ALERE INC.
Form 8-K
June 12, 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): June 11, 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 an additional recall of Alere Triage® meter-based products, as a result of the continuing inspection by the U.S. Food & Drug Administration, or FDA, involving the company s quality control methods for these products. Alere has recalled an additional 48 unexpired lots of Alere Triage cardiology products and 36 unexpired lots of its Alere Triage TOX Drug Screen that do not satisfy interim quality control methods agreed upon for purposes of the recall and that will apply to release of the products through September 30, 2012. With respect to the recall of Alere Triage cardiology products, customers who do not have an alternate testing method may continue using the recalled lots. In addition, Alere has recalled 3 lots of Alere Triage cardiology panels due to an elevated frequency of high Troponin readings for low concentration samples. The recalled lots of Alere Triage cardiology products are in addition to the 104 unexpired lots recalled on May 22, 2012.

Alere remains in discussions with the FDA regarding final quality control methods to be in effect for Alere Triage products released after September 30, 2012. Alere does not anticipate that additional product recalls relating to quality control methods will be required as a result of implementing the final quality control methods.

The 51 lots of cardiology tests recalled, which constitutes approximately 650,000 individual tests, includes 456,000 Alere Triage BNP tests, 2,000 Alere Triage D-dimer tests and 192,000 Alere Triage cardiology panel tests. Additionally, the 36 lots of Alere Triage TOX tests recalled constitute approximately 247,000 individual tests. Of the tests recalled, 68,000 of the Alere Triage BNP tests, none of the Alere Triage D-dimer tests, 28,000 of the Alere Triage cardiology panel tests, and 58,000 of the Alere Triage TOX products were manufactured by Alere during Q1 2012, with the balance of each manufactured during 2011.

With respect to the 104 unexpired lots of Alere Triage cardiology products previously recalled on May 22, 2012, which constituted 803,000 individual tests, customers who received 398,000 of such individual tests have sent responses to Alere through June 8, 2012. In these responses, customers have indicated that 317,000 of such individual tests require no action because they were either already used or will continue to be utilized due to the lack of an alternate testing method, with the balance, or 81,000 tests, either requiring refund or replacement.

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 for each facility. As previously disclosed, Alere anticipates that its efforts to increase production will lead to increased manufacturing costs, commencing in the second quarter of 2012.

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 review statements 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 additional product recall; potential changes in the FDA s current position, which could lead to additional recalls of Alere Triage products before September 30, 2012; 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: June 12, 2012