ALERE INC.
Form 8-K
October 03, 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): September 28, 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 2.02 Results of Operations and Financial Condition

Item 8.01 Other Events

On Friday, September 28, 2012, we agreed with the U.S. Food and Drug Administration, or the FDA, on a set of final release specifications for our Alere Triage meter-based products to further align the product release specifications to the package insert. As anticipated, this represents a further tightening of the release specifications for our Triage products.

Consistent with our previously disclosed experience under the interim release specifications in effect since April 2012, we expect that the final release specifications will result in lower manufacturing yields for the Alere Triage products. While we continue to make significant progress in controlling our manufacturing process to improve overall yields, we also continue to expand our manufacturing capacity to address the expected lower yield rates. Previously we had estimated that our capacity would have to expand to 2.7 million tests per month; we now expect that we will have to produce an additional 600,000 tests per month, for a total of 3.3 million tests per month, in an effort to meet demand.

We had previously estimated that our revenues from the sale of Alere Triage Cardiac Panel products in the US would be $4 to $8 million for the third quarter of 2012 and $5 to $12 million for the fourth quarter of 2012. For the third quarter, actual US sales of Cardiac Panel products were approximately $6 million. As a result of the implementation of the final release specifications, we are projecting a shortfall in supply for our Cardiac Panel products for the month of October. However, we expect to be able meet demand from November onwards. Considering this projection, we now estimate that our fourth quarter US Cardiac Panel revenues will be approximately $6 to $8 million.

In the short term, we are also projecting a shortfall in supply for our Alere Triage TOX product line and therefore will be continuing our allocation of this product through Q4. Revenues from sales of our TOX product line in the US were $7 million in each of the second and third quarters of 2012. We anticipate revenues of approximately $4 to $5 million in the fourth quarter of 2012.

Outside the United States, we expect that we will continue to meet demand for all of our Alere Triage meter-based products.

With the capacity increases and the manufacturing process improvements that we are implementing in the fourth quarter of 2012, we currently estimate that the availability for all of our Alere Triage meter-based products in the US will continue to improve during the fourth quarter and 2013. With the incremental availability of product supply, we will continue to seek to move customers who have sought alternative testing methods as a result of limitations in our supply back to the Alere Triage platform.

Additionally, we continue to meet our commitments included in our response to the FDA s Form 483, which we submitted to the FDA in July, and we are committed to implementing the remaining changes in accordance with the timelines set forth in our response.

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 our inability to predict the yield rates for the impacted products; uncertainties regarding our ability to expand production as required to meet demand; 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 continue 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; uncertainties regarding our ability to continue to implement corrective actions necessary to address the FDA s Form 483; 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 reports on Form 10-Q, which we filed with the SEC on May 10, 2012 and August 8, 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: October 3, 2012