

ALERE INC.
Form 8-K
April 17, 2017

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 12, 2017

ALERE INC.
(Exact name of registrant as specified in charter)
Delaware 1 16789 04 3565120
(State or Other Jurisdiction (Commission File Number) (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):

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 4.02 Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

(a) On April 12, 2017 the Audit Committee of the Board of Directors of Alere Inc. (the “Company”), after considering the recommendations of management, concluded that the Company’s financial statements and other financial data as of December 31, 2015 and 2014 and for each of the years ended December 31, 2015, 2014 and 2013, and for each quarterly and year-to-date periods in 2015 and the first three quarterly and year-to-date periods in 2016 (collectively, the “Non-Reliance Periods”) should not be relied upon because of misstatements described below. The misstatements that caused the Company to conclude that its financial statements and other financial information for the Non-Reliance Periods should not be relied upon were related to matters that were initially identified in late-January 2017 and subsequently reviewed and evaluated.

Accordingly, investors, analysts and other persons should not rely upon the Company’s previously released financial statements and other financial data for the Non-Reliance Periods or any press releases, investor presentations or other communications that relate to that information. The Company anticipates that it will file restated financial statements as soon as practicable.

The Audit Committee and management have discussed the matters disclosed in this Item 4.02(a) with PricewaterhouseCoopers LLP, the Company’s independent registered public accounting firm.

Additional Information on Restatement

Based on its review to date of certain aspects of revenue recognition at its South Korean and Japanese locations, the Company preliminarily anticipates that the restatements will relate primarily to certain aspects of revenue recognition at the Company’s South Korean location. Specifically, certain financial information for periods to be presented in the Company’s 2016 Annual Report on Form 10-K will be restated (the “Restatement”) because we had incorrectly recorded certain revenue transactions at our South Korean subsidiary, Standard Diagnostics Inc. (“SD”). We also have preliminarily identified a revenue recognition error related to one transaction at our Japanese location that impacts 2013 and 2012, as further described below.

The Restatement is the result of the failure to correctly apply U.S. GAAP rules regarding the timing of revenue recognition in connection with transactions in which we recognized revenue prior to full satisfaction of all contractual criteria for title and risk of loss passing to the customer. The principal cause of these misstatements in the timing of revenue recognition is attributable to inappropriate conduct at our SD subsidiary. Specifically, these misstatements were primarily the result of conduct and practices initiated by a former employee in the sales organization. The inappropriate conduct and practices involved, among other things, misrepresentation and/or fabrication of documents used to validate revenue recognition that were intentionally concealed from the Company’s senior leadership team and its external auditors at the time of the transactions and during the global revenue recognition assessment conducted as part of the filing of the Annual Report on Form 10-K for the fiscal year ended December 31, 2015. Further, other SD employees (in some cases subordinates of the initiating employee and local finance management responsible for other controls at SD) were involved in the inappropriate conduct or acted to conceal it.

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It is expected that the misstatements identified in the Restatement will not impact the total amount of revenue reported related to any transaction. However, the misstatements will require adjustments to the period in which certain revenues were recognized so that such revenues are recognized in the period in which title and risk of loss had transferred to the buyer, as required by U.S. GAAP revenue recognition rules and our accounting policy related to revenue recognition.

The Restatement is expected to result in the following changes to the previously reported financial information as set forth in the tables below. The following amounts are preliminary, unaudited and are subject to change, and any such changes may be material in amount (certain amounts presented in these tables may not recalculate directly, due to rounding):

		Twelve Months		Twelve Months
Annual Restatement Impact	Nine Months Ended	Ended December 31,	Twelve Months Ended	Months
(in millions)	September 30, 2016	2015	December 31, 2014	Ended
Revenue	\$8	\$ (8)	\$2	December
Operating Income	\$ (1)	\$ (4)	\$0	31, 2013
				\$ (1)
				\$ 1
				Three
				Months
2015 Quarterly Restatement	Three Months Ended	Three Months Ended	Three Months Ended	Ended
Impact (in millions)	March 31, 2015	June 30, 2015	September 30, 2015	December
Revenue	\$ (3)	\$ 1	\$ 1	31, 2015
Operating Income	\$ (1)	\$ 0	\$ 1	\$ (6)
				\$ (4)
		Three Months		
2016 Quarterly Restatement	Three Months Ended	Ended June 30,	Three Months Ended	
Impact (in millions)	March 31, 2016	2016	September 30, 2016	
Revenue	\$9	\$ (1)	\$0	
Operating Income	\$4	\$2	\$ (6)	

The Company's review is also expected to produce a revenue adjustment related to one transaction in Japan, which resulted in the recognition of approximately \$1 million in 2013 instead of 2012, the period in which this revenue was previously reported. We determined that the recognition of revenue in this instance was in error and did not involve any inappropriate conduct by any person. This revenue adjustment is incorporated in the table above. All other revenue adjustments identified to date in connection with the Restatement are due to the SD matter.

The Restatement is expected to also reflect corrections for certain other identified misstatements in 2015 and 2016, many of which had been identified by the Company at the time of the issuance of the financial statements but were not deemed material at the time. These corrections are incorporated into the tables above.

The Company has not yet completed its review of these items, and therefore the information set forth above is preliminary and subject to change. While the Company expects to report the estimated adjustments described herein, there can be no assurance that the final adjustments will not differ materially from the information discussed herein, or that additional misstatements will not be identified.

In Item 9A of the Company's Annual Report on Form 10-K for the year ended December 31, 2015, the Company disclosed that its internal control over financial reporting and its disclosure controls

and procedures were not effective as of December 31, 2015 because of material weaknesses in the Company's internal financial controls over revenue recognition and income taxes. Based on its review to date, the Company expects that, as of December 31, 2016, the material weaknesses relating to revenue recognition that existed at December 31, 2015 will be unremediated, and the Company will have an additional material weakness related to the control environment at SD. The Company is continuing to take steps to implement remedial measures with respect to the revenue recognition material weaknesses. As the Company stated in its previous Item 9A, the remediation plan is subject to ongoing review by the Company's senior management, as well as oversight by the Audit Committee of the Board of Directors. The Company cannot estimate when such remediation may occur, and its initiatives may not prove successful in remediating the material weaknesses. Management may determine to enhance other existing controls and/or implement additional controls as the implementation progresses. Accordingly, the material weaknesses may continue for a period of time.

The misstatements in connection with the Restatement will be reflected in the audited restated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016. The Restatement will also be reflected in Item 6 "Selected Consolidated Financial Data" and the notes to the financial statements, in each case as included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

The Company is working to file its 2016 Form 10-K as soon as practicable. The Company is also working to complete its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 but may need to file a Form 12b-25 in order to obtain additional time beyond the May 15, 2017 filing deadline in which to complete such Quarterly Report on Form 10-Q.

Cautionary Note Regarding Forward-Looking Statements

This report 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. For example, forward-looking statements include statements regarding the filing of financial statements, the content and timing thereof, the anticipated effect of the errors, including the anticipated change in the Company's revenue and operating income, the scope of the errors, and the timing and effectiveness of the Company's remediation plan for the material weaknesses. In some cases, forward-looking statements can be identified by terms such as "may," "will," "intend," "expect," "plan," "believe," "estimate," "predict" or the like. These statements involve risks and uncertainties, and actual results could differ materially from the statements made in this report. Factors that might cause these differences include, but are not limited to, potential delays in the preparation of restated financial statements, the risk that additional information will come to light during the course of the preparation of restated financial statements that alters the scope or magnitude of the restatement, potential reviews, investigations or other proceedings by government authorities, stockholders or other parties, the risk that the Company experiences an acceleration of amounts due under its senior secured credit facility due to the events at SD, the Restatement or the failure to timely file the Annual Report on Form 10-K for 2016 (or that the Company could be required to obtain a waiver under such credit agreement), the risk that the Company's remediation plan will be unsuccessful to prevent or detect additional misstatements and potential delays arising from the Restatement, including a potential inability to prepare financial statements or file periodic reports on a timely basis, which would be a default under the Company's senior secured credit facility and note indentures as well as a violation of the Securities Exchange Act and the listing rules of the NYSE. These and other risk factors are discussed in more detail under the heading "Risk Factors" in Item 1A of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on August 8, 2016. Copies are available through the Company's Investor Relations department and at www.alere.com. The Company does not assume any obligation to update its forward-looking statements to reflect new information and developments.

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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: April 17, 2017 By: /s/ James Hinrichs

James Hinrichs

Executive Vice President and Chief Financial Officer
