#### 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): April 28, 2015

# **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 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)

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

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

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#### Section 2 Financial Information

#### Item 2.02 Results of Operations and Financial Condition.

On April 28, 2015, CryoLife, Inc. ("CryoLife" or the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2015. CryoLife hereby incorporates by reference herein the information set forth in its press release dated April 28, 2015, a copy of which is attached hereto as Exhibit 99.1. Except as otherwise provided in the press release, the press release speaks only as of the date of such press release, and it shall not create any implication that the affairs of the Company have continued unchanged since such date.

The information provided pursuant to this Item 2.02 is to be considered "furnished" pursuant to Item 2.02 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. CryoLife's future financial performance could differ significantly from the expectations of management and from results expressed or implied in the press release. Please refer to the last paragraph of the text portion of the press release for further discussion about forward-looking statements. For further information on risk factors, please refer to "Risk Factors" contained in CryoLife's Form 10-K filed for the year ended December 31, 2014 and its subsequent filings with the Securities and Exchange Commission, as well as in the press release attached hereto as Exhibit 99.1. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

#### Section 9 Financial Statements and Exhibits.

#### Item 9.01(d) Exhibits.

(a) Financial Statements. Not applicable.

(b) Pro Forma Financial Information. Not applicable.

(c) Shell Company Transactions. Not applicable.

(d) Exhibits.

Exhibit Number Description 99.1\* Press release dated April 28, 2015

\* This exhibit is furnished, not filed.

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# 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.

By:

#### CRYOLIFE, INC.

Date: April 28, 2015

/s/ D. Ashley Lee

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

# FOR IMMEDIATE RELEASE

**Contacts:** 

**CryoLife** D. Ashley Lee Executive Vice President, Chief Financial Officer and Chief Operating Officer

Phone:

770-419-3355

# **CryoLife Reports First Quarter Results**

### **Recent Highlights:**

- Cleared FDA Warning Letter
- Enrolled first patient in PerClot<sup>®</sup> IDE

ATLANTA, GA – (April 28, 2015) – CryoLife, Inc. (NYSE: CRY), a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced today its results for the first quarter of 2015.

Pat Mackin, Chairman, President and Chief Executive Officer, said, "We recently achieved significant milestones regarding two of our top organizational objectives. First, following a recently completed re-inspection of our facility by the FDA for which we did not receive any 483 observations, the FDA cleared the warning letter that we received in 2013. Additionally, we enrolled the first patient in our PerClot IDE trial, positioning us for pre-market approval and a significant expansion of the PerClot market opportunity in 2017."

Mr. Mackin continued, "Our first quarter revenues decreased due to anticipated temporary reductions in tissue availability resulting from quality enhancements in our tissue processing operations, our continued transition from a distributor to a direct sales model in a major European market, and challenges associated with the continued strengthening of the US dollar. Our results also included continued positive growth from several key product segment categories, including CardioGenesis cardiac laser therapy, HeRO<sup>®</sup>, and PerClot, along with the recent launches of ProCol<sup>®</sup> and PhotoFix<sup>TM</sup>."

Revenues for the first quarter of 2015 decreased 5 percent to \$33.8 million compared to \$35.7 million for the first quarter of 2014. Product revenues were \$19.4 million for the first quarter of 2015, down slightly from \$19.5 million in the first quarter of 2014. Product revenues reflect year-over-year increases in CardioGenesis cardiac laser therapy, HeRO, and PerClot revenues, and the recent launches of ProCol and PhotoFix, offset by decreases in BioGlue revenues due to changes in distribution models and the strengthening dollar. Tissue processing revenues were \$14.4 million for the first quarter of 2015 compared to \$16.3 million for the first quarter of 2014. Tissue processing revenues decreased due to a temporary reduction in tissue availability resulting from quality systems enhancements.

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# The Ruth Group

Nick Laudico / Zack Kubow 646-536-7030 / 7020 nlaudico@theruthgroup.com zkubow@theruthgroup.com Net loss for the first quarter of 2015 was (\$274,000), or (\$0.01) per basic and fully diluted common share, compared to net income of \$1.1 million, or \$0.04 per basic and fully diluted common share, for the first quarter of 2014. First quarter results include a write-off of approximately \$500,000 of PerClot Topical inventory, which is included in cost of goods sold, a \$457,000 impairment of a PerClot Topical intangible asset, and approximately \$470,000 of charges related to severance benefits, both of which are included in general, administrative, and marketing expenses.

| 2015 Financial Guidance Summary |   |   |  |  |  |
|---------------------------------|---|---|--|--|--|
|                                 | Previous  | Current   |  |  |  |
| Total revenues                  | \$151.0 million - \$153.0 million<br>4% - 6% increase | \$148.5 million – \$150.5 million<br>3% – 4% increase |  |  |  |
| Product revenues                | Mid-single digits % increase                          | Mid-single digits % increase                          |  |  |  |
| Tissue processing revenues      | Low-single digits % increase                          | Low-single digits % increase                          |  |  |  |
| Gross margins                   | Approximately 60%                                     | Approximately 60%                                     |  |  |  |
| R&D expenses                    | \$13.0 million - \$14.0 million                       | \$13.0 million - \$14.0 million                       |  |  |  |
| Earnings (loss) per share       | \$(.03) to breakeven                                  | Breakeven   |  |  |  |

The Company's updated 2015 financial guidance is summarized below.

Mr. Mackin stated, "We've revised our top line guidance to take into account the effects of the injunction on PerClot Topical as well as the continued strengthening of the U.S. dollar. On the bottom line, we raised our guidance to reflect, among other things, a reduction in estimated legal expenses resulting from the injunction on PerClot Topical."

Our guidance does not include the impact of any ongoing or future business development activities.

The Company's financial guidance for the full year of fiscal 2015 is subject to the risks described below in the last paragraph of this press release, prior to the financial tables.

# Webcast and Conference Call Information

The Company will hold a teleconference call and live webcast today at 10:00 a.m. Eastern Time to discuss the results followed by a question and answer session hosted by Mr. Mackin.

To listen to the live teleconference, please dial 201-689-8261 a few minutes prior to 10:00 a.m. A replay of the teleconference will be available April 28 through May 4 and can be accessed by calling (toll free) 877-660-6853 or 201-612-7415. The conference number for the replay is 13607118.

The live webcast and replay can be accessed by going to the Investor Relations section of the CryoLife Web site at www.cryolife.com and selecting the heading Webcasts & Presentations.

### About CryoLife, Inc.

Headquartered in suburban Atlanta, Georgia, CryoLife is a leader in the manufacturing, processing, and distribution of implantable living tissues and medical devices used in cardiac and vascular surgical procedures. CryoLife markets and sells products in more than 75 countries worldwide. For additional information about CryoLife, visit our website, www.cryolife.com.

Statements made in this press release and during the accompanying earnings webcast that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made and are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These statements include those regarding: the timing of patient enrollment in our PerClot IDE clinical trial and FDA approval of various indications for PerClot; our expectations regarding the timing, cost, and outcome of the litigation with Medafor, Inc.; the timing and effect on our financial performance of implementing enhanced quality and regulatory controls for our tissue processing business; our plans and expectations related to ProCol and PhotoFix; our plans to transition to a direct sales organization in a major European market and our expectations regarding the benefits of that transition; expansion of the indication for BioGlue in Japan; our 2015 effective tax rate; our expectations regarding foreign exchange rates; and our anticipated performance for the remainder of fiscal 2015. The risks and uncertainties affecting these statements include that: our anticipated performance for fiscal 2015 is subject to the general risks associated with our business, including that our product lines and tissues are subject to general economic conditions, physician and patient acceptance, our ability to obtain reimbursement approvals and maintain and expand reimbursement rates and regulatory approvals; we are significantly dependent on our revenues from BioGlue, which is subject to a variety of risks; we may not receive expanded indications for BioGlue in Japan in the timeframe anticipated or at all, which could materially, adversely affect our ability to realize growth strategies in the Asia-Pacific region and overall: there is no guarantee that the FDA will approve the surgical version of PerClot for distribution in the U.S. in accordance with our expected timeframe, or at all; our PerClot and other clinical trials are subject to a number of risks, including unanticipated reactions or results, delays, and cost overages, and PerClot and other trials may ultimately be unsuccessful; there is no guarantee that we will be able to attain the levels of revenue and profitability that we anticipate for PerClot; as part of our patent litigation against Medafor, Inc. regarding PerClot (the "Medafor Litigation"), we have been enjoined from selling, marketing, and distributing PerClot in the U.S.; there is no guarantee that we will ultimately prevail in the Medafor Litigation, and if we do not prevail, we will continue to be prohibited from selling PerClot in the U.S., or we may have to pay substantial royalties to sell PerClot in the U.S. until Medafor's patent expires; our beliefs regarding the market opportunities for ProCol and PhotoFix may be incorrect, and even if correct, there is no guarantee that we will successfully grow ProCol and PhotoFix sales or fully realize the potential benefits of any clinical advantages of these products; we may not complete the transition to a direct sales organization in a major European territory, or recognize the anticipated benefits of such transition, within our anticipated timeframe, or at all; continued fluctuation of foreign currencies relative to the U.S. dollar could materially, adversely affect our business; and although our guidance does not reflect activities related to ongoing or future business development activities, consummation of material business development transactions during fiscal 2015 could have a significant impact on our business and could cause our actual performance for 2015 to change materially from our current predictions. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2014 and our subsequent filings with the SEC. CryoLife does not undertake to update its forward-looking statements.

# CRYOLIFE, INC. AND SUBSIDIARIES Financial Highlights (In thousands, except per share data)

|  |    | Three Months Ended<br>March 31, |    |        |
|--|----|---------------------------------|----|--------|
|  |    | 2015                            |    | 2014   |
| Revenues:  | •  |                                 | â  |        |
| Products   | \$ | 19,391                          | \$ | 19,455 |
| Preservation services                            |    | 14,440                          |    | 16,276 |
| Total revenues                                   |    | 33,831                          |    | 35,731 |
| Cost of products and preservation services:      |    |                                 |    |        |
| Products   |    | 5,033                           |    | 3,801  |
| Preservation services                            |    | 9,131                           |    | 9,457  |
| Total cost of products and preservation services |    | 14,164                          |    | 13,258 |
| Gross margin                                     |    | 19,667                          |    | 22,473 |
| Operating expenses:                              |    |                                 |    |        |
| General, administrative, and marketing           |    | 18,969                          |    | 18,275 |
| Research and development                         |    | 2,252                           |    | 2,502  |
| Total operating expenses                         |    | 21,221                          |    | 20,777 |
| Operating (loss) income                          |    | (1,554)                         |    | 1,696  |
| Interest expense                                 |    | 30                              |    | 61     |
| Interest income                                  |    | (3)                             |    | (3)    |
| Other expense (income), net                      |    | 192                             |    | (99)   |
| (Loss) income before income taxes                |    | (1,773)                         |    | 1,737  |
| Income tax (benefit) expense                     |    | (1,499)                         |    | 678    |
| Net (loss) income                                | \$ | (274)                           | \$ | 1,059  |
| (Loss) income per common share:                  |    |                                 |    |        |
| Basic  | \$ | (0.01)                          | \$ | 0.04   |
| Diluted  | \$ | (0.01)                          | \$ | 0.04   |
| Dividends declared per common share              | \$ | 0.0300                          | \$ | 0.0275 |
| Weighted-average common shares outstanding:      |    |                                 |    |        |
| Basic  |    | 27,523                          |    | 27,376 |
| Diluted  |    | 27,523                          |    | 28,463 |
|  |    |                                 |    |        |

# CRYOLIFE, INC. AND SUBSIDIARIES Financial Highlights (In thousands)

|                 | Three Months Ended<br>March 31, |    |        |  |
|-----------------|---------------------------------|----|--------|--|
|                 | 2015                            |    | 2014   |  |
| Products:       |                                 |    |        |  |
| BioGlue and     | \$ 14,042                       | \$ | 15,240 |  |
| BioFoam         |                                 |    |        |  |
| PerClot         | 976                             |    | 916    |  |
| CardioGenesis   | 2,137                           |    | 1,684  |  |
| cardiac laser   |                                 |    |        |  |
| therapy         |                                 |    |        |  |
| HeRO Graft      | 1,860                           |    | 1,615  |  |
| ProCol          | 204                             |    |        |  |
| PhotoFix        | 172                             |    |        |  |
| Total           | 19,391                          |    | 19,455 |  |
| products        |                                 |    |        |  |
| Preservation    |                                 |    |        |  |
| services:       |                                 |    |        |  |
| Cardiac tissue  | 6,663                           |    | 7,190  |  |
| Vascular tissue | 7,777                           |    | 9,086  |  |
| Total           | 14,440                          |    | 16,276 |  |
| preservation    |                                 |    |        |  |
| services        |                                 |    |        |  |
| Total revenues  | \$ 33,831                       | \$ | 35,731 |  |
|                 |                                 |    | )      |  |
| Revenues:       |                                 |    |        |  |
| U.S.            | \$ 27,034                       | \$ | 27,432 |  |
| International   | 6,797                           |    | 8,299  |  |
| Total revenues  | \$ 33,831                       | \$ | 35,731 |  |

|  | March 31,<br>2015 |         | December 31,<br>2014 |         |
|--|-------------------|---------|----------------------|---------|
| Cash, cash equivalents, and restricted cash and securities | \$                | 38,241  | \$                   | 39,259  |
| Total current assets                                       |                   | 103,349 |                      | 106,028 |
| Total assets   |                   | 173,203 |                      | 176,157 |
| Total current liabilities                                  |                   | 17,202  |                      | 20,627  |
| Total liabilities  |                   | 24,352  |                      | 27,472  |
| Shareholders' equity                                       |                   | 148,851 |                      | 148,685 |
|  |                   |         |                      | Dense   |

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