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ALERE INC. Form 8-K July 12, 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): July 11, 2016

ALERE INC.

(Exact name of registrant as specified in charter)

Delaware (State or Other Jurisdiction 1-16789 (Commission File Number) 04-3565120 (IRS Employer

of Incorporation)

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):

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- 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 2.06 Material Impairment.

On July 11, 2016, Alere Inc. (the Company) issued a press release announcing that, following a collaborative process with the U.S. Food and Drug Administration, the Company will be initiating a voluntary withdrawal of the Alere INRatio® and INRatio®2 PT/INR Monitoring System. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Although planning is not finalized, as a result of this voluntary withdrawal in the United States and related action outside the U.S., the Company expects to record approximately \$70 \$90 million of related charges in 2016. Of this amount, the Company expects an immediate non-cash impairment charge of approximately \$20 23 million, which is attributable primarily to write-offs related to the Company s INRatio inventory and production equipment. Additionally, in 2016, the Company expects to incur non-cash charges of approximately \$33 37 million in the form of accelerated depreciation of tangible assets, principally field-based INRatio monitors and accelerated amortization of intangible assets, principally customer lists. Finally, the Company expects to incur one-time cash expenditures during 2016 in connection with this voluntary withdrawal of approximately \$17 30 million largely attributable to the costs of removing the INRatio monitors from the market, including: notifications to users and return and disposal costs and other related amounts.

During the nine months ended September 30, 2015, revenue related to the INRatio[®] and INRatio[®] 2 PT/INR Monitoring System was approximately \$16.3 million.

Forward Looking Statements

This Current Report on Form 8-K 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. These forward looking statements include statements regarding the anticipated charges (cash and non-cash) expected to be incurred in connection with this voluntary recall. These are only estimates and actual results may differ materially from those set forth in this Current Report on Form 8-K. These forward-looking statements are based on information, plans and estimates at the date of this report. We undertake 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 July 11, 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.

By: /s/ Douglas Barry

Date: July 11, 2016

Douglas Barry

Associate General Counsel

EXHIBIT INDEX

EXHIBIT

NO. DESCRIPTION

99.1 Press Release dated July 11, 2016.