LANNETT CO INC
Form 8-K
October 21, 2016

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): **October 18, 2016**

LANNETT COMPANY, INC.

(Exact Name of Registrant as Specified in Its Charter)

Commission File No. 001-31298

State of Delaware	**23-0787699**
(State of Incorporation)	(I.R.S. Employer I.D. No.)

9000 State Road

Philadelphia, PA 19136

(215) 333-9000

(Address of principal executive offices and telephone number)

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 2.06 MATERIAL IMPAIRMENT

As more fully discussed in Item 8.01 below, on October 18, 2016, Lannett Company, Inc. (the Company) received a notice from the U.S. Food and Drug Administration (FDA) that the FDA will seek to withdraw approval of the Company s Abbreviated New Drug Application (ANDA) for Methylphenidate Hydrochloride (HCl) Extended-Release (ER) Tablets (Methylphenidate). As a result of receiving the FDA notice, the Company will perform an impairment analysis for the value attributable to the Methylphenidate intangible asset recorded in connection with the November 25, 2015 acquisition of Kremers Urban Pharmaceuticals Inc. Management is currently re-evaluating the long-term revenue projections relied upon to perform that fair value assessment. Management believes that its impairment assessment will likely result in an impairment of the intangible asset related to Methylphenidate; however, at this time the Company cannot estimate an amount or range of amounts for such impairment. The Company does not expect the estimated impairment charge will result in any future cash expenditures.

ITEM 8.01 OTHER EVENTS

On October 18, 2016, the Company received a notice from the FDA that it will seek to withdraw approval of the Company s ANDA for Methylphenidate. The FDA s proposal includes an opportunity for the Company to request a hearing on this matter. The Company has until November 17, 2016 to request the hearing and until December 19, 2016 to submit all data, information and analyses upon which the request for a hearing relies.

On October 19, 2016, the Company issued a press release commenting on the FDA proposal regarding Methylphenidate, a copy of which is included as Exhibit 99.1 hereto. This information shall not be deemed filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date of this report, regardless of any general incorporation language in the filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

99.1 October 19, 2016 press release

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

LANNETT COMPANY, INC

By: /s/ Arthur P. Bedrosian
Chief Executive Officer
Date: October 21, 2016

EXHIBIT INDEX

Exhibit:	**Description:**
99.1	October 19, 2016 Press Release