

CRYOLIFE INC
Form 8-K
March 05, 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): March 2, 2010

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

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|---|--------------------------|--------------------------------------|
| 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):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- 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))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 7 Regulation FD

Item 7.01 Regulation FD Disclosure.

CryoLife, Inc. (“CryoLife”) is currently party to a nullity action with Tenaxis, Inc. (“Tenaxis”) in Federal Patent Court in the State of Bavaria in the Federal Republic of Germany in which Tenaxis is seeking to invalidate CryoLife’s main BioGlue® patent in Germany. On March 2, 2010, CryoLife received notice from the Federal Patent Court in Munich that CryoLife’s main BioGlue patent in Germany will be declared invalid.

Because we have not received an official court order or pronouncement regarding the patent, but only a brief notice from the Court, we are not yet able to complete a more detailed evaluation of the Court’s ruling. However, we currently expect to appeal the Court’s ruling after we receive the official court order.

We do not believe the pronouncement will have a material impact on our BioGlue revenues in Germany in the near term as Tenaxis has already been selling its product in Germany. We reiterate our previous guidance given in our February 18, 2010 press release, but we note that our net income guidance for 2010 does not assume the charges discussed below, that have been accrued with respect to Tenaxis litigation, will be expensed in 2010.

In the event that this main BioGlue patent is ultimately declared invalid, CryoLife would still be able to sell BioGlue in Germany and the rest of the Europe. The German court’s ruling, if upheld on appeal, would merely prevent CryoLife from suing a party to prevent them from infringing the main BioGlue patent in Germany.

We are also currently unable to determine the impact this ruling will have on our patent infringement suit against Tenaxis in Patent Court in the State of North Rhein-Westphalia in Düsseldorf in the Federal Republic of Germany, although it is likely that our infringement action, originally scheduled for March 30, 2010, will ultimately be postponed or stayed. It is also possible that it could be dismissed.

Both the nullity action and the patent infringement suit are described in our previous filings with the Securities and Exchange Commission, most recently in our annual report on Form 10-K for the year ended December 31, 2009, and the descriptions of both actions described therein are incorporated into this Form 8-K by reference.

We have capitalized legal expenses of approximately \$680,000 associated with the patent nullity action and patent infringement action for this BioGlue patent in Germany. In the event that the Company determines that it is not probable it will ultimately prevail in these matters, it will expense those costs at the time of the determination. We currently do not have enough information to make this determination, as we have not received the final decision from the German Patent Court. We will not be able to determine the likelihood of prevailing on appeal until we are able to review the final decision. We also do not know when we will receive the final decision from the German Patent Court.

The information provided pursuant to this Item 7.01 is to be considered “furnished” pursuant to Item 7.01 of Form 8-K and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be deemed incorporated by reference into any of CryoLife’s reports or filings with the Securities and Exchange Commission, whether made before or after the date hereof, except as expressly set forth by specific reference in such report or filing.

Except for the historical information contained in this report, the statements made by CryoLife are forward-looking statements that involve risks and uncertainties. All such statements are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. These statements include CryoLife's expectation that it will appeal the Court's decision and that the pronouncement will not have a material impact on BioGlue revenues in the near term, as well as CryoLife's guidance for 2010. These statements are subject to a number of risks that are outside of our control, including the potential responses and actions of German courts and judges, Tenaxis and current and potential CryoLife customers. These risks and uncertainties also include that actions by the German Patent Court or other events could cause us to conclude that our main German BioGlue patent is likely to ultimately be held invalid, in which event we would recognize a \$680,000 expense related to capitalized legal costs from the patent nullity and infringement actions associated with this German BioGlue patent, we are significantly dependent on our revenues from BioGlue and are subject to a variety of risks affecting this product, we are subject to stringent domestic and foreign regulation which may impede the approval process of our tissues and products, hinder our development activities and manufacturing processes and, in some cases, result in the recall or seizure of previously cleared or approved tissues and products, our proposed acquisition of Medafor poses a number of risks, Medafor's management has rejected our acquisition offer and refused to negotiate with us, and if we attempt to launch a hostile offer to acquire Medafor we will incur significant expense and may not succeed; in the event such a hostile offer does succeed, , we will not have the benefit of due diligence and may incur unanticipated costs or liabilities, the lawsuit we filed against Medafor regarding our distribution agreement with Medafor may adversely impact our relationship with Medafor and could hinder our distribution of HemoStase or prevent us from distributing HemoStase, healthcare policy changes, including pending proposals to reform the U.S. healthcare system, may have a material adverse effect on us, uncertainties related to patents and protection of proprietary technology may adversely affect the value of our intellectual property, uncertainties related to patents and protection of proprietary technology for products distributed by CryoLife may adversely affect our ability to distribute those products, the tissues we process and our products allegedly have caused and may in the future cause injury to patients, and we have been and may be exposed to product liability claims and additional regulatory scrutiny as a result, we are dependent on the availability of sufficient quantities of tissue from human donors, our CryoValve SGPV post-clearance study may not provide expected results, demand for our tissues and products could decrease in the future, which could have a material adverse effect on our business, the success of many of our tissues and products depends upon strong relationships with physicians, consolidation in the health care industry could lead to demands for price concessions or limits or eliminate our ability to sell to certain of our significant market segments, our existing insurance policies may not be sufficient to cover our actual claims liability, we may be unable to obtain adequate insurance at a reasonable cost, if at all, the loss of any of our sole-source suppliers could have an adverse effect on our revenues, financial condition, profitability, and cash flows, intense competition may affect our ability to operate profitably, regulatory action outside of the U.S. has affected our business in the past and may affect our business in the future, rapid technological change could cause our services and products to become obsolete, continued fluctuation of foreign currencies relative to the U.S. dollar could materially and adversely impact our business, our credit facility limits our ability to pursue significant acquisitions, key growth strategies may not generate the anticipated benefits, there are limitations on the use of our net operating loss carry forwards, our ability to borrow under our credit facility may be limited, we may not be successful in obtaining necessary clinical results and regulatory approvals for services and products in development, and our new services and products may not achieve market acceptance, extensive government regulation may adversely affect our ability to develop and market services and products, investments in new technologies and acquisitions of products or distribution rights may not be successful, if we are not successful in expanding our business activities in international markets, we may be unable to increase our revenues, we are not insured against all potential losses, and natural disasters or other catastrophes could adversely affect our business, financial condition, and profitability, and we are dependent on key personnel. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-Q filing for the quarter ended March 31, 2009, our Form 10-Q filing for the quarter ended June 30, 2009, our Form 10-Q filing for the quarter ended September 30, 2009, our Form 10-K filing for the year ended December 31, 2009 and the Company's other SEC filings. The Company does not undertake to update its forward-looking statements For further information on additional risk factors, please refer to

“Risk Factors” contained in CryoLife’s Form 10-K for the year ended December 31, 2009, as filed with the SEC, and any subsequent SEC filings. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

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: March 5, 2010

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