

AKORN INC
Form 8-K
October 29, 2018

**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 29, 2018

Akorn, Inc.

(Exact Name of Registrant as Specified in Charter)

Louisiana

(State or Other Jurisdiction of
Incorporation)

001-32360

(Commission File Number)

72-0717400

(I.R.S. Employer Identification
Number)

**1925 W. Field Court, Suite 300, Lake Forest, Illinois
60045**

(Address of Principal Executive Offices) (Zip Code)

(847) 279-6100

(Registrant's telephone number, including area code)

(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:

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))

]

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Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company []

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

Item 7.01. Regulation FD Disclosure.

On October 29, 2018, Akorn, Inc. ("Akorn") announced that, on October 26, 2018, it received a new Abbreviated New Drug Application (ANDA) approval from the U.S. Food and Drug Administration for Clobetasol Propionate Lotion, 0.05%.

This ANDA was filed in December 2017 and therefore was a first cycle approval. The product is manufactured at Akorn's Amityville, New York manufacturing facility.

According to IQVIA, sales of Clobetasol Propionate Lotion, 0.05% were approximately \$10.7 million for the twelve months ended August 2018.

Clobetasol Propionate Lotion 0.05% is a super-high potent topical corticosteroid formulation indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses only in patients 18 years of age or older.

The information in this Item 7.01, including exhibit 99.1 attached hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits. See attached exhibit index.

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.

Akorn, Inc.

Date: October 29, 2018

By: /s/ Duane A. Portwood
Duane A. Portwood
Chief Financial Officer

Exhibit Index

Exhibit No. Description of Exhibit

99.1 Press release dated October 29, 2018 entitled “Akorn Receives Product Approval.”