ALERE INC.
Form 8-K
May 23, 2012

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): May 22, 2012

Alere Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-16789**	**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)

Registrant s telephone number, including area code: (781) 647-3900

Not Applicable

(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 240.142-12)

¨ 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 8.01 Other Events

Alere Inc. has commenced a recall of certain lots of its Alere Triage meter-based cardiology products as a result of the previously disclosed concerns raised by the U.S. Food & Drug Administration, or FDA, involving the company s quality control method for these products. The recall covers unexpired lots of Alere Triage cardiology products sold in the U.S. that do not satisfy a particular quality control method agreed upon for purposes of the recall, but allows customers who do not have an alternate testing method to continue using these lots. The FDA has agreed that the quality control method agreed upon for purposes of the recall also may be applied to the release and shipment of additional supplies of the Alere Triage meter-based cardiology products through June 30, 2012.

A total of 104 lots manufactured by Alere, constituting 803,000 individual tests, have been recalled. Tests recalled include 287,000 Alere Triage BNP tests, 46,000 Alere Triage D-dimer tests and 470,000 Alere Triage cardiology panel tests. Of the tests recalled, all of the Alere Triage BNP tests and Alere Triage D-dimer tests and 390,000 of the Alere Triage cardiology panel tests were manufactured by Alere during 2011, with the balance manufactured during the first quarter of 2012.

Alere expects to have limited inventory of its Alere Triage cardiology panels available for an unknown duration of time, but it is significantly increasing production in an effort to accommodate customer needs. Alere representatives will be working closely with customers to determine and manage product availability. As previously disclosed, Alere anticipates that its efforts to increase production will lead to increased manufacturing costs, commencing in the second quarter of 2012.

Alere and the FDA are working cooperatively to establish the quality control release method for the Alere Triage cardiology products that will apply after June 30, 2012. The FDA is considering Alere s proposals for an interim quality control method that would remain in effect through September 30, 2012, to be followed by a final revised specification. Alere is currently unable to determine the outcome of these discussion with the FDA or their impact on its future revenues, results of operations, earnings, cash flows or financial condition.

Alere is also working with the FDA to establish the criteria against which a recall of Alere Triage TOX Drug Screen test products previously supplied will be executed, as well as an interim quality control release method and a final quality control release method for future shipments of those products. Alere expects to reach an arrangement for its Alere Triage TOX Drug Screen test products on a basis similar to what is discussed above for its Alere Triage cardiology products. However, because the quality control release methods that Alere must apply to these products in the future have not been determined, Alere is unable to determine the scope of any potential recall or the financial implications of the revised release methods.

Cautionary Note Regarding Forward-Looking Statements

This disclosure 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, believe, estimate, continue or similar words. Readers should carefully r that

contain these words because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. We caution investors that all such forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from any projected results or expectations that we discuss in this report. These risks and uncertainties include uncertainties regarding the occurrence and scope of any product recall, including any recall of the Alere Triage TOX Drug Screen test; potential changes in the FDA s current position, which could lead to additional recalls of Alere Triage products before June 30, 2012, including cardiology products;; our inability to predict the duration of any product shortages; the potential for shortages of products for which our inventory appears adequate; the possibility that revenues and market share could be adversely affected by customer decisions to switch to competing products; uncertainties regarding the extent to which our manufacturing costs will increase as a result of these matters; uncertainties regarding the impact of these matters on the profitability of these products; the impact of the revised release methods on our manufacturing yields; the possibility that our discussions with the FDA could lead to further changes in our release criteria or other manufacturing or quality control procedures, which could result in additional product shortages or additional cost increases; potential enforcement proceedings by the government; potential civil or criminal fines and penalties, including disgorgement of amounts received for any adulterated products; uncertainties regarding the costs of potential investigations of these matters; potential withdrawals of regulatory approvals; the possibility of injunctive relief, which could limit, modify or constrain our ability to manufacture, market and sell our products; possible exclusion from participation in government healthcare programs, such as Medicare and Medicaid; potential product liability litigation; and the other risk factors and uncertainties discussed in Part I, Item 1A entitled Risk Factors of our annual report on Form 10-K, which we filed with the Securities and Exchange Commission, or SEC, on February 29, 2012, or in Part II, Item 1A entitled Risk Factors of our quarterly report on Form 10-Q, which we filed with the SEC on May 10, 2012. Any of these risks and uncertainties could adversely affect our revenues, results of operations, earnings, cash flows and financial condition. We undertake no obligation to update any forward-looking statements.

SIGNATURE

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/ David Teitel
David Teitel
Chief Financial Officer

Dated: May 23, 2012