INTERCEPT PHARMACEUTICALS INC
Form S-1
September 04, 2012

As filed with the Securities and Exchange Commission on September 4, 2012

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

INTERCEPT PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	2834	22-3868459
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

18 Desbrosses Street
New York, NY 10013
(646) 747-1000

(Address, including zip code, and telephone number,
including area code, of Registrant s principal executive offices)

Mark Pruzanski, M.D.
President and Chief Executive Officer
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting

company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o	Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

The Registrant is an emerging growth company, as defined in Section 2(a) of the Securities Act. This registration statement complies with the requirements that apply to an issuer that is an emerging growth company.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee[2]
Common stock, par value $0.001 per share	$ 75,000,000	$ 8,595

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price of the securities registered hereunder to be sold by the Registrant.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated September 4, 2012

P R O S P E C T U S

Shares

Common Stock

This is Intercept Pharmaceuticals initial public offering. We are selling shares of our common stock.

We expect the initial offering price to be between $ and $ per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on the Nasdaq Global Market under the symbol ICPT.

We are an emerging growth company under federal securities laws and are subject to reduced public company disclosure standards. See Prospectus Summary Implications of Being an Emerging Growth Company.

Investing in our common stock involves risks that are described in the Risk Factors section beginning on page 10 of this prospectus.

	Per Share	Total
Public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to us	$	$

The underwriters may also exercise their option to purchase up to an additional shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing up to approximately $ million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2012.

BofA Merrill Lynch

BMO Capital Markets

Needham & Company

Wedbush PacGrow Life Sciences

ThinkEquity LLC

The date of this prospectus is , 2012.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock.

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PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under Risk Factors and our consolidated financial statements and notes thereto that appear elsewhere in this prospectus. Unless otherwise indicated herein, the terms we, our, us, or the Company refer to Intercept Pharmaceuticals, Inc.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver disease utilizing our expertise in bile acid chemistry. Our product candidates have the potential to treat orphan and more prevalent liver diseases for which there currently are limited therapeutic solutions.

Our Lead Product Candidate

Our lead product candidate, obeticholic acid, or OCA, is a bile acid analog and first-in-class agonist of the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. We are developing OCA initially for the second line treatment of primary biliary cirrhosis, or PBC. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. We are conducting a Phase 3 clinical trial of OCA in PBC, which we call the POISE trial, that we anticipate will serve as the basis for seeking regulatory approval in the United States and Europe. We currently expect results from the trial to be available by mid-2014. OCA has received orphan drug designation in the United States and Europe for the treatment of PBC.

We own worldwide rights to OCA outside of Japan and China, where we have exclusively licensed the compound to Dainippon Sumitomo Pharma, or DSP, and granted it an option to exclusively license OCA in certain other Asian countries. Patents covering the composition of matter for OCA expire in 2022, before any patent term adjustments or patent term extensions. Our current plan is to commercialize OCA in the United States and Europe ourselves for the treatment of PBC by targeting a limited and focused group of specialist physicians.

The liver performs many essential functions that are crucial for survival, including the regulation of bile acid metabolism. A critical function of bile acids is to facilitate the absorption of dietary cholesterol and other nutrients by acting as natural detergent-like emulsifying agents in the intestine. In the past decade, we have learned that bile acids are also complex signaling molecules that integrate metabolic, immune and inflammatory pathways involved in the healthy functioning of various tissues and organs. The biological effects of bile acids are mediated through dedicated receptors such as FXR, which regulates bile acid synthesis and clearance from the liver, thereby preventing excessive bile acid build-up in the liver, which may be toxic. In addition, bile acid activation of FXR induces anti-fibrotic, anti-inflammatory and other mechanisms that are necessary for the normal regeneration of the liver. We believe this makes FXR an attractive drug target in a broad spectrum of chronic liver diseases. Similar FXR-mediated protective mechanisms in other organs exposed to bile acids also make it a potential target for the treatment of a number of intestinal, kidney and other diseases.

PBC is a rare liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver. The disease causes a toxic build-up of bile acids in the liver, resulting in progressive liver damage

marked by chronic inflammation and fibrosis, or scarring. In response to the bile acid mediated toxicity seen in PBC, liver cells release alkaline phosphatase, or ALP, a liver enzyme that is a key biomarker of the disease pathology. Elevated blood levels of ALP are used as the primary means of diagnosis of PBC and are closely monitored in patients as the most important indicator of treatment response and prognosis.

The only approved drug for the treatment of PBC is ursodeoxycholic acid, which is available generically as ursodiol. Ursodiol is itself a bile acid that is present in small quantities in humans, and is the least detergent of the various types of bile acids that make up the bile pool. Its primary mechanism of action at

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therapeutic doses is to dilute more detergent bile acids, but it has no known pharmacological effects mediated by FXR or other bile acid receptors. Although ursodiol is the standard of care, studies have shown that up to 50% of PBC patients fail to respond adequately to treatment, meaning that they continue to be at significant risk of progressing to liver failure even with treatment. The options for end-stage PBC patients who fail to respond to ursodiol are limited, and include liver transplant, which is associated with significant complications and costs. Patients typically need to take approximately one gram of ursodiol daily in divided doses, which we believe presents a compliance challenge for some patients. Given this issue, coupled with ursodiol s limited efficacy in up to 50% of PBC patients, we believe that there is a significant unmet need for a novel second line therapy in PBC. We believe that OCA has the potential to provide significant benefits in the treatment of PBC, including efficacy, pharmacological activity and ease of use.

According to industry data, there are approximately 300,000 people with PBC in developed countries, of whom we believe approximately 60,000 have been diagnosed and are on ursodiol therapy. Based on this estimate, we believe there are up to 30,000 PBC patients who may currently be eligible for treatment with OCA. With increasing identification of PBC through routine liver function testing in primary care, we believe that there may be significantly more patients who will potentially be eligible for, and be interested in, receiving a new therapy if it becomes available on the market.

We have previously completed two randomized, placebo-controlled Phase 2 trials with OCA in PBC patients, one with OCA in combination with ursodiol and one with OCA as monotherapy. The results demonstrated that over a 12-week period single daily doses of OCA at the lowest dose of 10 milligrams (mg) met the primary endpoint in both Phase 2 trials, producing statistically significant reductions in ALP levels of greater than 20%. We consider reductions in ALP levels of greater than 10% to be a clinically meaningful improvement. Pruritus, or itching, a very common symptom in PBC patients, was the most common adverse event reported in our Phase 2 trials, with severity increasing with dose.

Our Phase 3 POISE trial has been designed to study the safety and efficacy of OCA in patients with an inadequate therapeutic response to ursodiol or who are unable to tolerate ursodiol. The primary endpoint of the 12-month double-blind portion of the POISE trial is the achievement of both an ALP level of less than 1.67 times upper limit normal, or ULN, and a minimum 15% reduction in ALP level from baseline, together with a normal bilirubin level, as compared to placebo. Patients with ALP and bilirubin levels within these thresholds have been shown in long-term studies to be at significantly lower risk of progressing to liver transplant and death.

We are advancing a once daily 10 mg dose of OCA in the POISE trial as our potential approvable dose. We recently completed an intention to treat analysis for the 10 mg dose groups in our two Phase 2 trials that was limited to those patients who would have met the POISE trial entry criteria. This analysis demonstrated that after 12 weeks of treatment approximately 40% to 45% of OCA-treated patients would have met the POISE trial primary endpoint, as compared to 5% to 9% of the placebo-treated patients. In addition, 80% of OCA-treated patients across our Phase 2 trials had a reduction in ALP levels of at least 10%, as compared to 13% of placebo-treated patients.

If the POISE trial is successful, we intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for approval of OCA for the treatment of PBC in the United States and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, for approval in Europe. Based on written scientific advice from the EMA, we believe that the EMA will accept our current clinical program as the basis for considering approval of OCA for PBC. With respect to the FDA, we intend to request that the POISE trial primary endpoint be accepted as a basis for approval of OCA under the FDA s accelerated approval regulation that enables the use of a surrogate endpoint reasonably likely to predict clinical benefit. If the FDA agrees to consider the potential approval of OCA in accordance with its accelerated approval regulation based on the POISE trial results, we will likely have to conduct a Phase 3 clinical outcomes trial to confirm the clinical benefit predicted by the biochemical

therapeutic response. This Phase 3 clinical outcomes trial would have to be substantially underway at the time of the NDA submission and would be completed after accelerated approval. We are in discussions with the FDA about the details of such a clinical trial and are planning to initiate it as early as the second half of 2013.

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A number of published clinical studies have demonstrated that, as a measure of therapeutic response, lower levels of ALP, on its own or in conjunction with normal bilirubin levels, correlate with a significant reduction in adverse clinical outcomes such as liver transplant and death. We believe that one of the key factors in the FDA s acceptance of our POISE trial primary endpoint as a basis for approval will be the result of additional analysis of the already available PBC clinical outcomes data. We are sponsoring an independent study involving more than ten leading PBC centers in North America and Europe that are pooling their long-term patient data, anticipated to be from at least 4,000 patients, in order to further substantiate that our POISE trial primary endpoint is predictive of clinical benefit. We anticipate these results will be available in 2013 and will support what we believe is an emerging consensus among PBC opinion leaders concerning the clinical utility of our selected endpoint.

Additional Pipeline Opportunities Beyond OCA in PBC

In addition to PBC, we are pursuing other indications in our OCA development program, including portal hypertension, nonalcoholic steatohepatitis, or NASH, and bile acid diarrhea. The pipeline chart below shows the current stage of development of OCA for these indications, as well as the preclinical programs for our other product candidates.

* An agonist is a substance that binds to a receptor of a cell and triggers a response by that cell.

We are currently conducting an open label Phase 2a trial of OCA in patients with portal hypertension, and we anticipate receiving results from the 10 mg dose group of this trial by the end of 2012. There are currently no approved therapies for the treatment of portal hypertension, although beta blockers are commonly used to treat patients. In addition, OCA is currently being tested in a Phase 2b trial for the treatment of NASH, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, in collaboration with us. Based on the interim analysis that was completed in June 2012, the NIDDK decided to continue this Phase 2b trial and we anticipate that final results will be available in late 2014. There are currently no approved therapies for the treatment of NASH. In addition, investigators at the Imperial College of London initiated enrollment in July 2012 in an open label Phase 2a trial of OCA as a treatment for bile acid diarrhea.

By virtue of our patent portfolio and the proprietary knowhow of our employees and our collaborators at the University of Perugia, we believe that we hold a leading position in the bile acid chemistry therapeutic field. Through a longstanding exclusive collaboration with Professor Roberto Pellicciari, Ph.D., one of our co-founders, and certain scientists in the medicinal chemistry group at the University of Perugia, we have gained the capability to rationally design compounds that bind selectively and potently to FXR and other bile

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acid receptors. Starting with OCA, which was invented by Professor Pellicciari and, together with its underlying patents, was assigned to us under our agreements with him and the University of Perugia, our collaboration has resulted in a pipeline of bile acid analogs in addition to OCA, which target both FXR and a second dedicated bile acid receptor called TGR5, a target of interest for the treatment of type 2 diabetes and associated metabolic diseases. We intend to continue developing these and other product candidates as we advance our pipeline, in some cases subject to the procurement of additional funding or through strategic collaborations.

Our Strategy

Our strategy is to develop and commercialize novel therapeutics for patients with chronic liver and other diseases, beginning with OCA for the second line treatment of PBC and other follow-on indications that we believe are underserved by existing therapies. The key elements of our strategy are to:

complete the development of OCA for its lead indication, PBC;
obtain regulatory approval of OCA for the treatment of PBC in the United States, Europe and other countries;
commercialize OCA in the United States, Europe and other countries, initially for the treatment of PBC;
continue to develop OCA in other orphan and more prevalent liver and other diseases; and
advance the earlier stage product candidates in our pipeline.

We may enter into strategic collaborations to implement our strategy.

Risks Relating to Our Business

We are a development stage biopharmaceutical company, and our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in the section entitled Risk Factors :

we have never been profitable, have no products approved for commercial sale and to date have not generated any revenue from product sales;
we will require substantial additional funding beyond this contemplated offering to complete the development and commercialization of OCA and to continue to advance the development of our other product candidates, and such funding may not be available on acceptable terms or at all;
OCA and/or our other product candidates may not receive regulatory approval in a timely manner or at all;
the FDA may not agree to our proposed surrogate endpoint for accelerated approval of OCA for the treatment of PBC, in which case we would need to complete an additional Phase 3 trial in order to seek approval in the United States;
we may be subject to delays in our clinical trials, which could result in increased costs and delays or limit our ability to obtain regulatory approval for our product candidates;
because the results of earlier studies and clinical trials of our product candidates may not be predictive of future clinical trial results, our product candidates may not have favorable results in future clinical trials, which would delay or limit their future development;
we have never commercialized any of our product candidates and our products, even if approved, may not be accepted by healthcare providers or healthcare payors;
the failure of our collaborators to perform their obligations under our collaboration agreements may delay or otherwise harm the development and commercialization of our product candidates; and
we may be unable to maintain and protect our intellectual property assets, which could impair the advancement of our pipeline and commercial opportunities.

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Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;

reduced disclosure about our executive compensation arrangements;

no non-binding advisory votes on executive compensation or golden parachute arrangements; and

exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

Corporate Information

We were incorporated in the State of Delaware on September 4, 2002. Our principal executive offices are located at 18 Desbrosses Street, New York, NY 10013, and our telephone number is (646) 747-1000. We also have an office in San Diego, CA. Our website address is *www.interceptpharma.com*. The information contained on, or that can be accessed through, our website is not part of this prospectus.

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THE OFFERING

Common stock offered by us
shares

Common stock to be outstanding after this offering
shares

Over-allotment option
We have granted the underwriters an option for a period of up to 30 days to purchase up to additional shares of common stock at the initial public offering price.

Use of proceeds
We estimate that the net proceeds from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use substantially all of the net proceeds from this offering to fund (i) the continued clinical development of OCA in PBC, including our Phase 3 POISE trial and other studies and work necessary for anticipated FDA and EMA filings; (ii) the continuation of the long-term safety extension portion of our POISE trial and the Phase 3 clinical outcomes trial after the anticipated FDA and EMA filings; (iii) certain pre-commercialization activities of OCA for PBC; (iv) further preclinical development work on INT-767 and, if warranted, Phase 1 clinical trials of INT-767; and (v) if warranted, initiation of a Phase 2 clinical trial for an additional indication for OCA, such as portal hypertension. Any remaining amounts will be used for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. See Use of Proceeds for a more complete description of the intended use of proceeds from this offering.

Risk factors
You should read the Risk Factors section of this prospectus beginning on page 10 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed Nasdaq Global Market symbol
ICPT

Certain of our existing stockholders and their affiliated entities have indicated an interest in purchasing up to approximately $ million in shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these existing stockholders and any of these existing stockholders could determine to purchase more, less or no shares in this offering. Any shares purchased by these existing stockholders will be subject to lock-up restrictions described in Shares Eligible for Future Sale.

The number of shares of common stock to be outstanding after this offering is based on an aggregate of 62,016,196 shares, consisting of (i) 19,238,418 shares of common stock outstanding on June 30, 2012, (ii) 27,777,778 shares of common stock into which all of our preferred stock outstanding as of June 30, 2012 will be converted upon the completion of this offering and (iii) 15,000,000 shares of common stock into which the shares of preferred stock issued on August 9, 2012 will be converted upon the completion of this offering. The number of shares of our common stock outstanding immediately after this offering excludes:

7,565,535 shares of common stock issuable upon exercise of outstanding options as of June 30, 2012, at a weighted average exercise price of $1.55 per share, of which 5,627,135 shares are vested as of such date;

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137,500 shares of common stock issuable upon exercise of options granted on July 31, 2012 under our 2003 Stock Incentive Plan, as amended, or 2003 Plan, at an exercise price of $1.61 per share, to our non-employee directors as of January 1, 2012 for service during fiscal year 2012;

3,211,554 shares of our common stock reserved for future issuance under our 2003 Plan; provided, however, that (i) immediately upon completion of this offering, our 2003 Plan will terminate so that no further awards may be granted under the 2003 Plan; (ii) all the shares of common stock reserved for future issuance under our 2003 Plan will be added to the shares to be reserved under our 2012 Equity Incentive Plan, or 2012 Plan, upon its effectiveness at the completion of this offering; and (iii) all or some of these shares added to the 2012 Plan may be granted under the 2012 Plan to our employees and directors shortl