

INTERCEPT PHARMACEUTICALS INC
Form S-1/A
October 08, 2013

As filed with the Securities and Exchange Commission on October 7, 2013

Registration No. 333-191501

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

**AMENDMENT NO. 1
TO
FORM S-1**

**REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933**

INTERCEPT PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
*(State or other jurisdiction of
incorporation or organization)*

2834
*(Primary Standard Industrial
Classification Code Number)*

22-3868459
*(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
Intercept Pharmaceuticals, Inc.
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*(Name, address, including zip code, and telephone number,
including area code, of agent for service)*

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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.

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.

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.

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.

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

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 | Amount to be Registered ⁽¹⁾ | Proposed Maximum Offering Price Per Share ⁽²⁾ | Proposed Maximum Aggregate Offering Price ⁽²⁾ | Amount of Registration Fee ⁽³⁾ |
|--|--|--|--|---|
| Common Stock, par value \$0.001 per share | 1,725,000 | \$69.14 | \$119,266,500 | \$15,361.53 |

(1) Includes shares that the underwriter has the option to purchase.

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, on the basis of the average of the high and low selling prices of the Registrant's Common Stock reported on the NASDAQ Global Market as of a date (October 4, 2013) within five business days prior to filing this Registration Statement.

(3) The Registrant previously paid \$14,812 in connection with the initial filing of this Registration Statement.

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 October 7, 2013**

PROSPECTUS

1,500,000 Shares

Common Stock

The selling stockholders identified in this prospectus are offering 1,500,000 shares of our common stock. We will not receive any proceeds from the sale of shares to be offered by the selling stockholders.

Our shares trade on the Nasdaq Global Market under the symbol ICPT. On October 4, 2013, the last sale price of our common stock as reported on the Nasdaq Global Market was \$68.89 per share.

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

We are an emerging growth company and are subject to reduced public company reporting requirements. See Prospectus Summary Implications of Being an Emerging Growth Company.

| | <u>Per Share</u> | <u>Total</u> |
|--|------------------|--------------|
| Public offering price | \$ | \$ |
| Underwriting discount ⁽¹⁾ | \$ | \$ |
| Proceeds, before expenses, to the selling stockholders | \$ | \$ |

(1) See Underwriting for additional compensation details.

The underwriter may also exercise its option to purchase up to an additional 225,000 shares of our common stock from the selling stockholders at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

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 _____, 2013.

BofA Merrill Lynch

The date of this prospectus is _____, 2013.

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You should rely only on the information contained or otherwise incorporated by reference in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we, the selling stockholders nor the underwriter have authorized anyone to provide you with information that is different. The selling stockholders 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, any free writing prospectus, or any document incorporated by reference herein is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of common stock. To the extent there is a conflict between the information contained in this prospectus and the information contained in any document incorporated by reference herein filed prior to the date of this prospectus, you should rely on the information in this prospectus; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference herein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled *Where You Can Find More Information* and *Incorporation of Documents by Reference* in this prospectus.

For investors outside of the United States: neither we, the selling stockholders nor the underwriter have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

We further note that the representations, warranties and covenants made by us or the selling stockholders in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part or to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a

representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs or the affairs of any selling stockholder.

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PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus or incorporated by reference into this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2012 and our other filings with the Securities and Exchange Commission listed in the section of this prospectus entitled Incorporation of Documents by Reference and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus, the registration statement of which this prospectus is a part and the information incorporated by reference herein in their entirety before investing in our common stock, including the information discussed under Risk Factors in this prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2012 and our subsequent periodic and current reports filed with the Securities and Exchange Commission incorporated by reference herein, along with our consolidated financial statements and notes thereto that are incorporated by reference herein. Unless otherwise indicated herein, the terms we, our, us, or the Company refer to Intercept Pharmaceuticals, Inc. and its wholly-owned subsidiary.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver diseases 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, a chemical substance that has a structure based on a naturally occurring human bile acid. OCA is a first-in-class product candidate that selectively binds to and induces activity in the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. We are developing OCA initially for primary biliary cirrhosis, or PBC, as a second line treatment for patients who have an inadequate response to or who are unable to tolerate standard of care therapy and therefore need additional treatment. 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. In December 2012, we completed enrollment of the POISE trial approximately three months ahead of schedule with 217 patients, exceeding the originally targeted number of patients by approximately 20% and thereby improving the statistical power of the trial from 90% to 95%. We currently expect results from the POISE trial to be available in the second quarter of 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. Bile acids are natural detergent-like emulsifying agents that are released from the gallbladder into the intestine when food is ingested, and are essential for the absorption of dietary cholesterol and other nutrients. In the past decade, we have learned that bile acids are also complex signaling molecules that integrate metabolic and

immune 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, a nuclear receptor that 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. Based on the discovery of similar FXR-mediated protective mechanisms in other organs exposed to bile acids, we believe that FXR may also be a potential target for the treatment of a number of intestinal, kidney and other diseases.

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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 a naturally occurring bile acid found 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 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 established standard of care for the treatment of PBC, 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 outlook and treatment 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 of 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 PBC 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, with a minimum 15% reduction in ALP level from baseline, and 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 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 currently 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

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approval in Europe, by the end of 2014. 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 an accelerated approval of our NDA for OCA based on the use of the POISE trial primary endpoint as a surrogate endpoint that is reasonably likely to predict clinical benefit. If the 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.

Although the FDA has not confirmed our use of a surrogate endpoint in the POISE trial as a basis for regulatory approval, we are in discussions with the FDA about the design of the clinical outcomes trial and plan to initiate it during the first half of 2014.

A number of published clinical studies have demonstrated that lower levels of ALP, both independently 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 potential 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 believe that the Global PBC Study Group that we are sponsoring, which is anticipated to involve a dataset of more than 4,000 PBC patients from 15 academic centers in eight countries, and the UK-based PBC research cohort, involving a dataset of over 2,300 PBC patients from every hospital in the UK, represent the largest PBC clinical datasets assembled to analyze the correlation of biochemical therapeutic response with clinical outcomes in PBC patients. We further believe that the analyses already available confirm the results recently published, or made available to us, by four different members of the Global PBC Study Group (the University of Toronto, Mayo Clinic, University of Paris and Erasmus MC (Rotterdam)). These groups have all independently corroborated that the achievement of an ALP level of less than 1.67 times ULN, together with a normal bilirubin level, correlate with a statistically significant reduction of risk of adverse clinical outcomes such as liver transplant and death.

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.

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We are currently conducting an open label Phase 2a trial of OCA in patients with portal hypertension, studying once-daily doses of 10 mg and 25 mg, and we presented results from the 10 mg dose group of this trial at the annual meeting of the American Association for the Study of Liver Diseases in November 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, known as the FLINT trial, which is sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, in collaboration with us. In November 2012, the NIDDK completed enrollment, achieving the target of 280 patients for this trial. 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 the fourth quarter of 2014. In addition, our collaborator, DSP, has initiated a second Phase 2 NASH trial in Japan, with a targeted enrollment of 200 patients, that is anticipated to be completed in the first half of 2016. 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, which we refer to as the OBADIAH trial, and presented initial results in patients with primary bile acid diarrhea at the 2013 Digestive Diseases Week annual meeting in May 2013. We expect final results from this trial will be available in the fourth quarter of 2013.

By virtue of our patent portfolio and the proprietary know-how 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 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 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.

Recent Developments and Business Updates

Interactions with the U.S. Food and Drug Administration

We intend to request an accelerated approval of our NDA for OCA based on the use of the POISE trial primary endpoint as a surrogate endpoint that is reasonably likely to predict clinical benefit. If the 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 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 an 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., ALP <1.67 times ULN and normal bilirubin) is strongly predictive of adverse clinical outcomes in PBC patients.

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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" in this prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2012 and our subsequent periodic and current reports filed with the Securities and Exchange Commission incorporated by reference herein.

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 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 instead of being able to seek approval based on a clinical outcomes trial to be completed after accelerated approval; 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 are in a highly competitive industry and face competition from existing and new treatments that may be more effective and less costly than our products;

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 currently take advantage of reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

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 until such 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) December 31, 2017; (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. Accordingly, the information contained or incorporated by reference 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. We have included our website address in this prospectus solely as an inactive textual reference, and the information contained on, or that can be accessed through, our website is not part of this prospectus.

All brand names or trademarks appearing in this prospectus and the documents incorporated by reference are the property of their respective holders. We own or have rights to trademarks or trade names that we use in connection with the operation of our business, including our corporate names, logos and website names.

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THE OFFERING

Common stock offered by the selling stockholders

1,500,000 shares

Common stock to be outstanding after this offering

19,261,799 shares. This offering will have no effect on the number of shares of our common stock outstanding.

Option to purchase additional shares

The selling stockholders have granted the underwriter an option for a period of up to 30 days to purchase up to 225,000 additional shares of common stock at the offering price.

Use of proceeds

We will not receive any proceeds from the sale of common stock by the selling stockholders in this offering.

Risk factors

You should read the Risk Factors section of this prospectus, our Annual Report on Form 10-K for the year ended December 31, 2012 and our subsequent periodic and current reports filed with the Securities and Exchange Commission incorporated by reference herein for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Nasdaq Global Market symbol

ICPT

The number of shares of common stock to be outstanding after this offering is based on an aggregate of 19,261,799 shares outstanding as of September 16, 2013. The number of shares of our common stock outstanding immediately after this offering excludes:

1,563,496 shares of common stock issuable upon exercise of outstanding options as of September 16, 2013, at a weighted average exercise price of \$18.74 per share, of which 824,439 shares were vested as of such date;

restricted stock units for 134,569 shares of our common stock that were unvested as of September 16, 2013; 878,201 shares of common stock issuable upon the exercise of warrants outstanding as of September 16, 2013, at a weighted average exercise price of \$10.33 per share; and

481,714 shares of our common stock reserved for future issuance under our 2012 Equity Incentive Plan, or the 2012 Plan, plus any future increases in the number of shares of common stock reserved for issuance under the 2012 Plan pursuant to evergreen provisions.

Except as otherwise indicated, all information in this prospectus assumes no exercise by the underwriter of its option to purchase additional shares of our common stock from the selling stockholders.

TABLE OF CONTENTS**SUMMARY CONSOLIDATED FINANCIAL DATA**

The summary consolidated financial data presented below for the years ended December 31, 2010, 2011 and 2012 are derived from our audited consolidated financial statements incorporated by reference in this prospectus from our Annual Report on Form 10-K for the year ended December 31, 2012. The summary consolidated financial data presented below for the six months ended June 30, 2012 and 2013, and for the period from inception (September 4, 2002) to June 30, 2013 (required to be included since we are a development stage company), are derived from our unaudited financial statements incorporated by reference in this prospectus from our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013. The unaudited consolidated financial statements have been prepared on the same basis as our audited consolidated financial statements and include, in the opinion of management, all adjustments necessary for a fair presentation of the financial information set forth in those statements.

Our historical results are not necessarily indicative of future operating results. You should read this summary consolidated financial data in conjunction with the sections entitled Risk Factors, Capitalization and Management Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes, all included elsewhere or incorporated by reference in this prospectus. For more details on how you can obtain the documents incorporated by reference in this prospectus, see Where You Can Find More Information and Incorporation of Documents by Reference.

| | Year Ended December 31, | | | Six Months Ended June 30, | | Period From |
|---|--|-------------|-------------|---------------------------|-------------|---|
| | 2010 | 2011 | 2012 | 2012 | 2013 | September 4, 2002 (Inception) Through June 30, 2013 |
| | (in thousands, except share and per share amounts) | | | | | (unaudited) |
| | | | | | | (unaudited) |
| Statement of Operations Data: | | | | | | |
| Licensing revenue | \$ | \$1,805 | \$2,446 | \$1,518 | \$811 | \$5,062 |
| Costs and expenses: | | | | | | |
| Research and development | 12,710 | 11,426 | 16,183 | 8,078 | 9,966 | 81,400 |
| General and administrative | 3,644 | 4,209 | 5,177 | 2,003 | 5,287 | 34,885 |
| Total operating expenses | 16,354 | 15,635 | 21,360 | 10,081 | 15,253 | 116,286 |
| Other income (expense): | | | | | | |
| Revaluation of warrants | 672 | 1,045 | (24,626) | 979 | (9,255) | (32,330) |
| Other income (expense), net | 594 | 48 | (104) | (182) | 10 | 1,683 |
| | 1,266 | 1,093 | (24,730) | 797 | (9,245) | (30,647) |
| Net loss | (15,088) | (12,737) | (43,643) | (7,766) | (23,687) | (141,870) |
| Dividends on preferred stock, not declared | (2,901) | (3,000) | (2,630) | (1,500) | | (10,944) |
| Net loss attributable to common stockholders | \$(17,989) | \$(15,737) | \$(46,273) | \$(9,266) | \$(23,687) | \$(152,815) |
| Net loss per common share, basic and diluted: | \$(5.40) | \$(4.73) | \$(7.36) | \$(2.78) | \$(1.41) | |
| | 3,329,666 | 3,329,666 | 6,283,238 | 3,329,266 | 16,765,464 | |

Weighted average number of
shares of common stock
outstanding, basic and diluted:
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The following summary unaudited balance sheet data as of June 30, 2013 is presented:

| | June 30, 2013 (unaudited) (In thousands) |
|--|---|
| Balance Sheet Data: | |
| Cash, cash equivalents and investment securities | \$ 161,799 |
| Total assets | 163,869 |
| Working capital | 156,299 |
| Warrant liability, total | 32,574 |
| Deferred revenue, total | 11,351 |
| Total liabilities | 47,597 |
| Common and preferred stock | 19 |
| Additional paid-in capital | 258,233 |
| Accumulated deficit during development stage | (141,870) |
| Total stockholders' equity | 116,272 |

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RISK FACTORS

A purchase of shares of our common stock is an investment in our securities and involves a high degree of risk. You should carefully consider the risks and uncertainties and all other information contained in or incorporated by reference in this prospectus, including the risks and uncertainties discussed under Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2012 and our subsequent periodic and current reports filed with the Securities and Exchange Commission incorporated by reference herein. All of these risk factors are incorporated by reference herein in their entirety. If any of these risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of our common stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to This Offering and Ownership of our Common Stock

We have a significant stockholder, which will limit your ability to influence corporate matters and may give rise to conflicts of interest.

Genextra S.p.A., together with its affiliates, whom we refer to collectively as Genextra, is our largest stockholder. As of September 16, 2013, Genextra owned 7,187,217 shares of our common stock and warrants to purchase an additional 865,381 shares of our common stock. The shares of common stock owned by Genextra represented approximately 37.3% of our outstanding common stock as of September 16, 2013. Following this offering, we anticipate that Genextra will own 6,063,802 shares of common stock, or approximately 31.5% of our outstanding shares of common stock. Accordingly, Genextra exerts and will continue to exert significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors and amendments to our organizational documents, such as increases in our authorized shares of common stock, and approval of significant corporate transactions. This concentration of voting power makes it less likely that any other holder of common stock or directors of our business will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other stockholders may desire. In addition, if Genextra obtains a majority of our common stock, Genextra would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Genextra would be able to control the election of directors, amendments to our organizational documents and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. In addition, if Genextra obtains a majority of our common stock, we would be deemed a controlled company for purposes of Nasdaq listing requirements. Under Nasdaq rules, a controlled company may elect not to comply with certain Nasdaq corporate governance requirements, including (i) the requirement that a majority of our board of directors consist of independent directors, (ii) the requirement that the compensation of our officers be determined or recommended to the board by a compensation committee that is composed entirely of independent directors, and (iii) the requirement that director nominees be selected or recommended to the board by a majority of independent directors or a nominating committee that is composed entirely of independent directors. Furthermore, the interests of Genextra may not always coincide with your interests or the interests of other stockholders and Genextra may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, and might affect the prevailing market price for our common stock. Our board of directors, which consists of seven directors, including two affiliated with Genextra, has the power to set the number of directors on our board from time to time.

A significant portion of our total outstanding shares of common stock is restricted from resale but may be sold into the market in the future. The sale of these shares could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. This offering, any additional sales in the future, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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As of September 16, 2013, we had 19,261,799 shares of common stock outstanding. Of these shares, an aggregate of 9,745,598 shares of our common stock, or 50.6% of our outstanding shares, were held by our officers, directors, beneficial owners of 5% or more of our securities (other than FMR LLC and its affiliates) and their respective affiliates, which may be sold subject to Rule 144. Following this offering, it is anticipated that our officers, directors, beneficial owners of 5% or more of our securities (other than FMR LLC and its affiliates) and their respective affiliates will collectively hold 8,245,598 shares of our common stock, or 43.1% of our outstanding shares. In addition, all of our directors and officers and the selling stockholders are subject to lock-up agreements with the underwriter for this offering that restrict their ability to transfer shares of our common stock for 90 days from the date of this prospectus, subject to certain exceptions. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the public offering. Subject to limitations, approximately 8,245,598 shares will become eligible for sale upon expiration of the lock-up period, as calculated and described in more detail in the section entitled Shares Eligible for Future Sale. In addition, shares issued or issuable upon conversion or exercise of vested options and other securities convertible or exercisable into common stock as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

In addition, as of September 16, 2013, holders of an aggregate of 10,598,862 shares of our common stock, including shares underlying warrants held by Genextra and those offered by the selling stockholders under this prospectus, have rights, subject to certain conditions and the lock-up described above, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered 2,712,103 shares of common stock, a portion of which we have issued and a portion of which we may issue under our equity compensation plans. Once issued and vested, these shares of common stock can be freely sold in the public market. Any sales of securities by these stockholders, option holders and holders of other securities convertible or exercisable into common stock could have a material adverse effect on the trading price of our common stock.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into it contain, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, should, continue, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval of obeticholic acid, or OCA, and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our future product candidates;
- our collaborators' election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our ability to obtain additional financing;
- our use of the proceeds from our initial public offering in October 2012 and our follow-on offering in June 2013;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; and
- our ability to attract and retain key scientific or management personnel.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the

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cautionary statements included in this prospectus and other documents incorporated by reference herein, particularly under the heading Risk Factors, that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

Industry and Market Data

This prospectus and the documents incorporated by reference herein contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained such industry and market data from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

Further, industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these publications, studies and surveys are reliable, we have not independently verified the data contained in them. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

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USE OF PROCEEDS

We will not receive any proceeds from the sale of shares of common stock by the selling stockholders in this offering.
See Principal and Selling Stockholders.

PRICE RANGE OF OUR COMMON STOCK

Our common stock has been listed on the Nasdaq Global Market since October 11, 2012 under the symbol ICPT. Prior to that date, there was no public market for our common stock. Shares sold in our initial public offering on October 10, 2012 were priced at \$15.00 per share.

On October 4, 2013, the closing price for our common stock as reported on the Nasdaq Global Market was \$68.89 per share. The following table sets forth the ranges of high and low sales prices per share of our common stock as reported on the Nasdaq Global Market for the period indicated. Such quotations represent inter-dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions.

| | | |
|--|----------|----------|
| Year Ended December 31, 2012 | High | Low |
| Fourth quarter (from October 11, 2012) | \$ 35.99 | \$ 17.96 |
| Year Ended December 31, 2013 | High | Low |
| First quarter | \$ 42.67 | \$ 33.45 |
| Second quarter | \$ 45.00 | \$ 30.38 |
| Third quarter | \$ 72.64 | \$ 42.41 |
| Fourth quarter (through October 4, 2013) | \$ 77.53 | \$ 68.29 |

Stockholders

As of September 20, 2013, there were 34 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

TABLE OF CONTENTS**SELECTED FINANCIAL DATA**

The following table sets forth our selected financial data for the periods and as of the dates indicated. You should read the following selected financial data in conjunction with our audited and unaudited financial statements and the related notes thereto and the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the year ended December 31, 2012 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 incorporated by reference herein.

The statement of operations data for the years ended December 31, 2010, 2011 and 2012, and the balance sheet data as of December 31, 2010, 2011 and 2012, are derived from our audited financial statements incorporated by reference in this prospectus. The statement of operations data for the six months ended June 30, 2012 and 2013, and for the period from inception (September 4, 2002) to June 30, 2013 (required to be included since we are a development stage company) and the balance sheet data as of June 30, 2013, are derived from our unaudited financial statements and the related notes from our unaudited financial statements incorporated by reference in this prospectus. Our interim unaudited financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP, on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to present a fair statement of our financial position as of June 30, 2013 and the results of our operations for the six months ended June 30, 2012 and 2013 and for the period from inception (September 4, 2002) to June 30, 2013.

Our historical results are not necessarily indicative of the results that may be expected in the future and interim results are not necessarily indicative of results to be expected for any other period or the full year. For more details on how you can obtain the documents incorporated by reference in this prospectus, see [Where You Can Find More Information](#) and [Incorporation of Documents by Reference](#).

| | Year Ended December 31, | | | Six Months Ended June 30, | | Period From September 4, 2002 (Inception) Through June 30, 2013 |
|-------------------------------|--|-----------|-----------|------------------------------|-----------|---|
| | 2010 | 2011 | 2012 | 2012 | 2013 | |
| | (in thousands, except share and per share amounts) | | | | | |
| | | | | | | (unaudited) |
| Statement of Operations Data: | | | | | | (unaudited) |
| Licensing revenue | \$ | \$1,805 | \$2,446 | \$1,518 | \$811 | \$5,062 |
| Costs and expenses: | | | | | | |
| Research and development | 12,710 | 11,426 | 16,183 | 8,078 | 9,966 | 81,400 |
| General and administrative | 3,644 | 4,209 | 5,177 | 2,003 | 5,287 | 34,885 |
| Total operating expenses | 16,354 | 15,635 | 21,360 | 10,081 | 15,253 | 116,286 |
| Other income (expense): | | | | | | |
| Revaluation of warrants | 672 | 1,045 | (24,626) | 979 | (9,255) | (32,330) |
| Other income (expense), net | 594 | 48 | (104) | (182) | 10 | 1,683 |
| | 1,266 | 1,093 | (24,730) | 797 | (9,245) | (30,647) |
| Net loss | (15,088) | (12,737) | (43,643) | (7,766) | (23,687) | (141,870) |
| | (2,901) | (3,000) | (2,630) | (1,500) | | (10,944) |

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| | | | | | | |
|--|-------------|-------------|-------------|------------|-------------|-------------|
| Dividends on preferred stock, not declared | | | | | | |
| Net loss attributable to common stockholders | \$(17,989) | \$(15,737) | \$(46,273) | \$(9,266) | \$(23,687) | \$(152,815) |
| Net loss per common share, basic and diluted: | \$(5.40) | \$(4.73) | \$(7.36) | \$(2.78) | \$(1.41) | |
| Weighted average shares outstanding, basic and diluted: | 3,329,666 | 3,329,666 | 6,283,238 | 3,329,266 | 16,765,464 | |

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| | December 31, | | 2012 | June 30, |
|--|----------------|-----------|------------|-------------|
| | 2010 | 2011 | | 2013 |
| | (in thousands) | | | (unaudited) |
| Balance Sheet Data: | | | | |
| Cash, cash equivalents and investment securities | \$ 15,424 | \$ 17,707 | \$ 110,194 | \$ 161,799 |
| Total assets | 17,118 | 19,470 | 112,179 | 163,869 |
| Working capital | 13,890 | 14,872 | 98,814 | 156,299 |
| Accounts payable, accrued expenses and other liabilities | 1,587 | 1,504 | 3,746 | 3,672 |
| Warrant liability, total | 6,881 | 5,836 | 30,359 | 32,574 |
| Deferred revenue, total | | 14,608 | 12,162 | 11,351 |
| Common and preferred stock | 31 | 31 | 17 | 19 |
| Additional paid-in capital | 70,268 | 72,134 | 184,100 | 258,233 |
| Accumulated deficit during development stage | (61,803) | (74,540) | (118,183) | (141,870) |
| Total stockholder's equity (deficit) | 8,318 | (2,560) | 65,912 | 116,272 |

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TABLE OF CONTENTS**PRINCIPAL AND SELLING STOCKHOLDERS**

The following table sets forth certain information regarding the beneficial ownership of our common stock as of September 16, 2013, on an actual basis and as adjusted to reflect the sale of our common stock by the selling stockholders in this offering, by:

our named executive officers;
each of our directors;
all of our current directors and executive officers as a group;
each stockholder known by us to own beneficially more than five percent of our common stock; and
each of the selling stockholders.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of September 16, 2013, pursuant to the exercise of options or warrants or the vesting of restricted stock units, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership before this offering is based on an aggregate of 19,261,799 shares of common stock outstanding as of September 16, 2013. The table below does not give effect to the exercise by the underwriter of its option to purchase additional shares of our common stock from the selling stockholders.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer is: c/o Intercept Pharmaceuticals, Inc., 18 Desbrosses Street, New York, NY 10013.

| Name | Shares of Common Stock Owned Before This Offering | | Shares Offered | Shares of Common Stock Owned After This Offering | |
|--|---|---------|-------------------|--|---------|
| | Number | Percent | | Number | Percent |
| Named Executive Officers and Directors: | | | | | |
| Mark Pruzanski, M.D. ⁽¹⁾ | 776,518 | 4.0 % | | 776,518 | 4.0 % |
| David Shapiro, M.D., Ph.D. ⁽²⁾ | 150,123 | * | | 150,123 | * |
| Barbara Duncan ⁽³⁾ | 43,116 | * | | 43,116 | * |
| Srinivas Akkaraju, M.D., Ph.D. ⁽⁴⁾ | 6,923 | * | | 6,923 | * |
| Paolo Fundaro ⁽⁵⁾ | 17,669 | * | | 17,669 | * |
| Jonathan Silverstein ⁽⁶⁾ | 2,159,288 | 11.2 % | 376,585 | 1,782,703 | 9.3 % |
| Lorenzo Tallarigo, M.D. ⁽⁷⁾ | 8,078,173 | 40.1 % | 1,123,415 | 6,954,758 | 34.5 % |
| Klaus Veitinger, M.D., Ph.D. ⁽⁸⁾ | 9,736 | * | | 9,736 | * |
| Nicole Williams ⁽⁹⁾ | 27,887 | * | | 27,887 | * |
| All current executive officers and directors as a group (11 persons) ⁽¹⁰⁾ | 11,313,909 | 54.3 % | 1,500,000 | 9,813,909 | 47.1 % |
| Selling Stockholders: | | | | | |
| Genextra S.p.A. ⁽¹¹⁾ | 8,052,598 | 40.0 % | 1,123,415 | 6,929,183 | 34.4 % |
| OrbiMed Private Investments IV, LP ⁽¹²⁾ | 2,151,932 | 11.2 % | 376,585 | 1,775,347 | 9.2 % |
| Other Five Percent Stockholder: | | | | | |

| | | | | | |
|----|-------------------------|-----------|-------|-----------|--------|
| 17 | FMR LLC ⁽¹³⁾ | 2,006,569 | 10.4% | 2,006,569 | 10.4 % |
|----|-------------------------|-----------|-------|-----------|--------|

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* Represents beneficial ownership of less than 1% of the shares of common stock.

Consists of 394,332 shares of common stock, options to purchase 377,319 shares of common stock that are (1) exercisable within 60 days of September 16, 2013 and restricted stock units, or RSUs, for 4,867 shares of common stock that will vest within 60 days of September 16, 2013.

Consists of 1,266 shares of common stock, options to purchase 147,235 shares of common stock that are (2) exercisable within 60 days of September 16, 2013 and RSUs for 1,622 shares of common stock that will vest within 60 days of September 16, 2013.

Consists of 3,814 shares of common stock, options to purchase 38,004 shares of common stock that are exercisable (3) within 60 days of September 16, 2013 and RSUs for 1,298 shares of common stock that will vest within 60 days of September 16, 2013.

Consists of 974 shares of common stock, options to purchase 5,625 shares of common stock that are exercisable (4) within 60 days of September 16, 2013 and RSUs for 324 shares of common stock that will vest within 60 days of September 16, 2013.

Consists of options to purchase 17,344 shares of common stock that are exercisable within 60 days of September (5) 16, 2013 and RSUs for 325 shares of common stock that will vest within 60 days of September 16, 2013.

Consists of (a) the shares described in note (12) below and (b) RSUs for 325 shares of common stock that will vest (6) within 60 days of September 16, 2013 and options to purchase 7,031 shares of common stock that are exercisable within 60 days of September 16, 2013 that are held directly by Mr. Silverstein. The reporting person is a member of OrbiMed Advisors LLC and is obligated to transfer any shares issued under any equity grants made to him to OrbiMed Advisors LLC and certain of its related entities. Mr. Silverstein disclaims beneficial ownership of these shares, except to the extent of his pecuniary interest therein, if any.

Consists of (a) the shares described in note (11) below and (b) RSUs for 1,839 shares of common stock that will (7) vest within 60 days of September 16, 2013 and options to purchase 23,736 shares of common stock which are exercisable within 60 days of September 16, 2013 that are held directly by Dr. Tallarigo. The vesting of all stock options and RSUs granted to Dr. Tallarigo has been suspended from October 10, 2012 until October 10, 2013, at which time all such stock options and RSUs that would have vested as of such date will vest and all remaining (7) unvested stock options and RSUs will continue vesting in accordance with their original terms. Dr. Tallarigo is the chief executive officer of Genextra S.p.A. and, in such capacity, Dr. Tallarigo exercises voting control over the shares of common stock owned by Genextra S.p.A. and investment control over such shares as authorized by the board of directors of Genextra S.p.A. Dr. Tallarigo disclaims beneficial ownership with respect to any such shares, except to the extent of his pecuniary interest therein, if any. See also note (11) regarding the shares beneficially owned by Genextra S.p.A.

Consists of 1,298 shares of common stock, options to purchase 8,113 shares of common stock that are exercisable (8) within 60 days of September 16, 2013 and RSUs for 325 shares of common stock that will vest within 60 days of September 16, 2013.

Consists of 871 shares of common stock, options to purchase 26,648 shares of common stock that are exercisable (9) within 60 days of September 16, 2013 and RSUs for 368 shares of common stock that will vest within 60 days of September 16, 2013.

Consists of (a) 9,745,598 shares of common stock beneficially owned by our officers and directors, (b) 865,381 (10) shares of common stock underlying the warrants beneficially owned by Dr. Tallarigo, (c) options to purchase 690,988 shares of common stock beneficially owned by our officers and directors which are exercisable within 60 days of September 16, 2013 and (d) RSUs for 11,942 shares of common stock beneficially owned by our officers and directors that will vest within 60 days of September 16, 2013.

(11) Consists of (a) 7,187,217 shares of common stock owned by Genextra S.p.A. and (b) 865,381 shares underlying (11) warrants held by Genextra S.p.A. Dr. Tallarigo is the chief executive officer of Genextra S.p.A. and Francesco Micheli is the executive director of Genextra S.p.A. and, in such capacities, Dr. Tallarigo and Mr. Micheli exercise voting control over the shares of common stock owned by Genextra S.p.A. and investment control over

such shares as authorized by the board of directors of Genextra S.p.A. An increase or decrease of 100,000 shares in the number of shares offered by Genextra S.p.A. would decrease or increase the percentage of shares beneficially owned by Genextra S.p.A. by approximately 0.5%. Each of Dr. Tallarigo and Mr. Micheli disclaims beneficial ownership with respect

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to any such shares, except to the extent of his pecuniary interest therein, if any. The address of each of Genextra S.p.A. and its affiliates is Via G. De Grassi, 11, 20123 Milan, Italy. Information relating to Mr. Micheli is based on Schedule 13G of Genextra S.p.A. filed with the Securities and Exchange Commission on February 14, 2013.

Represents shares of common stock owned by OrbiMed Private Investments IV, LP. OrbiMed Capital GP IV LLC is the general partner of OrbiMed Private Investments IV, LP and OrbiMed Advisors LLC is the managing member of OrbiMed Capital GP IV LLC. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors LLC and may be deemed to have voting and investment power over the shares held by OrbiMed Private Investments IV, LP noted above. An increase or decrease of 100,000 shares in the number of (12) shares offered by OrbiMed Private Investments IV, LP would decrease or increase the percentage of shares beneficially owned by OrbiMed Private Investments IV, LP by approximately 0.5%. Each of OrbiMed Capital GP IV LLC, OrbiMed Advisors LLC and Mr. Isaly disclaims beneficial ownership of such shares, except to the extent of its or his pecuniary interest therein, if any. Mr. Silverstein, a member of our board of directors, is a member of OrbiMed Advisors LLC. The address for OrbiMed Private Investments IV, LP is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.

Based on information supplied by FMR LLC on Schedule 13G/A filed with the Securities and Exchange Commission on July 10, 2013. Fidelity Management & Research Company (Fidelity), 82 Devonshire Street, Boston, Massachusetts 02109, a wholly-owned subsidiary of FMR LLC and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940, is the beneficial owner of 1,992,469 shares of our common stock as a result of acting as investment adviser to various investment companies registered under Section 8 of the Investment Company Act of 1940. Edward C. Johnson 3d and FMR LLC, through its control of Fidelity, and the funds each has sole power to dispose of the 1,992,469 shares owned by the Funds. Members of the family of Edward C. Johnson 3d, Chairman of FMR LLC, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B (13) voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d, Chairman of FMR LLC, has the sole power to vote or direct the voting of the shares owned directly by the Fidelity Funds, which power resides with the Funds' Boards of Trustees. Fidelity carries out the voting of the shares under written guidelines established by the Funds' Boards of Trustees. Pyramis Global Advisors Trust Company (PGATC), 900 Salem Street, Smithfield, Rhode Island, 02917, an indirect wholly-owned subsidiary of FMR LLC and a bank as defined in Section 3(a)(6) of the Securities Exchange Act of 1934, or Exchange Act, is the beneficial owner of 7,100 shares of our common stock as a result of its serving as investment manager of institutional accounts owning such shares. Edward C. Johnson 3d and FMR LLC, through its control of Pyramis Global Advisors Trust Company, each has sole dispositive power over 7,100 shares and sole power to vote or to direct the voting of 7,100 shares of Common Stock owned by the institutional accounts managed by PGATC as reported above.

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CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

In addition to the compensation arrangements that we have with our directors and executive officers, since January 1, 2011, we have engaged in the following transactions in which the amount involved exceeded \$120,000 and in which any director, executive officer or holder of more than 5% of our voting securities, whom we refer to as our principal stockholders, or affiliates or immediate family members of our directors, executive officers and principal stockholders, had or will have a material interest. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Some of our directors are affiliated with our principal and selling stockholders as indicated in the table below:

| | |
|-------------------------|--|
| Director | Affiliation with Principal and Selling Stockholder |
| Lorenzo Tallarigo, M.D. | Dr. Tallarigo is the chief executive officer of Genextra S.p.A., which is one of our principal and selling stockholders. |
| Paolo Fundaro | Mr. Fundaro is the chief financial officer of Genextra S.p.A., which is one of our principal and selling stockholders. |
| Jonathan Silverstein | Mr. Silverstein is a member of OrbiMed Advisors LLC, whose affiliated fund is one of our principal and selling stockholders. |

Private Placements of Securities

On August 9, 2012, we entered into a securities purchase agreement with an affiliated fund of OrbiMed Advisors LLC, or OrbiMed, and Genextra S.p.A., or Genextra, pursuant to which we agreed to issue up to an aggregate of 25,000,000 shares of our Series C preferred stock at a price of \$2.00 per share for gross proceeds of up to \$50.0 million. On August 9, 2012, we issued the first tranche of Series C preferred stock, which resulted in net proceeds of \$29.7 million to us. The closing of the second tranche was only contemplated to occur if we did not complete an initial public offering of our common stock on or prior to August 2013. Upon the completion of our initial public offering, the Series C preferred stock was converted into shares of common stock and the agreement to issue the second tranche of Series C preferred stock was nullified.

Under the securities purchase agreement, we have agreed to indemnify each purchaser of our Series C preferred stock and its employees, agents, stockholders and affiliates, up to an aggregate amount equal to the purchase price of the Series C preferred stock until August 9, 2015, for any and all losses, judgments or damages sustained or incurred by or asserted against such indemnified party arising out of or in any way relating to any material breach of our representations and warranties, the failure by us to fulfill any material obligation, agreement or covenant under the securities purchase agreement or the third amended and restated stockholders agreement, or any cost or expense, including reasonable legal fees incurred in connection with enforcing the rights of such indemnified party.

The investors have been granted certain demand and piggyback registration rights in respect of their securities under our third amended and restated stockholders agreement. The registration statement of which this prospectus forms a part was filed pursuant to the exercise by the selling stockholders of their demand registration rights under the third amended and restated stockholders agreement. See Description of Capital Stock Registration Rights for more information on the registration rights held by the investors.

Reimbursement of Expenses

In connection with the Series C preferred stock financing in August 2012, we reimbursed Genextra and OrbiMed \$50,000 and \$150,000, respectively, for legal and other transaction-related expenses incurred by such stockholders in connection with the transaction.

Pursuant to the third amended and restated stockholders agreement, we have agreed to reimburse the selling stockholders in this offering for the expenses related to this offering (other than any underwriting discounts and commissions), including up to \$60,000 for the legal fees of the selling stockholders.

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Participation in our Initial Public Offering

In our initial public offering, OrbiMed purchased an aggregate of 333,334 shares of our common stock and NewLeaf Venture Partners, an entity then affiliated with our director, Srinivas Akkaraju, purchased an aggregate of 700,000 shares of our common stock. These purchases were made through the underwriters at the initial public offering price.

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and officers. The indemnification agreements and our restated certificate of incorporation and restated by-laws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Policy for Approval of Related Person Transactions

Pursuant to the written charter of our audit committee, the audit committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us, including our executive officers, our directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons and any other persons whom our board of directors determines may be considered related parties under Item 404 of Regulation S-K, has or will have a direct or indirect material interest. In reviewing and approving such transactions, the audit committee shall obtain, or shall direct our management to obtain on its behalf, all information that the committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by the committee prior to approval. If a discussion is not deemed to be necessary, approval may be given by written consent of the committee. This approval authority may also be delegated to the chair of the audit committee in some circumstances. No related party transaction shall be entered into prior to the completion of these procedures.

The audit committee or its chair, as the case may be, shall approve only those related party transactions that are determined to be in, or not inconsistent with, the best interests of us and our stockholders, taking into account all available facts and circumstances as the committee or the chair determines in good faith to be necessary in accordance with principles of Delaware law generally applicable to directors of a Delaware corporation. These facts and circumstances will typically include, but not be limited to, the legal requirements, if any, to which we are subject giving rise to the transaction; the benefits of the transaction to us; the impact on a director's independence in the event the related party is a director, an immediate family member of a director or an entity in which a director is a partner, stockholder or executive officer; the availability of other sources for comparable products or services; the terms of the transaction; and the terms of comparable transactions that would be available to unrelated third parties or to employees generally. No member of the audit committee shall participate in any review, consideration or approval of any related party transaction with respect to which the member or any of his or her immediate family members has an interest.

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DESCRIPTION OF CAPITAL STOCK

The following is a summary of our capital stock and provisions of our restated certificate of incorporation and restated by-laws. For more detailed information, please see our restated certificate of incorporation and restated by-laws, which are filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus forms a part.

We are authorized to issue 25,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share. As of September 16, 2013, we had 19,261,799 shares of common stock outstanding, which were held of record by 34 stockholders, and no shares of preferred stock outstanding. In addition, as of September 16, 2013, there were outstanding options to purchase 1,563,496 shares of common stock, restricted stock units for 134,569 shares of common stock and outstanding warrants to purchase 878,201 shares of common stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments.

All outstanding shares of common stock are fully paid and nonassessable. The holders of common stock have no preferences or rights of conversion, exchange, pre-emptive or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in any of our assets remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

Preferred Stock

Our preferred stock, if issued, would have priority over our common stock with respect to dividends and other distributions, including the distribution of assets upon liquidation. Our board of directors has the authority, without further stockholder authorization, to issue from time to time shares of preferred stock in one or more series and to fix the terms, limitations, relative rights and preferences and variations of each series. Although we have no present plans to issue any shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal.

Warrants

As of September 16, 2013, we had warrants outstanding to purchase the number of shares of our common stock at the exercise prices and expiration dates set forth below. Warrants entitle the holder to purchase shares of our common stock, as applicable, at the specified exercise price at any time prior to the expiration date.

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| | Warrants to Purchase Common Stock | Weighted Average Exercise Price | Expiration |
|--|--|--|------------------|
| Warrants issued in 2003 ⁽¹⁾⁽²⁾⁽³⁾ | 2,163 | \$ 2.89 | October 24, 2013 |
| Warrants issued in 2003 ⁽¹⁾⁽²⁾ | 2,163 | 8.67 | October 24, 2013 |
| Warrants issued in 2004 ⁽¹⁾⁽²⁾⁽³⁾ | 4,074 | 2.89 | October 27, 2013 |
| Warrants issued in 2004 ⁽¹⁾⁽²⁾ | 4,420 | 8.67 | October 27, 2013 |
| Warrants issued in 2010 ⁽¹⁾⁽⁴⁾⁽⁵⁾ | 865,381 | 10.40 | January 25, 2015 |
| Total | 878,201 | \$ 10.33 | |

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- Each of these warrants has a net exercise provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of our common stock based on the fair market value of the underlying shares of our common stock at the time of exercise of the warrant, after deduction of the aggregate exercise price. Each warrant also contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations.
- (1)
- (2) Pursuant to the terms of these warrants, we have agreed to file a registration statement registering the shares underlying these warrants unless such shares are eligible for sale under Rule 144.
- Each of these warrants contains anti-dilution provisions providing for adjustments to the exercise price upon the issuance of shares of our common stock for no consideration or at a price less than the exercise price pursuant to a merger, asset acquisition or other business combination where a third party acquires a majority equity interest in or all or substantially all of the assets of our company. If such a lower-priced issuance occurs, the exercise price of these warrants will be reduced to the price at which our common stock is issued.
- (3)
- Each of these warrants contains anti-dilution provisions providing for adjustments to the exercise price upon the issuance of shares of our common stock for no consideration or at a price less than the exercise price, excluding certain shares of our common stock issuable upon exercise of options, warrants or conversion of convertible securities. If such a lower-priced issuance occurs, the exercise price of the warrants will be reduced based on a weighted average of the difference between the exercise price of the warrants and the issuance price of the shares.
- (4)
- (5) The shares underlying each of this warrant are entitled to certain registration rights set forth in our third amended and restated stockholders agreement. See Registration Rights below for a description of these registration rights.

Registration Rights

On August 9, 2012, we entered into a third amended and restated stockholders agreement with certain holders of our preferred stock, common stock and warrants, which provides such holders (including the selling stockholders in this offering) with registration rights with respect to certain shares of our common stock, including shares of our common stock issuable upon exercise of warrants. The summary of the registration rights below is qualified by reference to the third amended and restated stockholders agreement, a copy of which has been filed with the Securities and Exchange Commission as an exhibit and incorporated by reference to the registration statement of which this prospectus forms a part. As of September 16, 2013, an aggregate of 11,313,909 shares of outstanding common stock and shares of common stock underlying warrants, including those shares offered by the selling stockholders under this prospectus, are registrable securities pursuant to the terms of the third amended and restated stockholders agreement. Following this offering, it is anticipated that an aggregate of 9,098,862 shares of our outstanding common stock and shares of common stock underlying warrants will be registrable securities pursuant to the terms of this agreement.

Our warrants that were issued in 2003 and 2004 contain registration rights in the forms of the warrant, copies of which are filed as an exhibit and incorporated by reference to the registration statement of which this prospectus is a part.

See Warrants above for a description of the registration rights relating to these warrants.

Demand Registration Rights. The holders of the registrable shares are entitled to certain demand registration rights. If certain of our major security holders who are parties to the third amended and restated stockholders agreement request a registration of registrable shares having an aggregate value of at least \$25.0 million (based on the market price or fair value on the date of such request), we will be required to register their shares. We may be required to effect up to three registrations in accordance with such demand registration rights. Stockholders with these registration rights who are not part of an initial registration demand are entitled to notice and are entitled to include their registrable shares in the registration. Under certain circumstances, our board of directors may suspend our obligations to register registrable shares. The registration statement of which this prospectus forms a part was filed pursuant to the exercise

by the selling stockholders of their demand registration rights under the third amended and restated stockholders agreement.

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Piggyback Registration Rights. In the event that we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders (other than in connection with this offering, a registration statement on Form S-8 or Form S-4 or to cover securities proposed to be issued in exchange for securities or assets of another corporation), the holders of the registrable shares will be entitled to certain piggyback registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, the holders of these shares of our common stock are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. The security holders who are entitled to piggyback registration rights have waived their rights in respect of this offering and the filing of the registration statement of which this prospectus forms a part.

Shelf Registration Rights. If we become eligible to file registration statements on Form S-3 that will become automatically effective upon filing, the holders of the registrable shares will be entitled to require us to register all or a portion of their registrable shares on Form S-3 if the registrable shares held by such holders have an aggregate value of at least \$5.0 million (based on the public market price on the date of such request). If we become eligible to file use a Form S-3 that becomes automatically effective upon filing, we are required to use our commercially reasonable efforts to file a Form S-3 registration statement as soon as practicable, and in any event within 30 days after the request, except under limited circumstances. There is no limit to the number of registrations that we may be required to make in accordance with such Form S-3 registration rights. Stockholders with these registration rights who are not part of an initial registration demand are entitled to notice and are entitled to include their registrable shares in the registration. Under certain circumstances, our board of directors may suspend our obligations to register registrable shares.

We have agreed to pay certain registration expenses of the holders of the shares registered pursuant to any demand, piggyback and shelf registrations described above.

Anti-Takeover Effects of Delaware Law and Our Restated Certificate of Incorporation and Restated By-Laws

The provisions of Delaware law and our restated certificate of incorporation and restated by-laws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

Delaware Statutory Business Combinations Provision. We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a business combination is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an interested stockholder is a person who, together with his or her affiliates and associates, owns, or within three years

prior, did own, 15% or more of the corporation's voting stock.

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors. Our restated by-laws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our secretary. For an annual meeting, a stockholder's notice generally must be delivered not less than 90 days nor more than 120 days prior to the first anniversary of the previous year's

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annual meeting date. For a special meeting, the notice must generally be delivered not earlier than the 90th day prior to the meeting and not later than the later of (1) the 60th day prior to the meeting or (2) the 10th day following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in the restated by-laws. If it is determined that business was not properly brought before a meeting in accordance with our by-law provisions, such business will not be conducted at the meeting.

Special Meetings of Stockholders. Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

No Stockholder Action by Written Consent. Any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders *provided, however*, that if any one stockholder, together with its affiliates, collectively holds a majority of the voting power of the then-outstanding shares of our capital stock, action may be taken without a meeting and vote, through the written consent of holders of the requisite number of votes necessary to authorize or take such action at a meeting.

Super Majority Stockholder Vote Required for Certain Actions. The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless the corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our restated certificate of incorporation requires the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section of this prospectus entitled *Anti-Takeover Effects of Delaware Law and Our Restated Certificate of Incorporation and Restated By-Laws*. This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. A 80% vote is also required for any amendment to, or repeal of, our restated by-laws by the stockholders. Our restated by-laws may be amended or repealed by a simple majority vote of the board of directors.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC.

Stock Exchange

Our common stock is listed on the Nasdaq Global Market under the symbol ICPT.

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SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

As of September 16, 2013, we had outstanding 19,261,799 shares of common stock, of which 9,516,201 shares are freely tradable without restriction under the Securities Act of 1933, which we refer to as the Securities Act. Of the shares to be outstanding immediately after the closing of this offering, we expect that 11,016,201 shares of our common stock will be freely tradable without restriction under the Securities Act, unless purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act and 8,245,598 shares of our common stock will be restricted or control securities under Rule 144. These securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

In general, under Rule 144, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

A person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

1% of the number of shares of our common stock then outstanding; and
the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale. Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Subject to the 90-day lock-up period described below, approximately 8,245,598 shares of our common stock will be eligible for sale under Rule 144 upon the closing of this offering. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act, any of an issuer's employees, consultants or advisors who purchased shares from the issuer in connection with a qualified compensatory stock plan or other written agreement before the issuer became subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, which we refer to as the Exchange Act, is eligible to resell those shares in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of

Rule 144, and a non-affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144 and without regard to the volume of such sales or the availability of public information about the issuer.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act. We became subject to the reporting requirements of the Exchange Act in October 2012.

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In November 2012 and April 2013, we filed registration statements on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and other awards issuable pursuant to our 2012 equity incentive plan and our 2003 stock incentive plan.

Lock-Up Agreements

We and each of our directors and executive officers and the selling stockholders have agreed that, without the prior written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated, we and they will not, subject to certain exceptions, during the period ending 90 days after the date of this prospectus, either directly or indirectly:

offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock, or publicly announce an intention to do the same;

enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, whether such transaction is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise, or publicly announce an intention to do the same; or make any demand for or exercise any right with respect to the registration of any shares of our common stock or any security convertible into or exercisable or exchangeable for shares of our common stock, or with respect to the filing of any registration statement in connection therewith under the Securities Act.

The lock-up restrictions and specified exceptions are described in more detail in the Underwriting section of this prospectus. These lock-up restrictions do not apply to the shares of our common stock being offered by the selling stockholders by this prospectus.

Registration Rights

Subject to the lock-up agreements described above, as of September 16, 2013, the holders of an aggregate of 10,598,862 shares of our common stock, including those shares offered by the selling stockholders under this prospectus, have the right to require us to register these shares under the Securities Act under specified circumstances. Following this offering, holders of an aggregate of 9,098,862 shares of our common stock will have such rights. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See Description of Capital Stock Registration Rights for additional information regarding these registration rights. The registration statement of which this prospectus forms a part was filed pursuant to the exercise by the selling stockholders of certain demand registration rights. Our security holders who are entitled to certain piggy-back registration rights have waived their rights in respect of this offering and the filing of the registration statement of which this prospectus forms a part.

Stock Options, Restricted Stock Units and Warrants

As of September 16, 2013, we had outstanding options to purchase 1,563,496 shares of our common stock at a weighted average exercise price of \$18.74 per share, of which options to purchase 824,439 shares were vested, and we also had outstanding unvested restricted stock units for 134,569 shares of our common stock. In November 2012 and April 2013, we filed registration statements on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and options and other awards issuable pursuant to our 2012 equity incentive plan and our 2003 stock incentive plan. Accordingly, shares of our common stock registered under the registration statement are available for sale in the open market, subject to Rule 144 volume limitations applicable to

affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

As of September 16, 2013, we had outstanding warrants to purchase 878,201 shares of our common stock at a weighted average exercise price of \$10.33 per share. The warrants and the common stock issuable upon the exercise of the warrants have not been registered under the Securities Act and any resale of any of those securities must be made pursuant to a registration statement or an available exemption from registration.

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MATERIAL U.S. FEDERAL TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following is a general discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term non-U.S. holder means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

an individual who is a citizen or resident of the United States;
a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or of any political subdivision of the United States;

an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or if the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended (the Code), existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. In addition, the Internal Revenue Service, or the IRS, could challenge one or more of the tax consequences described in this prospectus.

We assume in this discussion that each non-U.S. holder holds shares of our common stock as a capital asset (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of state, local or non-U.S. taxes, or of the Medicare Contributions tax, or of U.S. federal taxes other than income and estate taxes. This discussion does not represent a detailed description of the U.S. federal income tax consequences applicable to a non-U.S. holder subject to special treatment under the U.S. federal income tax laws (including if the non-U.S. holder is a United States expatriate, controlled foreign corporation, or passive foreign investment company).

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other entities that are transparent for U.S. federal income tax purposes. A partner in a partnership or other transparent entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other transparent entity, as applicable.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock.

Dividends

If we pay distributions on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the

heading Gain on Disposition of Common Stock.

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. If we determine, at a time reasonably close to the date of payment of a distribution on our common stock, that the distribution will not constitute a dividend because we do not anticipate having current or accumulated earnings and profits, we intend not to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

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Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States, and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. To obtain this exemption, a non-U.S. holder must provide us or the applicable withholding agent with a properly executed original and unexpired IRS Form W-8ECI properly certifying such exemption. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence providing for a reduced withholding tax rate on dividends generally will be required to provide a properly executed IRS Form W-8BEN (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS.

Gain on Disposition of Common Stock

Any gain realized on the disposition of our common stock generally will not be subject to United States federal income tax unless:

the gain is effectively connected with a trade or business of the non-U.S. holder in the United States (and, if required by an applicable income tax treaty, is attributable to a United States permanent establishment of the non-U.S. holder); the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or

we are or have been a United States real property holding corporation for U.S. federal income tax purposes.

An individual non-U.S. holder described in the first bullet point immediately above will be subject to tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates. An individual non-U.S. holder described in the second bullet point immediately above will be subject to a flat 30% tax on the gain derived from the sale, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States. If a non-U.S. holder that is a foreign corporation falls under the first bullet point immediately above, it will be subject to tax on its net gain in the same manner as if it were a United States person as defined under the Code and, in addition, may be subject to the branch profits tax equal to 30% of its effectively connected earnings and profits or at such lower rate as may be specified by an applicable income tax treaty.

We believe we are not and do not anticipate becoming a United States real property holding corporation for U.S. federal income tax purposes.

Information Reporting and Backup Withholding Tax

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have

to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate (currently 28%) with respect to dividends on our common stock. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption.

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Information reporting and, depending on the circumstances, backup withholding will apply to the proceeds of a sale of our common stock within the United States or conducted through certain United States-related financial intermediaries, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that the beneficial owner is a United States person as defined under the Code), or such owner otherwise establishes an exemption.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided the required information is timely furnished to the IRS.

Additional Withholding Requirements

Under legislation enacted in 2010 and administrative guidance, a 30% U.S. federal withholding tax may apply to any dividends paid after December 31, 2013, and the gross proceeds from a disposition of our common stock occurring after December 31, 2016, in each case paid to (i) a foreign financial institution (as specifically defined in the legislation), whether such foreign financial institution is the beneficial owner or an intermediary, unless such foreign financial institution agrees to verify, report and disclose its United States account holders (as specifically defined in the legislation) and meets certain other specified requirements or (ii) a non-financial foreign entity, whether such non-financial foreign entity is the beneficial owner or an intermediary, unless such entity provides a certification that the beneficial owner of the payment does not have any substantial United States owners or provides the name, address and taxpayer identification number of each such substantial United States owner and certain other specified requirements are met. In certain cases, the relevant foreign financial institution or non-financial foreign entity may qualify for an exemption from, or be deemed to be in compliance with, these rules. Non-U.S. holders should consult their own tax advisors regarding this legislation and whether it may be relevant to their ownership and disposition of our common stock.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

The preceding discussion of material U.S. federal tax considerations is for general information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

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UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated is acting as the sole underwriter for this offering. Subject to the terms and conditions set forth in an underwriting agreement among us, the selling stockholders and the underwriter, the selling stockholders have agreed to sell to the underwriter, and the underwriter has agreed to purchase from the selling stockholders an aggregate 1,500,000 of shares of common stock.

Subject to the terms and conditions set forth in the underwriting agreement, the underwriter has agreed to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased.

We and the selling stockholders have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriter may be required to make in respect of those liabilities.

The underwriter is offering the shares, subject to prior sale, when, as and if accepted by it, subject to approval of legal matters by its counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriter of officer's certificates and legal opinions. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The underwriter has advised us that it proposes initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to the selling stockholders. The information assumes either no exercise or full exercise by the underwriter of its option to purchase additional shares.

| | Per Share | Without Option | With Option |
|--|-----------|-------------------|----------------|
| Public offering price | \$ | \$ | \$ |
| Underwriting discount | \$ | \$ | \$ |
| Proceeds, before expenses, to the selling stockholders | \$ | \$ | \$ |

We estimate that our share of the total expenses for the offering (including expenses to be reimbursed to the selling stockholders by us), not including the underwriting discount, will be approximately \$375,000. We have agreed to pay the filing fees incidental to, and the fees and disbursements of counsel for the underwriter in connection with, any required review by FINRA in connection with this offering, in an amount not to exceed \$10,000.

Option to Purchase Additional Shares

The selling stockholders have granted an option to the underwriter, exercisable for 30 days after the date of this prospectus, to purchase up to 225,000 additional shares at the public offering price, less the underwriting discount. If the underwriter exercises this option, it will be obligated, subject to conditions contained in the underwriting agreement, to purchase such number of additional shares.

No Sales of Similar Securities

We, our executive officers and directors, and the selling stockholders, Genextra S.p.A. and OrbiMed Private Investments IV, LP, have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, other than the shares of common stock offered by the selling stockholders by this prospectus, for 90 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated. Specifically, we and these other persons have agreed, with certain exceptions, not to directly or indirectly:

offer, pledge, sell or contract to sell any common stock,
sell any option or contract to purchase any common stock,

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purchase any option or contract to sell any common stock, grant any option, right or warrant for the sale of any common stock, lend or otherwise dispose of or transfer any common stock, request or demand that we file a registration statement related to the common stock, or enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Nasdaq Global Market Listing

Our common stock is listed on the Nasdaq Global Market under the symbol ICPT.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, the rules of the Securities and Exchange Commission may limit the underwriter and selling group members from bidding for and purchasing our common stock. However, the underwriter may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriter may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriter of a greater number of shares than it is required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriter's option to purchase additional shares described above. The underwriter may close out any covered short position by either exercising its option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which it may purchase shares through the option granted to it. Naked short sales are sales in excess of such option. The underwriter must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriter in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriter's purchases to cover short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriter may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we, the selling stockholders nor the underwriter makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we, the selling stockholders nor the underwriter makes any representation that the underwriter will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Passive Market Making

In connection with this offering, the underwriter and selling group members may engage in passive market making transactions in our common stock on the Nasdaq Global Select Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or

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sales of common stock and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriter and dealers are not required to engage in passive market making and may end passive market making activities at any time.

Electronic Distribution

In connection with the offering, certain of the underwriter or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriter and its affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriter and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or each, a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, no offer of shares may be made to the public in that Relevant Member State other than:

- A. to any legal entity which is a qualified investor as defined in the Prospectus Directive; to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD
- B. Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriter; or
- C. in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares shall require the Company or the underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State (other than a Relevant Member State where there is a Permitted Public Offer) who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that (A) it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive, and (B) in the case of any shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, the shares acquired by it in the

offerings have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors as defined in the Prospectus Directive, or in circumstances in which the prior consent of the underwriter has been given to the offer or resale. In the case of any shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other

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than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the underwriter has been obtained to each such proposed offer or resale.

The Company, the underwriter and their affiliates will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement.

This prospectus has been prepared on the basis that any offer of shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or the underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriter have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the underwriter to publish a prospectus for such offer.

For the purpose of the above provisions, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are qualified investors (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt

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Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of our common stock may only be made to persons (the Exempt Investors) who are sophisticated investors (within the meaning of section 708(8) of the Corporations Act), professional investors (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer our common stock without disclosure to investors under Chapter 6D of the Corporations Act.

Our shares of common stock applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares of common stock must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares of common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to professional investors as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a prospectus as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares of common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares of common stock have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, Japanese Person shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

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Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common stock pursuant to an offer made under Section 275 of the SFA except:
 - (a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
 - (b) where no consideration is or will be given for the transfer;
 - (c) where the transfer is by operation of law;
 - (d) as specified in Section 276(7) of the SFA; or
- (e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

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LEGAL MATTERS

The validity of the shares of common stock offered by the selling stockholders in this offering will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts. Goodwin Procter LLP, New York, New York, is acting as counsel for the underwriter in connection with this offering.

EXPERTS

The consolidated financial statements of Intercept Pharmaceuticals, Inc. (a development stage enterprise) as of December 31, 2010, December 31, 2011 and December 31, 2012 and for each of the years in the three-year period ended December 31, 2012 and the information included in the cumulative from inception presentation for the period September 4, 2002 (inception) to December 31, 2012, incorporated by reference in this prospectus from Intercept Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2012 have been so included in reliance on the report of KPMG LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The information incorporated by reference in this prospectus and included in the cumulative from inception presentation from September 4, 2002 (inception) to December 31, 2007 (not presented separately therein), has been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference, in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy these reports, proxy statements and other information at the public reference facilities of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC's website at <http://www.sec.gov>.

We have filed with the SEC a registration statement, of which this prospectus is a part, covering the securities offered hereby. As allowed by SEC rules, this prospectus does not include all of the information contained in the registration statement and the included exhibits and schedules. You are referred to the registration statement, the included exhibits and schedules for further information. This prospectus is qualified in its entirety by such other information.

We also maintain a website at www.interceptpharma.com, through which you can access our filings with the SEC. The information set forth on or accessible from our website is not part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-35668).

our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 filed on April 1, 2013;
our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 filed on May 14, 2013;
our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 filed on August 13, 2013;
our Current Reports on Form 8-K filed on February 22, 2013, March 18, 2013, March 22, 2013, April 15, 2013, April 30, 2013, May 13, 2013, May 17, 2013, May 31, 2013, June 24, 2013, July 2, 2013 and October 1, 2013 (other than the portions of those reports not deemed to be filed);

the portions of our Definitive Proxy Statement on Schedule 14A filed on April 12, 2013 that are deemed filed with the SEC under the Exchange Act; and

the description of our common stock contained in our Registration Statement on Form 8-A filed on September 27, 2012, including any amendment or report filed for the purpose of updating such description.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

You may request, orally or in writing, a copy of any or all of the documents incorporated herein by reference. These documents will be provided to you at no cost, by contacting: Investor Relations, Intercept Pharmaceuticals, Inc., 18 Desbrosses Street, New York, NY 10013, (646) 747-1000, email address: info@interceptpharma.com. In addition, copies of any or all of the documents incorporated herein by reference may be accessed at our website at www.interceptpharma.com.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any prospectus supplement. Neither we, the selling stockholders nor the underwriter have authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus.

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1,500,000 Shares

Common Stock

P R O S P E C T U S

BofA Merrill Lynch

, 2013

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The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of the common stock being registered. All the amounts shown are estimates except the SEC registration fee and the FINRA filing fee.

| | Total |
|--|------------|
| SEC registration fee | \$ 15,362 |
| FINRA filing fee | \$ 17,750 |
| Blue sky qualification fees and expenses | \$ 7,500 |
| Printing and engraving expenses | \$ 30,000 |
| Legal fees and expenses | \$ 210,000 |
| Accounting fees and expenses | \$ 75,000 |
| Transfer agent and registrar fees | \$ 1,000 |
| Miscellaneous | \$ 18,388 |
| Total | \$ 375,000 |

Item 14. Indemnification of Directors and Officers

Our restated certificate of incorporation and restated bylaws provide that we shall indemnify, to the fullest extent authorized by the Delaware General Corporation Law, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of Intercept Pharmaceuticals, Inc. or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our restated certificate of incorporation provides that the right to indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification. If we do not pay a proper claim for indemnification in full within 60 days after we receive a written claim for such indemnification, except in the case of a claim for an advancement of expenses, in which case such period is 20 days, our restated certificate of incorporation and our restated by-laws authorize the claimant to bring an action against us and prescribe what constitutes a defense to such action.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (*i.e.*, one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best

interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The rights conferred in the restated certificate of incorporation and the restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. We have entered into indemnification agreements with each of our officers and directors, the form of which is filed with the SEC.

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Pursuant to Section 102(b)(7) of the Delaware General Corporation Law, our restated certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

from any breach of the director's duty of loyalty to us or our stockholders;
from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
under Section 174 of the Delaware General Corporation Law; or
from any transaction from which the director derived an improper personal benefit.

We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacity as directors and officers.

Additionally, reference is made to the Underwriting Agreement, the form of which is filed as Exhibit 1.1 hereto, which provides for indemnification by the underwriters of Intercept Pharmaceuticals, Inc., our directors and officers who sign the registration statement and persons who control Intercept Pharmaceuticals, Inc., under certain circumstances.

Item 15. Recent Sales of Unregistered Securities

From January 2010, we have issued the following securities that were not registered under the Securities Act.

(a) *Issuances of Capital Stock and Warrants*

In January 2010, we sold 13,888,889 shares of Series B preferred stock and a warrant with a five-year term to purchase 865,381 shares of common stock at \$10.40 per share to Genextra S.p.A. for net proceeds of \$24.9 million. Upon the completion of our initial public offering in October 2012, the shares of Series B preferred stock were converted into 2,403,836 shares of our common stock.

On August 9, 2012, we entered into a securities purchase agreement with an affiliated fund of OrbiMed Advisors LLC and Genextra S.p.A., pursuant to which we agreed to issue in two tranches up to an aggregate of 25,000,000 shares of Series C preferred stock at a price of \$2.00 per share for gross proceeds of up to \$50.0 million. The first tranche of Series C preferred stock was issued on August 9, 2012, and resulted in \$29.8 million of net proceeds to us. The closing of the second tranche was only contemplated to occur if we did not complete an initial public offering of our common stock on or prior to August 2013. Upon the completion of our initial public offering, the Series C preferred stock was converted into 2,596,143 shares of common stock and the agreement to issue the second tranche of Series C preferred stock was nullified.

No underwriters were used in the foregoing transactions. The securities described above were issued and sold in reliance on the exemptions from registration provided by Section 4(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act. Each of the purchasers in these transactions represented to us in connection with its purchase that it was acquiring the securities for investment and not for distribution and that it could bear the risks of the investment. Each purchaser received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) *Exercises of Warrants*

Between October and December 2012, we issued an aggregate of 43,402 shares of common stock upon exercise of previously issued and outstanding warrants to purchase common stock, all of which were issued upon the cashless

exercise of such warrants.

Between January and August 2013, we issued an aggregate of 224,818 shares of common stock upon exercise of previously issued and outstanding warrants to purchase common stock. All such shares, except for 2,803 shares that were issued upon the exercise of a warrant for cash, were issued upon the cashless exercise of such warrants.

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No underwriters were used in the foregoing transactions. The warrants exercised into shares of common stock were issued and sold in reliance on the exemptions from registration provided by Section 4(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act. Each of the purchasers in these transactions represented to us in connection with its purchase that it was acquiring the securities for investment and not for distribution and that it could bear the risks of the investment. Each purchaser received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(c) *Grants and Exercises of Stock Options*

From January 2010 until October 2012, we granted stock options to purchase an aggregate of 700,861 shares of our common stock, with 23,794 of such stock options having an exercise price of \$9.30 per share and 677,067 of such stock options having an exercise price of \$8.67 per share, to employees, directors and consultants pursuant to our 2003 Plan. The issuances of common stock upon exercise of the options were exempt either pursuant to Rule 701, as a transaction pursuant to a compensatory benefit plan, or pursuant to Section 4(2), as a transaction by an issuer not involving a public offering. The shares of common stock issued upon exercise of options are deemed restricted securities for the purposes of the Securities Act.

Item 16. Exhibits and Financial Statement Schedules

(a) *Exhibits*

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this registration statement on Form S-1, which Exhibit Index is incorporated herein by reference.

(b) *Financial Statement Schedules*

Not applicable.

Item 17. Undertakings

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described under Item 14 above, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2)

For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, New York, on the 7th day of October, 2013.

INTERCEPT PHARMACEUTICALS, INC.

/s/ Mark Pruzanski

By:

Mark Pruzanski, M.D.

President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities indicated below on the 7th day of October, 2013.

| Signature | Title | Date |
|--|---|-----------------|
| /s/ Mark Pruzanski | President and Chief Executive Officer and Director (Principal Executive Officer) | October 7, 2013 |
| Mark Pruzanski, M.D. /s/ Barbara Duncan | Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer) | October 7, 2013 |
| Barbara Duncan * | Chairman of the Board of Directors | October 7, 2013 |
| Lorenzo Tallarigo, M.D. * | Director | October 7, 2013 |
| Srinivas Akkaraju * | Director | October 7, 2013 |
| Paolo Fundaro * | Director | October 7, 2013 |
| Jonathan T. Silverstein * | Director | October 7, 2013 |
| Klaus Veitinger, M.D. * | Director | October 7, 2013 |
| Nicole Williams | Director | October 7, 2013 |

* /s/ Barbara
Duncan

Barbara Duncan,

as
Attorney-in-Fact

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EXHIBIT INDEX

Exhibit Number Exhibit Description Filed Herewith Incorporated by Reference herein from Form or Schedule Filing Date SEC File/

| | | |
|------------------|--|---|
| Reg. Number | 1.1 Form of Underwriting Agreement X | 3.1 Restated Certificate of Incorporation of the Registrant |
| | Form 8-K | |
| (Exhibit 3.1) | 10/16/12 001-356683.2 Restated Bylaws of the Registrant | Form 8-K |
| (Exhibit 3.2) | 10/16/12 001-356684.1 Form of Common Stock Certificate of the Registrant | Form S-8 |
| (Exhibit 4.3) | 11/07/12 333-1848104.2 Third Amended and Restated Stockholders Agreement by and among the Registrant, the holders of the Registrant's convertible preferred stock, the Registrant's founders and certain other investors, dated August 9, 2012 | Form S-1 |
| (Exhibit 4.2) | 09/04/12 333-1837064.3 Form of Series A Warrant to purchase Common Stock issued in 2003, expiring in October 2013 | Form S-1 |
| (Exhibit 4.3) | 09/04/12 333-1837064.4 Form of Series B Warrant to purchase Common Stock issued in 2003, expiring in October 2013 | Form S-1 |
| (Exhibit 4.4) | 09/04/12 333-1837064.5 Form of Series A Warrant to purchase Common Stock issued in 2004, expiring in October 2013 | Form S-1 |
| (Exhibit 4.5) | 09/04/12 333-1837064.6 Form of Series A Warrant to purchase Common Stock issued in 2004, expiring in May 2014 | Form S-1 |
| (Exhibit 4.6) | 09/04/12 333-1837064.7 Form of Series B Warrant to purchase Common Stock issued in 2004, expiring in October 2013 | Form S-1 |
| (Exhibit 4.7) | 09/04/12 333-1837064.8 Form of Warrant to purchase Common Stock issued in 2010, expiring in January 2015 | Form S-1 |
| (Exhibit 4.9) | 09/04/12 333-1837065.1 Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. counsel to the Registrant, with respect to the legality of securities being registered X | Equity Compensation Plans |
| | 10.1.1 Amended and Restated 2003 Stock Incentive Plan of the Registrant+ | Form S-1 |
| (Exhibit 10.1.1) | 09/04/12 333-183706 .2 Form of Nonstatutory Stock Option Agreement granted under the 2003 Stock Incentive Plan of the Registrant+ | Form S-1 |
| (Exhibit 10.1.2) | 09/04/12 333-183706 .3 Form of Incentive Stock Option Agreement granted under the 2003 Stock Incentive Plan of the Registrant+ | Form S-1 |
| (Exhibit 10.1.3) | 09/04/12 333-183706 .4 Amendment to Amended and Restated 2003 Stock Incentive Plan of the Registrant+ | Form S-1 |
| (Exhibit 10.1.4) | 09/04/12 333-183706 | |

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| Exhibit Number | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule Amendment | Filing Date | SEC File/Reg. Number |
|----------------|---|----------------|--|-------------|----------------------|
| 10.2.1 | Form of 2012 Equity Incentive Plan of the Registrant+ | | No.1 to Form S-1 (Exhibit 10.2.1) | 09/27/12 | 333-183706 |
| .2 | Form of Stock Option Grant Notice for Directors under the 2012 Equity Incentive Plan of the Registrant+ | | No.1 to Form S-1 (Exhibit 10.2.2) | 09/27/12 | 333-183706 |
| .3 | Form of Stock Option Grant Notice for Employees and Consultants under the 2012 Equity Incentive Plan of the Registrant+ | | No.1 to Form S-1 (Exhibit 10.2.3) | 09/27/12 | 333-183706 |
| .4 | Form of Restricted Stock Unit Award Grant Notice for Directors under the 2012 Equity Incentive Plan of the Registrant+ | | No.1 to Form S-1 (Exhibit 10.2.4) | 09/27/12 | 333-183706 |
| .5 | Form of Restricted Stock Unit Award Grant Notice for Employees and Consultants under the 2012 Equity Incentive Plan of the Registrant+ | | No.1 to Form S-1 (Exhibit 10.2.5) | 09/27/12 | 333-183706 |
| 10.3 | 2013 Non-Employee Director Compensation Policy+ Agreements with Executive Officers and Directors | | Form 8-K (Exhibit 10.1) | 05/13/13 | 001-35668 |
| 10.4.1 | Amended and Restated Employment Agreement by and between the Registrant and Mark Pruzanski, dated May 14, 2013+ | | Form 10-Q (Exhibit 10.5) | 05/14/13 | 001-35668 |
| .2 | Non-Competition and Non-Solicitation Agreement by and between the Registrant and Mark Pruzanski, dated June 20, 2006+ | | Form S-1 (Exhibit 10.4.2) | 09/04/12 | 333-183706 |
| .3 | Invention, Non-Disclosure, and Non-Solicitation Agreement by and between the Registrant and Mark Pruzanski, dated December 31, 2009+ | | Form S-1 (Exhibit 10.4.3) | 09/04/12 | 333-183706 |
| 10.5.1 | Amended and Restated Employment Agreement by and between the Registrant and Barbara Duncan, dated May 14, 2013+ | | Form 10-Q (Exhibit 10.12) | 05/14/13 | 001-35668 |
| .2 | Invention, Non-Disclosure, and Non-Solicitation Agreement by and between the Registrant and Barbara Duncan, effective as of May 16, 2009+ | | Form S-1 (Exhibit 10.5.2) | 09/04/12 | 333-183706 |

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| Exhibit Number | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/Reg. Number |
|---|---|----------------|--|-------------|----------------------|
| 10.6.1 | Amended and Restated Employment Agreement by and between the Registrant and David Shapiro, dated May 14, 2013+ | | Form 10-Q (Exhibit 10.11) | 05/14/13 | 001-35668 |
| .2 | Invention, Non-Disclosure, and Non-Solicitation Agreement by and between the Registrant and David Shapiro, dated March 31, 2008+ | | Form S-1 (Exhibit 10.6.2) | 09/04/12 | 333-183706 |
| 10.7.1 | Amended and Restated Employment Agreement by and between Registrant and Daniel Regan, dated May 14, 2013+ | | Form 10-Q (Exhibit 10.9) | 05/14/13 | 001-35668 |
| .2 | Invention, Non-Disclosure, and Non-Solicitation Agreement by and between the Registrant and Daniel Regan, dated March 4, 2013+ | | Form 10-K (Exhibit 10.7.2) | 04/01/13 | 001-35668 |
| 10.8 | Amended and Restated Consulting Agreement between the Registrant and Luciano Adorini, dated May 14, 2013+ | | Form 10-Q (Exhibit 10.13) | 05/14/13 | 001-35668 |
| 10.9 | Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers | | Form S-1 (Exhibit 10.7) | 09/04/12 | 333-183706 |
| Lease Agreements | | | | | |
| 10.10 | Lease Agreement between Greenwich-Desbrosses Realty LLC and the Registrant, as amended, dated December 1, 2006 | | Form S-1 (Exhibit 10.8) | 09/04/12 | 333-183706 |
| 10.11.1 | Lease Agreement between 4350 La Jolla Village LLC and the Registrant, dated October 25, 2011 | | Form S-1 (Exhibit 10.9) | 09/04/12 | 333-183706 |
| .2 | First Amendment to Lease Agreement between 4350 La Jolla Village LLC and the Registrant, dated March 18, 2013 | | Form 8-K (Exhibit 10.1) | 03/22/13 | 001-35668 |
| Agreements with Respect to Collaborations, Licenses, Research and Development | | | | | |
| 10.12 | License Agreement by and between the Registrant and Dainippon Sumitomo Pharma Co. Ltd., dated March 29, 2011* | | Amendment No.1 to Form S-1 (Exhibit 10.10) | 09/27/12 | 333-183706 |
| 10.13.1 | Product Research, Development, License and Commercialization Agreement by and between the Registrant, Les Laboratoires Servier and Institut De Recherchés Servier, dated August 1, 2011 (the Servier Agreement)* | | Amendment No.1 to Form S-1 (Exhibit 10.11.1) | 09/27/12 | 333-183706 |
| .2 | Amendment No. 1 to the Servier Agreement, dated July 24, 2012* | | Form S-1 (Exhibit 10.11.2) | 09/04/12 | 333-183706 |
| .3 | Amendment No. 2 to the Servier Agreement, dated February 15, 2013* | | Form 8-K (Exhibit 10.1) | 02/22/13 | 001-35668 |

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| Exhibit Number | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|----------------|--|----------------|--|-------------|-----------------------|
| 10.14 | Cooperative Research and Development Agreement by and between the Registrant and The National Institute of Diabetes and Digestive and Kidney Diseases, dated July 1, 2010* | | Form S-1 (Exhibit 10.12) | 09/04/12 | 333-183706 |
| 10.15.1 | Sponsored Research Agreement by and between the Registrant, Dipartimento di Chimica e Tecnologia del Farmaco of the Università di Perugia, and Professor Roberto Pellicciari, dated January 1, 2012 | | Form S-1 (Exhibit 10.13) | 09/04/12 | 333-183706 |
| 10.16.2 | Amendment No. 1 to Sponsored Research Agreement between Registrant, Dipartimento di Chimica e Tecnologia del Farmaco of the Università di Perugia, and Professor Roberto Pellicciari, dated April 29, 2013 | | Form 8-K (Exhibit 10.1) | 04/30/13 | 001-35668 |
| 10.17.1 | Consulting and IP Agreement by and between the Registrant and Roberto Pellicciari, dated August 1, 2011* | | Amendment No.1 to Form S-1 (Exhibit 10.14.1) | 09/27/12 | 333-183706 |
| .2 | Amendment No. 1 to Consulting and IP Agreement by and between the Registrant and Roberto Pellicciari, dated July 30, 2012* | | Form S-1 (Exhibit 10.14.2) | 09/04/12 | 333-183706 |
| .3 | Amendment No. 2 to Consulting and IP Agreement with Professor Roberto Pellicciari, dated February 15, 2013* | | Form 8-K (Exhibit 10.2) | 02/22/13 | 001-35668 |
| 10.18.1 | Consulting and Intellectual Property (IP) Agreement by and between the Registrant and Roberto Pellicciari, dated January 1, 2012 | | Form S-1 (Exhibit 10.15) | 09/04/12 | 333-183706 |
| .2 | Amendment No. 1 to Consulting and IP Agreement by and between Registrant and Roberto Pellicciari, dated April 29, 2013 | | Form 8-K (Exhibit 10.2) | 04/30/13 | 001-35668 |
| 10.19.1 | Research and Development Agreement by and between the Registrant and TES Pharma Srl, dated August 1, 2011 (the TES Agreement)* | | Amendment No.1 to Form S-1 (Exhibit 10.16.1) | 09/27/12 | 333-183706 |
| .2 | Amendment No. 1 to the TES Agreement, dated July 27, 2012* | | Form S-1 (Exhibit 10.16.2) | 09/04/12 | 333-183706 |
| .3 | Amendment No. 2 to the TES Agreement, dated February 15, 2013* | | Form 8-K (Exhibit 10.3) | 02/22/13 | 001-35668 |
| 10.20.1 | Master Laboratory Services Agreement by and between the Registrant and WIL Research | | Form S-1 (Exhibit | 09/04/12 | 333-183706 |

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| | | | |
|----|--|----------|---------------------|
| | Laboratories, LLC, dated October 2, 2007 | 10.17.1) | |
| | Amendment No. 1 to the Master Laboratory Services | Form S-1 | |
| .2 | Agreement by and between the Registrant and WIL | (Exhibit | 09/04/12 333-183706 |
| | Research Laboratories, LLC, dated October 28, 2011 | 10.17.2) | |

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+ Management contract or compensatory plan or arrangement.

* Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.

** Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a

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registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability under these sections.

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