AKORN INC
Form 8-K
November 27, 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): November 26, 2018

Akorn, Inc.
(Exact Name of Registrant as Specified in Charter)

Louisiana	**001-32360**	**72-0717400**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

]

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 November 26, 2018 Akorn, Inc. ("Akorn") announced that it received a new Abbreviated New Drug Application (ANDA) approval from the U.S. Food and Drug Administration for diclofenac sodium topical gel, 1%. The product is manufactured at Akorn's Amityville, New York manufacturing facility.

According to IQVIA, the U.S. market for diclofenac sodium topical gel, 1% was approximately $357 million for the twelve months ended September 2018, with three current competitors. The IQVIA market size is not a forecast of our future sales.

Diclofenac sodium topical gel, 1% is indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands. Diclofenac sodium topical gel, 1% has not been evaluated for use on the spine, hip, or shoulder.

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: November 26, 2018

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

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
99.1	Press release dated November 26, 2018, entitled “Akorn Receives Product Approval.”