letter ("Warning Letter") dated January 29, 2013 from the Atlanta District Office of the Food and Drug Administration ("FDA"). As previously disclosed by the Company in its Form 10-Q for the Quarter ended September 30, 2012, on October 16, 2012 the Company received a Form FDA 483 Notice of Inspectional Observations from the FDA (the "483") related to our processing, preservation, and distribution of human tissue and the manufacture of our medical devices. The 483 followed a routine quality system inspection of the Company's facilities by the FDA during the period September 17, 2012 to October 16, 2012. Following the receipt of the 483, the Company provided written responses to the FDA detailing proposed corrective actions and immediately initiated efforts to address the FDA's observations.

The Warning Letter relates to certain Observations from the Form 483 that the FDA believes were either inadequately addressed by the Company's responses or for which the FDA required further information to fully assess the Company's corrective actions. The Warning Letter does not restrict production or shipment of the Company's medical devices or processed tissues or require the withdrawal of any device or tissue from the marketplace. Concerns expressed by the FDA include but are not limited to:

- The Company's responses did not identify adequate corrective actions to be taken to ensure that all complaint investigations are adequately conducted.
- The Company's responses did not identify corrective actions to assure that management reviews the Company's quality system on a regular and sufficiently frequent basis.
- The Company's responses did not identify corrective actions to prevent the reoccurrence of deficiencies noted in personnel training.
- The Company should provide additional information describing changes to the Company's disinfectant system as well as additional information concerning its environmental monitoring program.
- The Company's responses did not identify corrective actions to ensure environmental trending reports are generated pursuant to procedures.

The Company takes these matters seriously and intends to respond fully to the FDA's requests. The Company has provided detailed responses to the FDA as to its corrective actions on a monthly basis, and will continue to work expeditiously to address all of the issues that the FDA identified. The Company believes that these matters will not have a material impact on the Company's financial results. However, the Company cannot give any assurances that the FDA will be satisfied with its response to the Warning Letter or as to the expected date of the resolution of the matters included in the Warning Letter. The Warning Letter states that all corrective actions identified in the Company's response letters will be verified during the next inspection.

The Company's belief regarding the impact of the Warning Letter is a forward looking statement within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from our current expectations and are subject to a number of risks. For example, until the violations are corrected to the FDA's satisfaction, the Company may be subject to additional regulatory action by the FDA, including seizure, recalls, injunction and/or civil money penalties. In addition, demand for our services and products could be negatively impacted by adverse publicity with respect to the Warning Letter. Any of these, should they occur, could have a material adverse impact on our business.

SIGNATURES

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

CRYOLIFE, INC.

Date: February 1, 2013

By: /s/ D.A. Lee
Name: D. Ashley Lee
Title: Executive Vice President, Chief Operating Officer and Chief Financial Officer