INTERCEPT PHARMACEUTICALS INC
Form 8-K
April 30, 2013

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): April 29, 2013

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.)**
18 Desbrosses Street New York, New York		**10013**
(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 1.01 Entry into a Material Definitive Agreement.

On April 29, 2013, Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company") entered into an amendment to the Sponsored Research Agreement with the University of Perugia for the research and development of improvements to the process for synthesizing and supplying gram scale reference standard quantities of OCA, INT-767 and INT-777. Among other matters, the amendment extended the term of the Sponsored Research Agreement until December 31, 2013.

On April 29, 2013, the Company also entered into an amendment to the Consulting and Intellectual Property Agreement with Professor Roberto Pellicciari relating to the Company's research program for OCA, INT-767 and INT-777. Among other matters, the amendment extended the term of the Consulting and Intellectual Property Agreement with Professor Pellicciari until December 31, 2013.

Each of these agreements was extended on the same financial terms as the previously existing agreements.

The foregoing descriptions of the amendments to the Company's agreements with the University of Perugia and Professor Pellicciari are qualified in their entirety by reference to the amendments, copies of which are attached hereto as Exhibits 10.1 and 10.2, respectively, and are incorporated by reference into this Item 1.01.

Item 7.01 Regulation FD Disclosure.

On April 30, 2013, Intercept announced additional details relating to the analysis presented by the Global Primary Biliary Cirrhosis ("PBC") Study Group at the annual meeting of the European Association for the Study of the Liver (EASL) held in Amsterdam on April 24-28, 2013. The press release is attached hereto as Exhibit 99.1 and 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

Analysis of Data from Global Primary Biliary Cirrhosis Study Group

On April 26, 2013, the Global PBC Study Group ("Study Group") presented an analysis of data from over 2,100 PBC patients, among whom 981 patients met Intercept's ongoing Phase 3 POISE trial entry criteria at the time they initiated ursodiol therapy of having an alkaline phosphatase ("ALP") level exceeding 1.67 times upper limit normal ("ULN") and/or an abnormal bilirubin level. The analysis of this cohort of patients from the Study Group further substantiates the validity of the primary endpoint used in POISE as being strongly predictive of adverse clinical outcomes such as liver transplant and death in PBC patients.

The data show (Figure 1) that after one year of ursodiol therapy 58.7% of the patient cohort (n=576/981) had an inadequate therapeutic response, as determined by failure to meet the POISE trial primary endpoint ("POISE endpoint"), which is defined as the achievement of both an ALP level of less than 1.67 times ULN (with a minimum 15% reduction from baseline) together with a normal bilirubin level. In the non-responder group, 30.0% of patients went on to require a liver transplant or die (n=173/576) as compared to 12.6% of patients in the responder group (n=51/405), reflecting a 2.4-fold higher event rate for the non-responders (p=4.5x10E-10).

In order to censor out deaths due to causes other than PBC-associated liver failure, the Study Group analyzed younger subgroups of patients who were under 65 years old (n=789) and under 60 years old (n=666) at the time they initiated ursodiol therapy (Figures 2 and 3) and also met the POISE trial entry criteria. In the under 65 subgroup, 60.5% of patients (n=477/789) failed to meet the POISE endpoint after one year of ursodiol therapy and 28.9% of these patients went on to require a liver transplant or die (n=138/477) as compared to 8.7% of patients in the responder group (n=27/312), reflecting a 3.3-fold higher event rate for the non-responders (p=1x10E-7). In the under 60 subgroup, 61.3% of patients (n=408/666) failed to meet the POISE endpoint after one year of ursodiol therapy and 26.2% of these patients went on to require a liver transplant or die (n=107/408) as compared to 7.4% of patients in the responder group (n=19/258), reflecting a 3.6-fold higher event rate for the non-responders (p=1x10E-7).

The event rate amongst the responders in the under 65 and under 60 subgroups was, respectively, 30.9% and 41.3% lower than the event rate of the responder group in the overall patient cohort that included older patients. Intercept believes that this difference is likely due to the greater exclusion of mortality unrelated to PBC in the younger patient subgroups, resulting in even greater differentiation of the responder and non-responder groups.

The following figures show the results of the analyses conducted by the Study Group as described above.

Figure 1 - All Patients Meeting POISE Entry Criteria (p=4.5x10E-10)

Confidential Responders #events/n=51/405 Non - Responders #events/n=173/576 Events Responders: 12.6% Non - Responders: 30.0%

Figure 2 - Patients Meeting POISE Entry Criteria Under 65 Years of Age (p=1x10E-7)

Responders #events/n=27/312 Non - Responders #events/n=138/477 Events: Responders: 8.7% Non - Responders: 28.9% 2

Figure 3 - Patients Meeting POISE Entry Criteria Under 60 Years of Age (p=1x10E-7)

Responders #events/n=19/258 Non - Responders #events/n=107/408 Events: Responders: 7.4% Non - Responders: 26.2%

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

10.1	Amendment No. 1 to the Sponsored Research Agreement with the University of Perugia, dated April 29, 2013.
10.2	Amendment No. 1 to the Consulting and Intellectual Property Agreement with Professor Roberto Pellicciari, dated April 29, 2013.
99.1	Press release dated April 30, 2013.

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: April 30, 2013 /s/ Mark Pruzanski
Mark Pruzanski, M.D.

President and Chief Executive Officer