ALERE INC. Form 8-K August 08, 2016

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): August 8, 2016

ALERE INC.

(Exact name of registrant as specified in charter)

Delaware 1 16789 04 3565120 (State or Other Jurisdiction of Incorporation) (Commission File Number) (IRS Employer Identification No.)

51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453

(Address of Principal Executive Offices) (Zip Code)

(781) 647-3900

(Registrant's telephone number, including area code)

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))

Item 2.02 Results of Operations and Financial Condition

On August 8, 2016, Alere Inc. (the "Company" or "Alere") issued a press release announcing our financial results for both the fiscal quarter and fiscal year ended December 31, 2015. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under this Form 8-K (including Exhibit 99.1) is "furnished" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 2.06 Material Impairment

On July 12, 2016, the Company filed a Current Report on Form 8-K disclosing that, following a collaborative process with the U.S. Food and Drug Administration, the Company would be initiating a voluntary withdrawal of the Alere INRatio® and INRatio®2 PT/INR Monitoring System and that, at that time, Alere expected to record approximately \$70 — \$90 million of related charges in 2016 relating to this voluntary withdrawal in the United States and related action outside the U.S. On August 8, 2016, the Company filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 Annual Report"). As disclosed in the 2015 Annual Report, due to the fact that the circumstances giving rise to the voluntary withdrawal existed as of December 31, 2015, certain of these charges incurred in connection with the recall were recorded in 2015, rather than 2016. The Company has included this Item 2.06 to update the impairment charges described in our previous Current Report on Form 8-K filed on July 12, 2016.

Specifically, we recorded a charge of approximately \$38 million in the year ending December 31, 2015, of which approximately \$18 million is attributable to the impairment of certain inventory of our INRatio and INRatio2 products; approximately \$3 million is related to the impairment of production equipment; and approximately \$16 million is related to the estimated costs of removing our INRatio and INRatio2 PT/INR Monitoring Systems from the market, including: notifications to users, return and disposal costs and other related amounts. Additionally, our decision to withdraw the INRatio and INRatio2 PT/INR Monitoring Systems impacted the useful life assumptions of certain tangible and intangible assets. As a result of this change in estimate, we recorded approximately \$4 million of accelerated amortization of intangible assets and approximately \$1 million of accelerated depreciation of tangible assets in the year ending December 31, 2015. Finally, during fiscal year 2016, we expect to incur approximately \$16 million of accelerated amortization, approximately \$3 million of accelerated depreciation, and approximately \$2 million of other one-time cash expenditures.

Cautionary Statement Regarding Forward-Looking Statements

This communication contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "bel "estimate," "continue," "goal," "can" or similar words. For example, forward-looking statements include statements regarding: the implementation of remediation plans to address material weaknesses and the effectiveness of such remediation efforts, as well as the expected timing of filings of the Company's future quarterly reports on Form 10-Q and expected future charges related to the voluntary withdrawal of INRatio and INRatio 2 PT/INR Monitoring Systems. A number of important factors could cause actual results of the Company and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, (i) the risk that the proposed merger with Abbott Laboratories ("Abbott") may not be completed in a timely manner or at all; (ii) the failure to receive, on a timely basis or otherwise, the required approval of the proposed merger with Abbott by Alere's stockholders; (iii) the possibility that competing offers or acquisition proposals for Alere will be made; (iv) the possibility that any or all of the various conditions to the consummation of the merger may not be satisfied or waived, including the failure to receive any required regulatory approvals from any applicable governmental entities (or any conditions, limitations or restrictions placed on such approvals); (v) the occurrence of any event, change or other circumstance that could give rise to the termination of the Agreement and Plan of Merger (the "Merger Agreement") among Alere and Abbott pursuant to which Abbott will acquire Alere, including in circumstances which would require Alere to pay a termination fee or other expenses; (vi) the effect of the announcement or pendency of the transactions contemplated by the Merger Agreement on Alere's ability to retain and hire key personnel, its ability to maintain relationships with its customers, suppliers and others with whom it does business, or its operating results and business generally; (vii) risks related to diverting management's attention from Alere's ongoing business operations; (viii) the risk that stockholder litigation in connection with the transactions contemplated by the Merger Agreement may result in significant costs of defense, indemnification and liability, (ix) the risk that Alere fails to file its future Quarterly Reports on Form 10-Q in a timely manner which could, among other things, lead to the acceleration of the maturity of certain of Alere's indebtedness; (x) the possibility that any analysis of revenue recognition for future or past periods uncovers an error or misstatements in revenue recognition which require adjustment which may be material; or material weaknesses in the Company's internal controls over financial reporting; (xi) risks relating to the ongoing investigations by the SEC and the United States Department of Justice; (xiii) the risk that these or other risk factors impact the expected timing of the filing of the Quarterly Report on Form 10-Q for the first and second quarter of 2016; and (xiv) the risk factors detailed in Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (as filed with the SEC on August 8, 2016) and other risk factors identified herein or from time to time in our periodic filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. The Company undertakes no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits. The following exhibit is being furnished herewith this Current Report on Form 8-K.
- 99.1 Press Release dated August 8, 2016

SIGNATURES

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

ALERE INC.

Date: August 8, 2016 By:/s/ James F. Hinrichs

Name: James F. Hinrichs

Title: Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

EXHIBIT DESCRIPTION NO.

99.1 Press Release dated August 8, 2016.