ALERE INC.
Form 8-K
May 10, 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 10, 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

In March 2012, Food & Drug Administration, or FDA, began an inspection of our San Diego facility related to our Alere Triage products. During the inspection, the FDA expressed concern about the alignment between certain aspects of our labeling for the Alere Triage products and the quality control release method that had been in effect prior to the inspection. To our knowledge, the FDA has not yet closed the inspection and has not issued any inspectional observations on Form 483. We are continuing to engage in discussions with the FDA regarding the Alere Triage products and have adopted an interim revised release method which we have been shipping against since early April 2012, with plans to further tighten the release method by September 30, 2012. Although the discussions with the FDA are ongoing, we expect that resolution of the issues raised by the FDA will involve a recall of unexpired lots of Alere Triage products that do not satisfy the revised quality control release method set through such resolution. Based on customer order patterns, expected customer inventory levels and the passage of time between March 31, 2012 and the date of any potential recall, we do not believe that the quantity or value of products that were sold on or before March 31, 2012 that may ultimately be returned will be material and, accordingly, we do not believe that any such recall will have a material impact on our results of operations for the quarter ended March 31, 2012. However, because the quality control release methods that we will apply in the future have not been determined, at this time we are unable to determine the scope of any anticipated recall, including the type and number of products that may be returned. Similarly, we are unable to determine the impact on our ability to ship existing inventory of, and continue to manufacture, Alere Triage products that satisfy such release methods. Consequently, we are also unable to determine whether the anticipated recall or the revised release methods will have a material impact on our revenues, results of operations, earnings, cash flows or financial condition.

Despite these uncertainties, we expect that the modifications necessary to meet any interim and final release methods will lead to increased manufacturing costs for these products. We also anticipate that our ability to supply certain Alere Triage meter-based products may be limited, which may adversely affect revenues from sales of these products. For the first quarter of 2012, revenues from Triage cardiology and toxicology products sold in the U.S. totaled approximately $69 million. Of this amount, approximately $18 million related to BNP products that run on the Beckman Coulter automated platforms and which are not impacted by this matter. Of the remainder, approximately $31 million related to BNP, D-dimer and Toxicology tests, and approximately $20 million related to our cardiology panel tests. The interim and final release methods are expected to adversely impact our ability to supply the market with our cardiology panel tests and may also impact our BNP, D-dimer and Toxicology tests. At this time, we are unable to predict the scope or duration of any product shortages that we may encounter. We anticipate that any effort to substantially increase production to satisfy customer demand in the short term will lead to increased manufacturing costs. Our discussions with the FDA are ongoing and actual future results may be different than our current expectations as, summarized above.

Also, in May 2012, we received a subpoena from the Office of Inspector General of the Department of Health and Human Services. The subpoena seeks documents relating primarily to the quality control testing and performance characteristics of Alere Triage products. We are cooperating with the government and are in the process of responding to the subpoena.

We are unable to predict when these matters will be resolved, what action, if any, the government will take in connection with these matters or what impact, if any, these matters or ensuing proceedings, if any, will have on our financial condition, results of operations or cash flows.

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; 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 method 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 responding to the subpoena or other 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 Item 1A entitled Risk Factors of our Annual Report on Form 10-K, which we filed with the Securities and Exchange Commission on February 29, 2012. Any of these risks and uncertainties could adversely affect our revenues, results of operations, 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 10, 2012