INTERCEPT PHARMACEUTICALS INC
Form 8-K
May 28, 2014

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 28, 2014

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 28, 2014, Intercept Pharmaceuticals, Inc. (“Intercept” or the “Company”) announced that the U.S. Food and Drug Administration (“FDA”) had granted Fast Track designation to obeticholic acid (“OCA”) for the treatment of patients with primary biliary cirrhosis (“PBC”). 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 28, 2014, Intercept announced that the FDA had granted Fast Track designation to OCA for the treatment of patients with PBC. OCA is being developed to treat PBC patients with an inadequate therapeutic response to, or who are unable to tolerate, ursodiol, the only drug currently approved to treat the disease. Intercept intends to complete its New Drug Application (“NDA”) of OCA for PBC in the first half of 2015. The NDA will include data from the Phase 3 POISE trial and two randomized Phase 2 trials of OCA in PBC, all of which met their primary endpoints with high statistical significance.

Established under the FDA Modernization Act of 1997, the Fast Track program is designed to facilitate the development and review of drugs intended to treat serious conditions and fill an unmet medical need. A drug development program with Fast Track designation is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated May 28, 2014.

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.

Date: May 28, 2014 /s/ Mark Pruzanski
Mark Pruzanski, M.D.

President and Chief Executive Officer