INTERCEPT PHARMACEUTICALS INC
Form 8-K
May 31, 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): May 27, 2016

INTERCEPT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35668**	**22-3868459**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
450 W. 15th Street, Suite 505 New York, New York (Address of principal executive offices)		**10011 (Zip Code)**

Registrant's telephone number, including area code: (646) 747-1000

(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 240.14d-2(b))
¨Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On May 27, 2016, Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company") announced that the U.S. Food and Drug Administration ("FDA") has granted accelerated approval to Ocaliva™ (obeticholic acid) for the treatment of primary biliary cholangitis, previously known as primary biliary cirrhosis ("PBC"), in combination with ursodeoxycholic ("UDCA") in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

The full text of the press release has been attached hereto as Exhibit 99.1, and is incorporated by reference into this Item 7.01. In accordance with General Instruction B-2 of Form 8-K, the information set forth in or incorporated by reference into this Item 7.01 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On May 27, 2016, the Company announced that the FDA has granted accelerated approval to Ocaliva for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. Ocaliva is expected to be available to PBC patients in the United States within 7 to 10 days and will be distributed through a specialty pharmacy network.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase. An improvement in survival or disease-related symptoms has not been established. Continued approval of Ocaliva for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated May 27, 2016*

*Exhibit 99.1 is furnished as part of this Current Report on Form 8-K.

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.

INTERCEPT PHARMACEUTICALS, INC.

Dated: May 31, 2016 /s/ Mark Pruzanski
Mark Pruzanski, M.D.

President and Chief Executive Officer