Catalent, Inc.
Form 8-K
November 16, 2015

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): November 13, 2015

CATALENT, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-36587	20-8737688
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

14 Schoolhouse Road Somerset, New Jersey (Address of Principal Executive Offices) (732) 537-6200 (Registrant's telephone number, including area code)	8873 (Zip 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:

¨ 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 8.01 Other Events.

On November 13, 2015, a softgel manufacturing facility of Catalent, Inc. ("Catalent") located in Beinheim, France received a notification from l'Agence National de Sécurité du Médicament et des produits de santé ("ANSM"), the primary French pharmaceutical regulatory agency, requiring the suspension of manufacturing at the site. The Beinheim site is one of eleven softgel manufacturing facilities in Catalent's worldwide manufacturing network; Catalent currently has thirty-one sites overall. Catalent takes all matters related to the quality and supply of its products extremely seriously and has been working diligently with all relevant authorities in order to resolve the circumstances leading to the suspension as quickly as possible.

The suspension relates to the occurrence of out-of-place softgel capsules in several product batches that were detected during quality control procedures and removed prior to distribution to patients. Based on its preliminary investigation of this matter, Catalent believes that it is highly unlikely that the capsules could have been misplaced through unintentional human error or from failure of a control process, and that the incidents could be potentially related to a deliberate malicious action by one or more individuals. Catalent has notified the appropriate French law enforcement authorities of the incidents by filing a written complaint. Catalent is also cooperating fully with the ANSM during its inspection and investigation.

In accordance with Catalent's standard continuous process improvement and quality management deviation review systems, facility quality personnel conducted risk assessments of these incidents, including the re-assessment and re-inspection of batches produced during the periods in which these incidents occurred. As part of this process, Catalent has implemented significant additional security and access control measures to limit access to products, and it has been reinforcing all relevant policies and procedures with all production personnel in order to ensure utmost vigilance and compliance with Catalent's established standards. Catalent is also working with ANSM to determine any additional measure to aid in preventing any future occurrence. Catalent has assembled resources and experts from around its global quality and manufacturing organizations to provide full support in expediting the resolution of this issue.

Catalent employs a robust global quality management system throughout all of its operations, which incorporate, as applicable, national and international regulatory and quality standards, including those of ANSM (France), the Food and Drug Administration (USA), ANVISA (Brazil), and the MHRA (UK). Catalent considers its quality standards to be among the most rigorous in the industry. Catalent conducts regular cGMP (current Good Manufacturing Practice) training for all staff, and employees are tested in order to demonstrate competency in their roles.

Catalent is committed to its customers and their patients, and it will promptly take appropriate action to assure compliance in all respects. In addition, Catalent will work closely with regulators, government officials, and customers to minimize any interruption in the supply of medicines to patients. In that regard, Catalent notes that the suspension includes two exceptions: (1) Catalent's customers may apply to ANSM for an exception for medicines that must be available in order to continue treatment for patients, upon a showing that controls will prevent distributed medicines from including any out-of-place capsule, and (2) Catalent's customers may apply to ANSM for an exception for medicines being manufactured on the date of the suspension, upon a showing that their systems, including the systems used to package these medicines for distribution, can detect and exclude any out-of-place capsule.

Catalent is currently unable to predict the duration of the suspension and therefore cannot estimate the effect of the suspension on its results of operations and financial condition.

The forward-looking statements in this Current Report on Form 8-K are based on current expectations of future events. If the assumptions underlying these statements prove inaccurate or unknown risks or uncertainties materialize,

actual results could vary materially from Catalent's expectations and projections. Some of the factors that could cause actual results to differ include those set forth under the caption "Risk Factors" in Catalent's Annual Report on Form 10-K for the fiscal year ended June 30, 2015, filed with the Securities and Exchange Commission. All forward-looking statements speak only as of the date of this filing, and Catalent does not undertake to update any forward-looking statement as a result of new information or future events or developments, except to the extent required by law.

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.

CATALENT, INC.

Date: November 16, 2015

By: /s/ STEVEN FASMAN
Name: Steven Fasman
Title: Senior Vice President and General Counsel