CRYOLIFE INC
Form 8-K
October 04, 2010

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): September 28, 2010

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)

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

o 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 1 Registrant's Business and Operations

Item 1.01 Entry into a Material Definitive Agreement.

On September 28, 2010, CryoLife, Inc. ("CryoLife") entered into a worldwide distribution agreement (the "Distribution Agreement") and a manufacturing agreement (the "Manufacturing Agreement") with Starch Medical, Inc. ("SMI"). Pursuant to the terms of the agreements, CryoLife will manufacture and distribute PerClot®, a novel polysaccharide hemostatic agent used in surgery.

Under the terms of the agreements, CryoLife receives the exclusive worldwide rights, excluding China, Taiwan, Hong Kong, Macau, North Korea, Iran and Syria, to commercialize PerClot for all approved surgical indications, as defined in the Distribution Agreement, and a license to manufacture the PerClot product. SMI retains exclusive rights to market PerClot with an endoscope for minimally invasive procedures and to market products using the underlying technology in the form of non-powdered absorbable hemostats. The Manufacturing Agreement also authorizes CryoLife to pursue, obtain and maintain regulatory approval for PerClot in the United States, as such regulatory approvals do not yet exist in the United States. If this approval is not obtained prior to October 1, 2017, SMI may terminate CryoLife's rights with respect to United States regulatory approval and require CryoLife to negotiate a reasonable revision to the Agreement.

As part of the transaction, CryoLife agreed to pay SMI $6.75 million in cash and $1.25 million in restricted CryoLife common stock, which includes $1.5 million in prepaid royalties. CryoLife will issue 209,240 shares of restricted common stock in satisfaction of the stock portion of this obligation and has agreed to register the restricted stock upon the request of SMI once the restrictions lapse, beginning in April 2012. CryoLife will pay an additional $2.75 million to SMI if certain U.S. regulatory and other commercial milestones are achieved, and will also pay royalties on sales of PerClot manufactured by CryoLife.

The Distribution Agreement contains certain minimum purchase requirements and has a term of 15 years. Pursuant to the Manufacturing Agreement, which has a perpetual term, CryoLife may begin manufacturing PerClot from plant starch modified by SMI once the technology transfer from SMI has been completed. Following the technology transfer and U.S. regulatory approval, CryoLife may terminate the Distribution Agreement. In addition to allowing CryoLife to manufacture PerClot, the Manufacturing Agreement grants CryoLife a three-year option to purchase the remaining technology from SMI.

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: October 4, 2010

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