INTERCEPT PHARMACEUTICALS INC
Form 8-K
March 17, 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): March 17, 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		**10011**
(Address of principal executive offices)		**(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 March 16, 2014, Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company") announced that its Phase 3 POISE trial of the Company's lead product candidate, obeticholic acid ("OCA"), for the treatment of primary biliary cirrhosis ("PBC") met the trial's primary endpoint. The press release is 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.

Primary Endpoint Met in Phase 3 POISE Trial of OCA in PBC

On March 16, 2014, the Company announced that its international Phase 3 POISE trial of OCA for the treatment of PBC demonstrated that OCA, at both a 10 mg dose and a 5 mg dose titrated to 10 mg, met the trial's primary endpoint of achieving a reduction in serum alkaline phosphatase ("ALP") to below a threshold of 1.67 times upper limit normal, with a minimum of 15% reduction in ALP level from baseline, and a normal bilirubin level after 12 months of therapy. The proportion of patients meeting the POISE trial primary endpoint was 10% in the placebo group, 47% in the 10 mg OCA group and 46% in the OCA titration group (both dose groups $p<0.0001$ as compared to placebo) in an intention-to-treat analysis. The placebo group experienced a mean decrease in ALP from baseline of 5%, compared to a significant mean decrease of 39% in the 10 mg OCA dose group and 33% in the OCA titration group (both dose groups $p<0.0001$ as compared to placebo). In addition, both OCA dose groups met pre-specified secondary endpoints of improving other clinically relevant liver enzymes such as gamma glutamyl transferase (GGT), aspartate transaminase (ALT), alanine transaminase (AST) and total bilirubin (both dose groups $p<0.0005$ as compared to placebo).

Pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 68% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group. Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) patients were in the 10 mg OCA group and only one (1%) patient was in the OCA titration group. Apart from pruritus, the incidence of adverse events was generally similar across both OCA and placebo groups (placebo: 90%, OCA 10 mg: 86%, OCA titration: 89%). Overall, serious adverse events ("SAEs") occurred in 22 (10%) of the patients

and, although there were more SAEs in the OCA treatment groups, none were considered drug-related and there were no apparent patterns in the SAEs. PBC patients typically have significantly elevated HDL cholesterol levels and modest decreases in HDL were observed in both OCA dose groups, similar to those seen in the prior PBC clinical trials. In addition, slight decreases in triglycerides but no change in LDL cholesterol were observed in the OCA dose groups.

The POISE trial results will be presented in greater detail at the upcoming International Liver Congress of the European Association for the Study of the Liver (EASL) in April 2014.

The POISE trial studied the safety and efficacy of a once-daily treatment with OCA in PBC patients with an inadequate therapeutic response to, or who are unable to tolerate, ursodiol. Patients with ALP and bilirubin levels below the thresholds set forth in the POISE trial primary endpoint have been shown in long-term clinical studies to have a significantly lower risk of progressing to liver transplant and death. There were 217 patients randomized to one of three groups in the trial: placebo, 10 mg OCA or 5 mg OCA for six months titrated to 10 mg OCA based on clinical response. 216 patients were dosed.

Patients completing the 12-month double-blind phase of the POISE trial had the option to continue in an open-label, long-term safety extension (“LTSE”) phase for another five years, during which all patients receive OCA treatment with daily doses ranging from 5 mg to 25 mg, as clinically indicated. Of the 198 patients who completed the double-blind phase, more than 95% continued in the LTSE phase of the trial, and approximately 188 patients remained in the LTSE phase of the trial as of February 28, 2014.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated March 16, 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: March 17, 2014 /s/ Mark Pruzanski
Mark Pruzanski, M.D.
President and Chief Executive Officer