

CORCEPT THERAPEUTICS INC
Form 8-K
February 05, 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): February 5, 2018

Corcept Therapeutics Incorporated

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

000-50679
(Commission

File Number)
149 Commonwealth Drive

77-0487658
(I.R.S. Employer

Identification Number)

Menlo Park, CA 94025

(Address of principal executive offices, with zip code)

(650) 327-3270

(Registrant's telephone number, including area code)

Not Applicable

(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 (see General Instruction A.2. below):

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 240.14d2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01 Other Events

On February 5, 2018, Corcept Therapeutics Incorporated (the Company) announced that it has received a Paragraph IV Notice Letter advising that Teva Pharmaceuticals USA, Inc. (Teva) submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) seeking authorization from the FDA to manufacture, use or sell a generic version of KORLYM® Mifepristone Tablets, 300 mg (KORLYM®) in the United States.

The Notice Letter contains Paragraph IV certifications against certain of the Company's patents related to KORLYM®, U.S. Patent No. 8,921,348 (the 348 patent) and U.S. Patent No. 9,829,495 (the 495 patent, and together with the 348 patent the KORLYM® patents), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as the Orange Book). The Notice Letter alleges that the KORLYM® patents, the 348 patent with an expiration date in August 2028 and the 495 patent with an expiration date in August 2036, will not be infringed by Teva's proposed product, are invalid and/or are unenforceable. The Company intends to vigorously defend its extensive intellectual property rights related to KORLYM®.

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.

**CORCEPT THERAPEUTICS
INCORPORATED**

By: /s/ G. Charles Robb
Name: G. Charles Robb
Title: Chief Financial Officer and
Secretary

Date: February 5, 2018