AKORN INC
Form 8-K
January 09, 2019

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): January 9, 2019

Akorn, Inc.
(Exact name of registrant as specified in charter)

Louisiana	**001-32360**	**72-0717400**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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)

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 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 Securities Act. ¨

Item 7.01 Regulation FD Disclosure

On January 9, 2019, Akorn, Inc. (“Akorn” or the “Company”) issued a press release announcing that it received a warning letter, dated January 4, from the U.S. Food and Drug Administration (FDA) related to an inspection of its Decatur, Illinois manufacturing facility in April and May of 2018. A copy of the press release and the warning letter are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information in this Item 7.01, including exhibits 99.1 and 99.2 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.

Cautionary Statement Regarding Forward-Looking Statements

This filing includes statements that may constitute "forward looking statements", including expectations regarding continued production of product and other statements regarding Akorn's goals and strategy. When used in this document, the words “will,” “expect,” “continue," “believe,” “estimate,” “intend,” “could,” and similar expressions are general intended to identify forward-looking statements. These statements are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. A number of important factors could cause actual results of Akorn and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to: (i) the effect of the Delaware court’s recent decision against Akorn on Akorn’s ability to retain and hire key personnel, its ability to maintain relationships with its customers, suppliers and others with whom it does business, or its operating results and business generally, (ii) the risk that ongoing or future litigation related to the court’s decision may result in significant costs of defense, indemnification and/or liability, (iii) the outcome of the investigation conducted by Akorn with the assistance of outside consultants, into alleged breaches of FDA data integrity requirements relating to product development at Akorn and any actions taken by Akorn, third parties or the FDA as a result of such investigations, (iv) the difficulty of predicting the timing or outcome of product development efforts, including FDA and other regulatory agency approvals and actions, if any, (v) the timing and success of product launches, (vi) difficulties or delays in manufacturing, and (vii) such other risks and uncertainties outlined in the risk factors detailed in Part I, Item 1A, “Risk Factors,” of Akorn’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (as filed with the Securities and Exchange Commission (“SEC”) on February 28, 2018) and in Part II, Item 1A, “Risk Factors,” of Akorn’s Quarterly Reports on Form 10-Q for the periods ended March 31, June 30, and September 2018 (as filed with the SEC on May 2, August 1, and November 6, 2018), and other risk factors identified from time to time in our filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. Akorn undertakes no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press release dated January 9, 2019, entitled "Akorn Receives FDA Warning Letter."
99.2	FDA Warning Letter dated January 4, 2019.

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: January 9, 2019 By: /s/ Duane A. Portwood
Name: Duane A. Portwood
Title: Chief Financial Officer