INTERCEPT PHARMACEUTICALS INC
Form 8-K
October 01, 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): October 1, 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 8.01 Other Events.

The following updates certain information previously provided by us in our filings made with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended.

Interactions with the U.S. Food and Drug Administration

We intend to request an accelerated approval of our New Drug Application, or NDA, for obeticholic acid, or OCA, based on the use of the primary endpoint of our Phase 3 POISE trial as a surrogate endpoint that is reasonably likely to predict clinical benefit. If the U.S. Food and Drug Administration, or FDA, grants an accelerated approval of our NDA for OCA, we will be required to conduct one or more additional clinical trials post-approval to verify and confirm the clinical benefit predicted by achievement of the surrogate endpoint. This clinical outcomes trial must satisfy the FDA's definition of an adequate and well-controlled trial and is expected to be substantially underway at the time the FDA grants accelerated approval, with completion to follow after receiving accelerated approval. We intend to continue our discussions with the FDA around the analyses of the Global Primary Biliary Cirrhosis (PBC) Study Group and the use of such data in the design of our clinical outcomes trial, which we plan to initiate during the first half of 2014. We currently intend to submit an NDA and a Marketing Authorization Application, or MAA, for OCA in PBC by the end of 2014.

2013 Meeting of the American Association for the Study of Liver Disease (AASLD)

On October 1, 2013, we announced that two analyses by the Global PBC Study Group have been accepted for oral presentation at the AASLD meeting taking place November 1 – 5, 2013 in Washington, D.C. Data from over 3,895 PBC patients collected and pooled by an independent group of 15 academic medical centers across eight countries have been analyzed by the Global PBC Study Group. These analyses are expected to further confirm that the surrogate biochemical endpoint used in the POISE trial (i.e., alkaline phosphatase <1.67 times upper limit normal and normal bilirubin) is strongly predictive of adverse clinical outcomes in PBC patients.

Clinical Trials for New Indications

We plan to initiate a Phase 2 proof-of-concept study of OCA in primary sclerosing cholangitis, or PSC, in 2014. PSC is a disease that causes inflammation and subsequent obstruction of the bile ducts both inside and outside the liver. OCA has been granted orphan drug designation for the treatment of PSC in the United States.

Audit Committee Composition

On September 26, 2013, upon the recommendation of our nominating and governance committee, our board of directors elected Klaus Veitinger, M.D., Ph.D. to serve as a member of our audit committee. Simultaneously with Dr. Veitinger's election, Paolo Fundaro resigned from his position as a member of our audit committee. Mr. Fundaro will remain as a member of our board of directors and will continue to serve as the chairman of our nominating and governance committee. Our board of directors has determined that each member of our audit committee, including Dr. Veitinger, is an independent director under the NASDAQ Marketplace Rules and Rule 10A-3 of the Securities Exchange Act of 1934, as amended.

Collaboration with Servier

We are currently discussing an extension to our collaboration agreement with Les Laboratories Servier and Institut De Recherches Servier, or Servier, which expired on September 30, 2013. If we extend our collaboration with Servier, we anticipate that the ancillary agreements in relation to our Servier collaboration with Professor Roberto Pellicciari and TES Pharma Srl will also be extended for the same duration.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We have sought patent protection in the United States and internationally for OCA, INT-767 and INT-777, and our discovery programs, and any other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

OCA (formerly called INT-747) (first-in-class FXR agonist)

The patent portfolio for OCA contains patents and patent applications directed to compositions of matter, manufacturing methods, and methods of use. As of September 23, 2013, we owned five U.S. patents, four pending U.S. patent applications, and corresponding foreign patents and patent applications. Foreign patents have been granted in Europe (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom) Australia, Canada, China, Israel, Japan and Macau. We expect the composition of matter patents, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2022 (worldwide). It is possible that the term of the composition of matter patent in the United States may be extended up to five additional years under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. Patent term extension may be available in certain foreign countries upon regulatory approval. We expect the other patents and patent applications, if issued, in the portfolio, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2022 to 2033.

INT-767 (dual FXR/TGR5 agonist)

The patent portfolio for INT-767 contains patents and patent applications directed to compositions of matter, manufacturing methods, and methods of use. As of September 23, 2013, we owned two U.S. patents, two pending U.S. patent applications, and corresponding foreign patents and patent applications. Foreign patents have been granted in Australia, China, Israel and Japan. We expect the issued composition of matter patent in the U.S., if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2029. It is possible that the term of the composition of matter patent in the United States may be extended up to five additional years under the provisions of the Hatch-Waxman Act. We expect the foreign composition of matter patents, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2027. Patent term extension may be available in certain foreign countries upon regulatory approval. We expect the other patents and patent applications, if issued, in the portfolio, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2027 to 2033. We have received assignments of rights to the INT-767 patent portfolio from all inventors, with the exception of one inventor. That inventor is contractually obligated to provide an assignment to us. Thus, we believe that we are the owner of the INT-767 patent portfolio by virtue of this contractual obligation as well as the patent assignments we have received.

INT-777 (TGR5 agonist)

The patent portfolio for INT-777 contains patents and patent applications directed to compositions of matter and methods of use. As of September 23, 2013, we owned three U.S. patents, two pending U.S. patent applications, and corresponding foreign patents and patent applications. Foreign patents have been granted in Australia, Eurasia,

Europe, Japan, Mexico and South Africa. We expect the composition of matter patent in the United States, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2030. It is possible that the term of the composition of matter patent in the United States may be extended up to five additional years under the provisions of the Hatch-Waxman Act. We expect the foreign composition of matter patents, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire beginning in 2028. Patent term extension may be available in certain foreign countries upon regulatory approval. We expect the other patents and patent applications, if issued, in the portfolio, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2028 to 2029.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For

example:

- others may be able to develop a platform similar to, or better than, ours in a way that is not covered by the claims of our patents;

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

- we might not have been the first to make the inventions covered by our pending patent applications;

- we might not have been the first to file patent applications for these inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies;

- any patents that we obtain may not provide us with any competitive advantages;

- we may not develop additional proprietary technologies that are patentable; or

· the patents of others may have an adverse effect on our business.

As of September 23, 2013, we were the owner of record of over 50 issued or granted U.S. and non-U.S. patents relating to OCA with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds, and methods of using these compounds in various indications. We were also the owner of record of 8 pending U.S. and non-U.S. patent applications relating to OCA in these areas.

In addition, as of September 23, 2013, we were the owner of record of issued or granted U.S. and non-U.S. patents relating to our product candidates other than OCA, with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds, and methods of using these compounds in various indications. We were also the owner of record of pending U.S. and non-U.S. patent applications relating to such other product candidates in these areas.

Patents covering the composition of matter of OCA expire in 2022 if the appropriate maintenance fee renewal, annuity or other government fees are paid. We expect that the other patents and patent applications for the OCA portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2022 to 2033. We expect the issued INT-767 composition of matter patent in the United States, if the appropriate maintenance fee, renewal, annuity or other governmental fees are paid, to expire in 2029. We expect the other patents and patent applications, if issued, in the INT-767 portfolio, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2027 to 2033. We expect the issued INT-777 composition of matter patent in the United States, if the appropriate maintenance fee, renewal, annuity or other governmental fees are paid, to expire in 2030. We expect the other patents and patent applications, if issued, in the INT-777 portfolio, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2028 to 2029.

Without patent protection on the composition of matter of our product candidates, our ability to assert our patents to stop others from using or selling our product candidates in a non-pharmaceutically acceptable formulation may be limited.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our product candidates or methods involving these candidates in the parent patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in the parent patent application.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may

unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Competition

We have recently become aware that GENFIT and Gilead Sciences, Inc. have product candidates in Phase 2 clinical development for the treatment of nonalcoholic steatohepatitis (NASH). This information supplements our disclosures in “Item 1. Business—Competition” and “Item 1A. Risk Factors— Risks Relating to Our Business and Strategy—We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.” in our Form 10-K for the year ended December 31, 2012.

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: October 1, 2013 /s/ Mark Pruzanski
Mark Pruzanski, M.D.

President and Chief Executive Officer