

INTERCEPT PHARMACEUTICALS INC  
Form 424B5  
February 03, 2015

**Filed pursuant to Rule 424(b)(5)  
Registration File No. 333-194974**

The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and is effective. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities and they are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

## **Subject to Completion, Dated February 3, 2015**

### **PRELIMINARY PROSPECTUS SUPPLEMENT**

(To Prospectus Dated April 1, 2014)

## **800,000 Shares**

## **Common Stock**

We are offering 800,000 shares of our common stock.

Our common stock is listed on The NASDAQ Global Select Market under the symbol ICPT. On February 2, 2015, the last sale price of our common stock was \$188.66 per share, as reported on The NASDAQ Global Select Market.

**Investing in our common stock involves risks. See Risk Factors beginning on page S-13 of this prospectus supplement.**

**Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.**

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$

Proceeds, before expenses, to us \$ \$

(1) See Underwriting.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to an additional 120,000 shares of our common stock at the public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares to the investors on or about February , 2015.

*Joint Book-Running Managers*

**Citigroup**

**RBC Capital Markets**

The date of this prospectus supplement is February , 2015.

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## **ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; 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 accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

Neither we nor the underwriters have authorized anyone to provide any information other than that contained or incorporated by reference in this prospectus supplement, in the accompanying prospectus or in any free writing prospectus filed with the Securities and Exchange Commission by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction to or from any person to whom or from whom it is unlawful to make such offer or solicitation of an offer in such jurisdiction. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and in any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of the date of those respective documents. It is important for you to read and consider all information contained in this prospectus supplement and in the accompanying prospectus, including the documents incorporated by reference herein and therein, 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 by Reference* in this prospectus supplement and in the accompanying prospectus.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Unless the context otherwise indicates, references in this prospectus to *we*, *our*, *us* and *the Company* refer, collectively, to Intercept Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements contained or incorporated by reference herein or therein regarding our strategy, future operations, financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth, other than statements of historical facts, are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, potential, will, would, could, similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this prospectus supplement, the accompany prospectus and the information incorporated by reference herein and therein include, among other things:

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, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, and any related restrictions, limitations and/or warnings in the label of any approved product candidates;

- our plans to research, develop and commercialize our 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 need for and ability to obtain additional financing;

our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; our use of the proceeds from our initial public offering in October 2012, our follow-on public offerings in June 2013 and April 2014, and this offering; and

- our ability to attract and retain key scientific or management personnel.

We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our critical accounting estimates described in Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates of our most recent Annual Report filed on Form 10-K and the factors set forth under the caption Risk Factors in this prospectus supplement.

Any forward-looking statement speaks only as of the date on which it is made. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change. As a result, you should not rely on those forward-looking statements as representing our views as of any date

subsequent to the date the statements were made.

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## **INDUSTRY AND MARKET DATA**

This prospectus supplement contains 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 their information has 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 industry and general 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.

## **NON-GAAP FINANCIAL MEASURES**

This prospectus supplement presents projected adjusted operating expense, which is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP, and should be considered in addition to, but not as a substitute for, operating expense that we prepare and announce in accordance with GAAP. We exclude certain items from adjusted operating expense, such as stock-based compensation and other non-cash items, that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. We anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under GAAP. A reconciliation of projected non-GAAP adjusted operating expense to operating expense calculated in accordance with GAAP is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based compensation expense. Management also uses adjusted operating expense to establish budgets and operational goals and to manage our company's business. Other companies may define this measure in different ways. We believe this presentation provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

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## PROSPECTUS SUPPLEMENT SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus supplement, the accompanying prospectus and in the documents we incorporate by reference. This summary does not contain all of the information you should consider before making an investment decision. You should read carefully this entire prospectus supplement, the accompanying prospectus and any related free writing prospectus, especially the risks of investing in our common stock discussed under Risk Factors contained in this prospectus supplement, along with our consolidated financial statements and notes to those consolidated financial statements and the other information incorporated by reference in this prospectus supplement and the accompanying prospectus.*

### Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver diseases with high unmet medical need utilizing our proprietary 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, obeticholic acid, or OCA, is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid, that selectively binds to and activates the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. OCA has been tested in five placebo-controlled clinical trials, including a recently completed Phase 3 clinical trial in patients with primary biliary cirrhosis, or PBC, and two Phase 2 clinical trials in patients with nonalcoholic fatty liver disease, or NAFLD, and nonalcoholic steatohepatitis, or NASH. OCA met the primary efficacy endpoint in each of these trials with statistical significance.

OCA recently received breakthrough therapy designation from the U.S. Food and Drug Administration, or FDA, for the treatment of NASH patients with liver fibrosis. OCA has also been granted fast track designation by the FDA for the treatment of patients with PBC who have an inadequate response to or are intolerant of ursodiol. OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and primary sclerosing cholangitis, or PSC.

Our most advanced development program for OCA is for 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. In March 2014, we completed a Phase 3 clinical trial, known as the POISE trial, in which OCA achieved the primary endpoint for the treatment of PBC. We intend to use these results, along with two previously completed randomized Phase 2 clinical trials of OCA in PBC, as the basis for seeking the first regulatory approvals to market OCA in the United States and Europe. We initiated a rolling New Drug Application, or NDA, submission with the FDA for OCA in PBC in December 2014 under the FDA's accelerated approval pathway. We also plan to submit an application for marketing approval for OCA in PBC in Europe. We plan to complete our filings for marketing approval of OCA in PBC in the United States and Europe during the first half of 2015. If we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States and certain European countries in 2016.

OCA achieved the primary endpoint in a Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, which was sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health. The FLINT trial was completed in late July 2014. We are planning to finalize the



design of our Phase 3 clinical program in NASH in the second quarter of 2015, subject to the completion of our regulatory discussions with the FDA and the European Medicines Agency, or EMA, and then initiate the clinical program. We also intend to initiate a clinical trial in 2015 characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. Our collaborator, Sumitomo Dainippon Pharma Co. Ltd., or Sumitomo Dainippon, has completed enrollment in a 200-patient Phase 2 NASH clinical trial of OCA in Japan with a primary efficacy endpoint similar to that used in our Phase 2b FLINT trial, which is anticipated to be completed by the end of 2015.

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Our current patents for OCA are scheduled to expire at various times through 2028. We believe that coverage could be extended into 2033 based on our additional pending composition-of-matter and process patent applications. Our current plan is to commercialize OCA ourselves in the United States and Europe for the treatment of PBC, NASH and other indications primarily by targeting physicians who specialize in the treatment of liver and intestinal diseases, including both hepatologists and gastroenterologists. We own worldwide rights to OCA outside of Japan, China and Korea, where we have exclusively licensed OCA to Sumitomo Dainippon along with an option to exclusively license OCA in certain other Asian countries.

The following chart shows the current stage of development of OCA in different patient populations and the preclinical programs for our other product candidates.

## **OCA for Primary Biliary Cirrhosis (PBC)**

We are developing OCA initially for PBC as a second line treatment for patients who have an inadequate response to, or who are unable to tolerate ursodiol, the standard of care therapy, and therefore need additional treatment. PBC is a rare liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver, resulting in cholestasis. As the disease progresses, persistent toxic build-up of bile acids causes progressive liver damage marked by chronic inflammation and fibrosis. 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 being treated with ursodiol. As studies have shown that up to 50% of PBC patients fail to respond adequately to ursodiol treatment, we believe there are up to 30,000 diagnosed PBC patients who may currently be eligible for treatment with OCA, representing a significant unmet medical need for a second line therapy.

We have completed three double-blind, placebo-controlled trials of OCA in PBC patients, all of which met their primary and secondary endpoints. The most recent of these trials was our Phase 3 POISE trial which enrolled 217 patients. We believe that the results of our POISE trial and our long-term safety extension trials in PBC patients, which include a small group of patients who have been on OCA therapy for more than four years, demonstrate that OCA produces a durable therapeutic response. In our POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment.

We initiated a rolling NDA submission with the FDA for OCA in PBC in December 2014 under the FDA's accelerated approval pathway. We also plan to submit an application for marketing approval for OCA in PBC in Europe. We plan to complete our filings for marketing approval of OCA in PBC in the United States and Europe within the first half of 2015. As part of our strategy for filing the NDA under the

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accelerated approval pathway, we initiated a clinical outcomes confirmatory trial for OCA in PBC in December 2014, following discussions with both the FDA and EMA. We do not expect completion of this trial to be a condition to the receipt of marketing approval and, as a result, plan to complete the trial following our receipt of marketing approval.

If we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States and certain European countries in 2016.

## **OCA for Nonalcoholic Steatohepatitis (NASH)**

We are also developing OCA for the treatment of NASH, a common and serious chronic liver disease that develops in approximately one-third of NAFLD patients who have excessive fat accumulation in the liver, referred to as steatosis.

In NASH patients, for reasons that are as yet not completely understood, steatosis and other factors such as insulin resistance induce chronic inflammation in the liver and may lead to progressive fibrosis and cirrhosis, followed by eventual liver failure and death. NASH is believed to be one of the most common chronic liver diseases worldwide, with an estimated prevalence of more than 10% of the general adult population in the United States, with similar prevalence estimated in Europe, Japan and other developed countries. Additionally, NASH has become a highly prevalent liver disease in developing countries such as India and China. According to recent epidemiological studies, it is estimated that more than 10% of the U.S. adult population has NASH, with more than 60% of patients (potentially more than 14 million in total) believed to have liver fibrosis or cirrhosis due to progression of the disease. Although the prevalence of NASH is lower in children, it has also become a serious disease burden in the pediatric population.

There are currently no drugs approved for the treatment of NASH.

More than 20% of NASH patients progress to cirrhosis within a decade of diagnosis and, with the rapidly increasing prevalence of the disease, NASH has become the second most common reason for liver transplant in the United States. NASH is projected to become the leading indication for transplant in the next few years, overtaking both chronic hepatitis C infection and alcoholic liver disease. Additionally, NASH is now considered to be the leading, and a rapidly increasing, cause of hepatocellular carcinoma, or primary liver cancer, of which up to 40% of cases in NASH patients develop prior to developing cirrhosis. Other common co-existing conditions such as obesity and type 2 diabetes, which afflicts up to half of all NASH patients, are important risk factors in NASH.

OCA achieved the primary endpoint in the Phase 2b FLINT trial for the treatment of NASH, which was sponsored by the NIDDK. This trial was a double-blind, placebo-controlled trial of a once-daily dose of 25 mg of OCA or placebo given for 72 weeks in 283 patients with biopsy-proven NASH. We disclosed top-line FLINT results in our Quarterly

Report on Form 10-Q for the quarter ended June 30, 2014, and more detailed results from the FLINT trial were subsequently published online in *The Lancet* in November 2014. The summary of the FLINT trial results described below and the top-line results disclosed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 are based on information and data provided to us by NIDDK. Notable histologic findings from the FLINT trial include:

*Primary Endpoint:* 45% of OCA-treated patients compared to 21% of placebo-treated patients ( $p = 0.0002$ ,  $n=219$ ) achieved a decrease in the NAFLD activity score (a system of scoring the histopathological features in the liver) of at least two points with no increase in the fibrosis score.

*Fibrosis Improvement:* A significantly greater number of OCA-treated patients also achieved an improvement of at least one fibrosis stage (35% versus 19%,  $p=0.004$ ). Based on our retrospective analyses of the FLINT data, more OCA-treated patients exhibited fibrosis improvement of at least two fibrosis stages (15% versus 6%, not significant) and exhibited fibrosis improvements regardless of baseline fibrosis stage. The NASH clinical research network fibrosis staging system was used to categorize the pattern of fibrosis and architectural remodeling of the liver: no fibrosis (F0), perisinusoidal or periportal fibrosis (F1), perisinusoidal and periportal fibrosis (F2), bridging fibrosis (F3) and cirrhosis (F4). Fibrosis sub-stages 1a, 1b and 1c were considered F1 for the analysis.

*Fibrosis Resolution:* Based on our retrospective analysis of the FLINT data, a significantly greater number of OCA-treated patients also achieved complete resolution of fibrosis (17% versus 5%, p=0.0018).  
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*Fibrosis Progression:* Based on our retrospective analysis of the FLINT data, fewer OCA-treated patients progressed to bridging fibrosis (15% versus 18%, not significant) or to cirrhosis (2% versus 5%, not significant).

*NASH Resolution:* More OCA-treated patients achieved NASH resolution (22% versus 13%,  $p=0.0832$  (not significant)). Based on a retrospective subgroup analysis in which we excluded approximately 20% of FLINT patients without NASH at baseline, a significantly greater number of OCA-treated patients achieved NASH resolution compared with placebo-treated patients (19% versus 8%;  $p = 0.0278$ ).

The graph below shows these results from the FLINT trial for fibrosis improvement, fibrosis resolution, fibrosis progression and NASH resolution.

\*  $p < 0.05$ , \*\* $p < 0.01$ . *P-values calculated with the Cochran-Mantel-Haenszel test, stratified by clinic and diabetes status. NS indicates that the results are not significant.*

# *Retrospective analyses after the unblinding of results can potentially introduce bias and regulatory authorities typically give greatest weight to results from pre-specified analyses as compared to retrospective analyses.*

The histological improvements observed in OCA-treated patients versus placebo were accompanied by significant reductions in relevant biochemical parameters, including the serum liver enzymes alanine aminotransferase (ALT,  $p < 0.0001$ ), aspartate aminotransferase (AST,  $p=0.0001$ ), gamma-glutamyl transferase (GGT,  $p < 0.0001$ ), each of which were above generally accepted normal limits at baseline, and total bilirubin ( $p=0.002$ ). A modest but statistically significant increase in alkaline phosphatase (ALP,  $p < 0.0001$ ) in the OCA treatment group was also observed, but levels remained within typical normal limits. OCA treatment was associated with serum lipid changes, including average increases in total cholesterol and LDL cholesterol and an average decrease in HDL cholesterol, that developed within 12 weeks of treatment initiation, then began reversing through the end of treatment and returned to baseline during the 24-week post-treatment follow-up phase, as described in more detail in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. We intend to initiate a clinical trial in 2015 characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients.

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In the FLINT trial, statistically significant weight loss of an average of 2.3 kilograms was observed in OCA patients compared to no weight loss in the placebo group ( $p=0.008$ ), and this weight loss reverted towards baseline during the 24-week follow-up phase. A pre-specified sensitivity analysis conducted by the investigators showed that weight loss was not a driver of the primary endpoint. An increase in a marker of hepatic insulin resistance, HOMA-IR (calculated using the product of fasting plasma insulin and glucose) was observed at 72 weeks in the OCA treatment group ( $p=0.01$ ). However, there was an imbalance in baseline plasma insulin levels (201 pmol/L OCA versus 138 pmol/L placebo), and an even larger relative and absolute increase in HOMA-IR was observed in the placebo group at the conclusion of the 24-week follow-up phase. This is potentially attributable to the inherent variability in HOMA-IR measurements, particularly in patients with type 2 diabetes, that have been shown to make single time-point to time-point changes of this magnitude clinically uninterpretable. There were virtually no changes in mean hemoglobin A1c, a measure of average blood sugar control over a period of approximately three months, in either OCA or placebo groups at 72 weeks. In a previous study of OCA in diabetic NAFLD patients, described in more detail below, employing the hyperinsulinemic-euglycemic insulin clamp, the gold standard for detecting changes in insulin resistance, OCA improved the glucose disposal rate consistent with reduced insulin resistance.

OCA was generally well tolerated in the FLINT trial. Adverse events were generally mild to moderate in severity and the incidence in the OCA and placebo treatment groups was similar for all symptoms except pruritus. Pruritus in the OCA treatment group occurred more frequently (23% vs 6%,  $p < 0.0001$ ), at a higher grade (predominantly moderate pruritus) but resulted in only one patient discontinuation. The incidence of severe or life threatening events was not different between the two treatment groups and most of the events in both groups were deemed to be unrelated to treatment, including all severe or life threatening cardiovascular events. As previously disclosed, two deaths occurred in the OCA treatment group, but neither were considered related to OCA treatment.

We previously completed a double-blind, placebo-controlled Phase 2 clinical trial of OCA in 64 type 2 diabetic patients with NAFLD. We believe that a majority of the patients in this trial were likely to have had NASH, not just simple steatosis, given the disease's association with obesity and diabetes and based upon an evaluation of serum fibrosis biomarkers from trial participants. In this trial, OCA therapy significantly improved insulin sensitivity both in the liver and peripheral tissues, thereby meeting the primary endpoint in the trial with a mean improvement in liver insulin sensitization from baseline of approximately 24.5% in the combined OCA dose groups, as compared to a worsening of approximately 5.5% in the placebo group ( $p=0.011$ ). Insulin resistance, particularly in the liver, is considered to be an important contributor to NASH disease pathology. In this trial, significant improvements in weight loss were also noted in patients receiving OCA therapy, along with improvements in liver enzymes such as GGT and AST.

In January 2015, OCA received breakthrough therapy designation from the FDA for the treatment of NASH patients with liver fibrosis. We believe breakthrough therapy designation reinforces the potential for OCA to address the unmet need in patients with this serious condition. The breakthrough therapy designation was created by the FDA to speed the availability of new therapies for serious or life-threatening conditions. Drugs qualifying for this designation must show credible evidence of a substantial improvement on a clinically significant endpoint over available therapies, or over placebo if there is no available therapy. The breakthrough therapy designation constitutes one of four expedited programs for serious conditions including accelerated approval, priority review, and fast-track designation, all of which can also be granted to the same drug if relevant criteria are met. The breakthrough therapy designation confers several benefits, including intensive FDA guidance and discussion and eligibility for submission of a rolling NDA.

We are currently in discussions with regulators on a Phase 3 program for NASH. Subject to a detailed review of the FLINT trial results and completion of discussions with the FDA and EMA, we currently believe that we will conduct at least one Phase 3 clinical outcomes trial of OCA in NASH patients that would incorporate an interim surrogate

endpoint and that may serve as the basis for filing for accelerated approval in the United States and approval in Europe. Patients would then be followed for confirmation of clinical benefit under accelerated approval requirements.

Examples of potential surrogate endpoints include the use of histological improvement, using the NAS or another scoring system, or histological resolution of NASH, or improvements in fibrosis in pre-cirrhotic patients with NASH, and examples of potential endpoints to confirm clinical benefit include liver transplant-free survival or progression to cirrhosis. We expect to finalize the

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design of our Phase 3 clinical program in NASH in the second quarter of 2015, subject to the completion of our regulatory discussions with the FDA and the EMA, and then initiate the clinical program.

## **OCA for Primary Sclerosing Cholangitis (PSC)**

In December 2014, we initiated an international Phase 2 clinical trial to evaluate the effects of 24 weeks of treatment with varying doses of OCA compared to placebo in patients with PSC. The primary endpoint is the reduction of serum ALP levels, as compared to placebo. In addition, OCA's effect on other secondary liver function endpoints, as well as symptoms of ulcerative colitis (a disease occurring in a majority of patients with PSC), will be assessed. This trial is anticipated to enroll approximately 75 patients in the United States and Europe.

## **Our Strategy**

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

obtain marketing approval of OCA for the treatment of PBC in the United States, the European Union and other countries;

commercialize OCA in the United States, Europe and other countries, initially for the treatment of PBC;

continue to develop OCA for the treatment of NASH and seek regulatory approval of OCA in this indication;

continue to develop OCA in other orphan and more prevalent liver and other diseases; and

advance the development of earlier-stage product candidates in our pipeline.

In order to achieve our strategic objectives, we have, and will remain, focused on hiring and retaining a highly skilled management team and employee base with extensive experience and specific skill sets relating to the selection, development and commercialization of therapies for diseases with high unmet medical need. We anticipate that we will continue to increase our product development, scientific, commercial and administrative personnel significantly in the United States and abroad as part of our growth strategy.

## **Risks Related 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 important 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 supplement:

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 in both PBC and NASH and to continue to advance the development of OCA in other indications and our other product candidates, and such funding may not be available on acceptable terms or at all. We also anticipate incurring significant expenses in connection with our planned increase in our product development, scientific, commercial and administrative personnel and expansion of our facilities and infrastructure in the United States and abroad.

OCA and/or our other product candidates may not receive regulatory approval in a timely manner or at all and breakthrough therapy designation or other priority review programs may not benefit the regulatory or development



process for our product candidates.

Even though we have initiated a rolling NDA submission under the accelerated approval pathway, the FDA may not grant approval of OCA for the treatment of PBC based on the surrogate endpoints evaluated in the POISE trial, in which case we might need to complete the planned additional

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Phase 3 clinical outcomes trial prior to approval. There is also a similar risk in the European Union where the EMA may not grant full approval based on the POISE trial but rather grant conditional approval requiring a post-approval commitment or may require additional clinical outcomes data prior to marketing authorization.

We are currently in discussions with regulators on the design of our Phase 3 clinical program for NASH, in which we are seeking to incorporate an interim surrogate endpoint. Even though OCA has been granted breakthrough therapy designation by the FDA, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH.

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. Our clinical trial plans as described in this prospectus supplement may change based upon our discussions with regulators and many other factors.

Clinical failure can occur at any time during the development process for a product candidate. 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. This risk is particularly applicable in situations in which future trials differ from prior trials in terms of duration or design, which will be the case as to many of our future trials, including of OCA for the treatment of NASH.

Our product candidates could be found to have undesirable side effects that may delay or prevent regulatory approval or require our product candidates to include safety warnings or be taken off the market. We could also be required to conduct additional clinical trials or preclinical studies not currently planned to receive approval for our product candidates.

We are in a highly competitive industry and face competition from existing and treatments in development that may be more effective and less costly than our products. The results from the POISE and FLINT trials have brought more attention to our targeted indications and bile acid chemistry. As a result, we believe that more companies may seek to compete with us in the future.

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.

We may be unable to maintain and protect our intellectual property assets, which could impair the advancement of our pipeline and commercial opportunities.

## **Company Information**

We were incorporated in the State of Delaware on September 4, 2002. Our principal executive offices are located at 450 W. 15<sup>th</sup> Street, Suite 505, New York, New York 10011, and our telephone number is (646) 747-1000. We also have an office in San Diego, California. Our website address is *www.interceptpharma.com*. The information contained on or accessible through our website is not incorporated by reference into, and should not be considered part of, this prospectus supplement. We have included our website address in this prospectus supplement as an inactive textual reference only.

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## THE OFFERING

### Common Stock Offered by Us in This Offering

800,000 shares

### Option to Purchase Additional Shares of Common Stock

The underwriters have an option to purchase up to an additional 120,000 shares of our common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus supplement.

### Common Stock to be Outstanding After This Offering

22,215,243 shares

### Use of Proceeds

We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately \$142.6 million (or approximately \$164.1 if the underwriters exercise in full their option to purchase additional shares), based on an assumed public offering price of \$188.66 per share, the last sale price of our common stock on February 2, 2015, as reported on The NASDAQ Global Select Market.

We intend to use the net proceeds from the shares sold by us in this offering to fund:

expansion of our clinical, regulatory, medical affairs and commercial infrastructure in the United States and Europe;

continued clinical development of OCA in PBC, NASH and PSC;

expansion of OCA manufacturing activities;

advancement of INT-767 and other preclinical pipeline programs; and

preparation for and potential initiation of the commercial launch of OCA in PBC in the United States and certain European countries in 2016.

The balance, if any, will be used for general corporate purposes, including general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. See Use of Proceeds for more information.

### Risk Factors

You should read the Risk Factors section of this prospectus supplement for a discussion of factors to consider carefully before deciding to purchase shares of our common stock.

### NASDAQ Global Select Market Symbol

ICPT

The number of shares of our common stock to be outstanding after this offering is based on 21,415,243 shares outstanding as of December 31, 2014, including 60,149 shares of restricted stock awards granted under our 2012 Equity Incentive Plan, or the 2012 Plan, that were unvested as of December 31, 2014. The number of outstanding shares of common stock excludes:



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1,436,055 shares of common stock issuable upon the exercise of outstanding stock options as of December 31, 2014 at a weighted-average exercise price of \$75.81 per share;

restricted stock units for 59,199 shares of our common stock that were unvested as of December 31, 2014; and  
745,275 shares of common stock reserved for future issuance as of December 31, 2014 under our 2012 Plan.

Except as otherwise noted, we have presented the information in this prospectus supplement assuming:

no exercise by the underwriters in this offering of the option to purchase up to an additional 120,000 shares of our common stock from us in this offering; and

no exercise of outstanding stock options.

Our board of directors has not yet finalized the cash bonuses for our executive officers for 2014 or compensation arrangements for these persons for 2015. On January 1, 2015, 856,609 shares of common stock were added to the 2012 Plan in accordance with its terms.

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## RISK FACTORS

*Investing in our common stock involves significant risks. In deciding whether to invest, and in consultation with your own financial and legal advisors, you should carefully consider the risks and uncertainties described below, together with the other information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein and any free writing prospectus that we may authorize for use in connection with this offering. Any of these risks could have a material adverse effect on our business, financial condition, results of operations and prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.*

### **Risks Related to Our Financial Position and Need for Additional Capital**

**We have never been profitable. Currently, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.**

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any product candidates for approval by regulatory authorities in the United States or elsewhere for our lead indication, primary biliary cirrhosis, or PBC, or any other indication, including non-alcoholic steatohepatitis, or NASH. We have incurred net losses in each year since our inception, including net losses of \$12.7 million, \$43.6 million and \$67.8 million for the years ended December 31, 2011, 2012 and 2013, respectively. We incurred a net loss of \$248.4 million for the nine months ended September 30, 2014. To date, we have financed our operations primarily through private placements of our convertible preferred stock, convertible notes and warrants to purchase common stock, public offerings of our common stock and payments received under our licensing and collaboration agreements with Sumitomo Dainippon Pharma Co. Ltd., or Sumitomo Dainippon, and Les Laboratoires Servier and Institut de Recherches Servier, which are collectively referred to as Servier. As of September 30, 2014, our working capital was \$262.6 million and our cash, cash equivalents and investment securities available for sale was \$272.8 million. At December 31, 2014, we had approximately \$240 million in cash, cash equivalents and investment securities.

We have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials of our product candidates, providing general and administrative support for these operations, protecting our intellectual property and engaging in activities to prepare for the commercialization of our product candidates. We do not have any products approved for sale and have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, obeticholic acid, or OCA, which is our lead product candidate, and our other product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel in the United States and Europe to support our product development and commercialization efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years as we continue our confirmatory clinical outcomes trial of OCA in PBC, continue our long-term safety extension phases of our clinical trials of OCA in PBC, commence our Phase 3 clinical program of

OCA in nonalcoholic steatohepatitis, or NASH, continue our Phase 2 clinical trial of OCA for primary sclerosing cholangitis, or PSC, and finalize other planned activities for regulatory submission and approval of OCA in PBC. We also anticipate continuing the development of OCA in additional diseases, such as biliary atresia, a rare pediatric disease characterized by deficient bile duct development. We also anticipate initiating a clinical trial to assess the lipid metabolic effects of OCA and the effects of concomitant statin administration in NASH patients during 2015. Furthermore, we plan to complete IND-enabling studies of INT-767, an earlier stage product candidate for which we plan to initiate Phase 1 programs by the end of 2015. Our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. We also anticipate that we

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will continue to increase our product development, scientific, commercial and administrative personnel significantly and expand our facilities and infrastructure in the United States and abroad as part of our growth strategy.

Our ability to generate profits from operations and become profitable will depend on our ability to obtain marketing approval for, and commercialize, our product candidates. We do not expect to generate significant revenues unless and until we obtain marketing approval for, and commercialize, OCA for the treatment of PBC and other indications. This will require us to be successful in a range of challenging activities, including:

obtaining approval to market OCA for the treatment of PBC, NASH and other indications and patient populations;  
expanding our manufacturing of commercial supply for OCA;  
establishing sales, marketing and distribution capabilities to effectively market and sell OCA in the United States and Europe; and  
negotiating and securing reimbursement from third-party payors for OCA.

If OCA or any of our other product candidates fails in clinical trials or does not gain regulatory approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Our net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

**We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.**

We are currently advancing OCA through clinical development for multiple indications and other product candidates through preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. In December 2014, we initiated a rolling NDA submission for OCA in PBC under the FDA's accelerated approval pathway. We also plan to submit an application for marketing approval for OCA in PBC in Europe. We plan to complete our filings for marketing approval of OCA in PBC in the United States and Europe within the first half of 2015. If the FDA or EMA requires that we perform preclinical studies or clinical trials in addition to those contemplated or conducted by us, our expenses would further increase beyond what we currently expect and the anticipated timing for the completion of our potential NDA or MAA filing would likely be delayed. In addition, if we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States and certain European countries in 2016. We anticipate incurring significant expenses as we prepare for the potential commercialization of OCA in PBC, including significant expenses to establish our sales, marketing and distribution capabilities and increase our drug manufacturing activities. We will require substantial additional future capital in order to complete clinical development and commercialize OCA, and to conduct the research and development and clinical and regulatory activities necessary to bring other product candidates to market. We also anticipate incurring significant expenses in connection with our planned increase in our product development, scientific, commercial and administrative personnel and expansion of our facilities and infrastructure in the United States and abroad.

As of December 31, 2014, we had approximately \$240 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses in the range of \$180 million to \$200 million in the fiscal year ending December 31, 2015, which excludes stock-based compensation and other non-cash items. These expenses are planned to support the clinical development program for OCA in PBC, NASH and PSC, the expansion of our clinical,

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.



regulatory, medical affairs and commercial infrastructure in the United States and Europe, increased OCA manufacturing activities, as well as the continued development of INT-767 and other preclinical pipeline programs.

We anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under U.S. generally accepted accounting principles, or GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. See Non-GAAP Financial Measures for more

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information. Accordingly, we will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Due to the many variables inherent to the development and commercialization of novel therapies, such as the risks described in this Risk Factors section, and our rapid growth and expansion, we currently cannot accurately or precisely predict the duration beyond 2015 over which we expect our cash and cash equivalents, together with the net proceeds from this offering, to last. However, we currently believe that our cash and cash equivalents, together with the net proceeds from this offering, will be sufficient for us to:

expand our clinical, regulatory, medical affairs and commercial infrastructure in the United States and Europe; continue and expand our clinical development programs for OCA in PBC, NASH and PSC, such as initiating and/or continuing, but not completing, our planned Phase 3 clinical program for OCA in NASH, our planned clinical trial characterizing lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients, our ongoing Phase 2 clinical trial of OCA for PSC, and our ongoing confirmatory clinical outcomes trial of OCA in PBC; advance the continued development of INT-767, including the completion of IND-enabling preclinical studies for INT-767 and the initiation of a Phase 1 clinical trial, and other preclinical compounds; complete the filings of our NDA and MAA for OCA in PBC, but not complete our filings for marketing authorization in any other indication; increase OCA manufacturing activities, including investing in supply chain and product development, preparing for PBC commercial launch and planning for the continuation of our clinical program in NASH, but not manufacture the supply needed for any potential commercial launch of OCA in NASH; and prepare for and, if we obtain marketing approval on a timely basis, initiate the commercial launch of OCA in PBC in both the United States and certain European countries in 2016, but not commercially launch OCA in PBC in other countries across the world.

Accordingly, we will continue to require substantial additional capital to continue our clinical development, commercialization and other activities. Because successful development and commercialization of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

The amount and timing of our future funding requirements will depend on many factors, including:

the willingness of the FDA and EMA to accept the POISE trial, which is our completed phase 3 clinical trial for PBC, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and marketing approval of OCA for PBC;

the progress, costs, results of and timing of our recently initiated confirmatory clinical outcomes trial of OCA for the treatment of PBC, the completion of which we expect will not be a condition to the receipt of marketing approval in the United States or the European Union;

the design of our planned Phase 3 clinical program for OCA in NASH and the progress, costs, results of and timing of the Phase 3 program and other supporting trials and studies necessary to support anticipated filings for marketing approval in NASH, including the sufficiency of one pivotal clinical trial for marketing approval or the acceptability of a surrogate endpoint for accelerated approval of OCA for the treatment of NASH;

the progress, costs, results of and timing of clinical development of OCA for other indications, including our Phase 2 trial of OCA in PSC and biliary atresia;

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We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, i

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the significant expansion of our operations, personnel and the size of our company and our need to continue to expand;

the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals; the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development, such as INT-767 and INT-777;

the ability of our product candidates to progress through pre-clinical and clinical development successfully and in a timely manner;

the expansion of our research and development activities;

the costs and timing of commercialization activities, including product sales, marketing and distribution, for any of our product candidates that receive marketing approval;

the costs associated with securing and establishing manufacturing capabilities and procuring the materials necessary for our product candidates;

market acceptance of our product candidates;

the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies; our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

our need and ability to hire additional management, scientific and medical, commercial and other qualified personnel and the substantial cost of retaining such additional personnel;

the effect of competing technological and market developments;

our need to implement and maintain internal systems, software and infrastructure, including those to assist in our financial and reporting, clinical development and commercialization efforts and to support our existing and expanding personnel; and

the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail our planned activities, including research and development programs and commercialization activities. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

**Our revenues to date have been generated through our collaboration agreements and we may not receive any additional revenues under such agreements.**

To date, our sources of revenue have been the payments received under our collaboration and license agreements with Sumitomo Dainippon and Servier. Additional payments under each of the Sumitomo Dainippon and Servier agreements are based on the exercise of optional rights held by our collaborators under the agreements or the achievement of various research, development, regulatory and commercial sales milestones and royalty payments based on the sales of the products covered by such agreements. Future



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payments from Sumitomo Dainippon and Servier under their respective collaboration and license agreements are uncertain because Sumitomo Dainippon or Servier, as the case may be, may choose not to exercise their optional rights under the agreements or continue research or development activities for the product candidates under license in their licensed territory, the product candidates may not be approved for the proposed indications or, even if any product candidate is approved for one or more indications, it may not be commercially successful. If we are unable to develop and commercialize one or more of our product candidates, either alone or with collaborators, or if revenues from any such collaboration product candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability.

**We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.**

We are a development stage biopharmaceutical company with a limited operating history. Our operations to date have been limited to developing our technology and undertaking preclinical studies and clinical trials of our product candidates and engaging in pre-commercial activities for OCA in PBC. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our financial condition and operating results have varied significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control.

Factors relating to our business that may contribute to these fluctuations include:

any delays in regulatory review and approval of our product candidates in clinical development, including our ability to receive approval from the FDA and the EMA for OCA for the treatment of PBC based on our Phase 3 POISE trial, and our other completed and planned clinical and preclinical studies and other work, as the basis for review and approval of OCA for PBC;

delays in the commencement, enrollment and timing of clinical trials;

difficulties in identifying and treating patients suffering from our target indications, including those due to PBC and PSC being rare diseases and NASH currently requiring an invasive liver biopsy for diagnosis;

the success of our clinical trials through all phases of clinical development, such as the success of any pivotal Phase 3 clinical trial of OCA in NASH we may conduct;

potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;

the required timeframe for us to receive and analyze data from our clinical trials;

our ability to obtain additional funding to develop our product candidates;

our ability to identify and develop additional product candidates;

market acceptance of our product candidates;

our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties;

competition from existing products or new products that may emerge;

the ability of patients or healthcare providers to obtain coverage or reimbursement for our products and the extent to which such coverage or reimbursement will be provided;

our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations, or CROs;

our dependency on third-party manufacturers to manufacture our products and key ingredients;

our ability to establish or maintain collaborations, licensing or other arrangements;

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate or

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the costs to us, and our ability and our third-party collaborators' ability to obtain, maintain and protect our intellectual property rights;

costs related to and outcomes of potential intellectual property, securities and other litigation;

our ability to adequately support future growth;

our ability to attract and retain key personnel to manage our business effectively;

our ability to build and improve our company's infrastructure, systems and controls;

potential product liability claims; and

our ability to obtain and maintain adequate insurance coverage.

## **Risks Related to Regulatory Review and Approval of Our Product Candidates**

**We cannot be certain that OCA or any of our other product candidates will receive regulatory approval, and without regulatory approval we will not be able to market and commercialize our product candidates.**

We are initially developing OCA for the treatment of patient populations with chronic liver and other diseases, with a current principal focus on PBC, NASH and PSC, and our business currently depends entirely on the successful development and commercialization of OCA. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of OCA, particularly for the treatment of PBC and NASH, and our other product candidates.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States, the EMA in Europe and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States or Europe until we receive approval of an NDA from the FDA or an MAA from the EMA, respectively. We have not submitted any marketing applications for any of our product candidates.

NDAs and MAAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or an MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we complete our submission of an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Approvals may also be conditional upon the completion of one or more clinical trials. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and



results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn. Regulatory approval is also dependent on successfully passing regulatory inspection of our company, our clinical sites and key vendors and to ensure compliance with applicable good clinical, laboratory and manufacturing practices regulation. Critical findings could jeopardize or delay the approval of the NDA or MAA.

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We expect to complete our filings for marketing approval of OCA in PBC in the United States and Europe during the first half of 2015. We have completed a randomized, placebo-controlled Phase 3 trial of OCA in PBC patients, which we refer to as the POISE trial, and 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, and we are finalizing other preclinical and clinical studies required to complete the filings. Furthermore, we will need to complete a number of clinical trials and other studies for the continued development of OCA in indications other than PBC. For example, we are currently planning for our Phase 3 clinical program of OCA in NASH, together with a number of supporting studies and trials such as a Phase 2 trial characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. In each of these cases, our ability to obtain the approvals necessary to commercialize our product candidates will depend on our ability to conduct and complete these additional trials as well as assemble various other data to complete our regulatory filings for OCA in the relevant indication or patient population.

There can be no assurance that we will be able to complete our regulatory filings on a timely basis or that, even if the filings are completed, that the FDA or EMA will provide marketing approval for OCA in PBC. We cannot predict whether our trials and studies as to NASH or any other indication or patient population will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or require us to conduct additional studies or trials. For example, while OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis, we have not yet completed our discussions with regulatory agencies on the design of our Phase 3 clinical program for NASH, in which we are seeking to incorporate an interim surrogate endpoint. We do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. While the interim histological endpoint that could serve as the basis for accelerated approval is expected to be similar to that in the Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health, our Phase 3 clinical program for NASH will likely have different trial designs and include primary outcomes endpoints for full approval.

If we are unable to obtain approval from the FDA, the EMA or other regulatory agencies for OCA and our other product candidates, or if, subsequent to approval, we are unable to successfully commercialize OCA or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

**We are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited therapies and for some of which there is little clinical experience, and our development approach involves new endpoints and methodologies. As a result, there is increased risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.**

Currently, there are no approved therapies for NASH or PSC. In PBC, although ursodiol is the standard of care, studies have shown that up to 50% of PBC patients fail to respond adequately to treatment, meaning that they continue to be at significant risk of progressing to liver failure even with treatment. As a result, the design and conduct of clinical trials for these diseases and other indications we may pursue will be subject to increased risk.

We are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited

The FDA generally requires two pivotal clinical trials to approve an NDA. Furthermore, for full approval of an NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. Under Subpart H regulations, the FDA can grant accelerated approval based on a surrogate reasonably likely to predict clinical benefit. In December 2014, we submitted the non-clinical sections of a rolling NDA submission for accelerated approval of OCA as a treatment for patients with PBC who have an inadequate response to or intolerant of ursodiol based on the Phase 3 POISE trial. The POISE primary endpoint is a surrogate endpoint that we believe is reasonably likely to predict clinical benefit, therefore meeting the FDA's Subpart H requirements for consideration under its accelerated approval regulation. While the FDA has officially accepted our rolling submission of the NDA, formal review of the NDA will not commence until

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60 days after submission of the last section which is planned for June 2015. It is unlikely we will receive definitive written guidance from the FDA prior to formal review of our NDA as to the acceptability of the POISE trial surrogate endpoint to support an approval of OCA for the treatment of PBC. Although the results from our Phase 3 POISE trial are highly significant and supported by two controlled Phase 2 trials, our Phase 3 POISE trial and our regulatory submissions package may nonetheless not be sufficient to support approval in the United States. We anticipate that similar risks will apply to other indications for which we intend to seek marketing approval for our product candidates under accelerated approval regulations. For example, we will face these risks for OCA for the treatment of NASH because of our plan to seek accelerated approval based on a trial design that would incorporate an interim surrogate endpoint.

In order to support the clinical utility of the surrogate endpoint for OCA as a treatment for PBC, we have sponsored an independent study pooling and analyzing long-term PBC patient data from a number of leading PBC academic centers, which are referred to as the Global PBC Study Group. Furthermore, an academic consortium in the United Kingdom has published the results of another large observational study in PBC patients in the United Kingdom. Although we believe the results of both studies are supportive of the clinical utility of our surrogate endpoint for the use of OCA in PBC, the supporting data may still not be accepted by the FDA in its consideration of the adequacy of our surrogate endpoint under an NDA for OCA for the treatment of PBC. In addition to the risk around the acceptability of the surrogate biochemical endpoint to support accelerated approval, there are quality assurance risks around the data supporting assessment of the biochemical endpoint. It is possible that key parameters such as the validation of the assay and consistency across laboratories will not be acceptable to FDA and could delay or jeopardize approval of the NDA.

The FDA has also informed us that, even if it provides us an accelerated approval for OCA, we will be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of OCA in PBC by demonstrating the correlation of biochemical therapeutic response in patients taking OCA with a significant reduction in adverse clinical outcomes over time. Following discussions with the FDA, we initiated the trial in December 2014. There can be no assurance that our clinical outcomes confirmatory trial will confirm that the surrogate endpoints used for accelerated approval will eventually show an adequate correlation with clinical outcomes. If the clinical outcomes confirmatory trial fails to show such adequate correlation, we may not be able to maintain our previously granted marketing approval for OCA in PBC.

Likewise, we will not receive definitive feedback from the EMA prior to formal review of our MAA as to the acceptability of the POISE trial endpoint to support a marketing authorization of OCA for the treatment of PBC. It is also possible that any marketing authorization we receive from the EMA for OCA for the treatment of PBC could be conditional on post-approval studies and not considered a full approval. Our ability to obtain and maintain conditional marketing authorization in the European Union, will be limited to specific circumstances and subject to several conditions and obligations, if obtained at all, including the completion of a clinical outcomes trial to confirm the clinical benefit of OCA in PBC. Conditional marketing authorizations based on incomplete clinical data may be granted for a limited number of listed medicinal products for human use, including products designated as orphan medicinal products under European Union law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions.

In NASH, we currently anticipate that we will need to conduct either two pivotal trials or at least one Phase 3 clinical outcomes trial providing a highly significant demonstration of clinical efficacy prior to applying for marketing approval for OCA in NASH. We expect a Phase 3 clinical outcomes trial would incorporate an interim surrogate endpoint that may serve as the basis for a supplemental NDA filing for accelerated approval in the United States and approval in Europe. Accelerated approval in the United States and conditional approval in the European Union for OCA in NASH are subject to similar risks as discussed above in relation to OCA for PBC. The primary endpoint in the Phase 2b FLINT trial of OCA in NASH

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patients was based on liver biopsy and was defined as an improvement of two or more points in the NAFLD activity score (a system of scoring the histopathological features in the liver) with no worsening of liver fibrosis. Currently, other biopharmaceutical companies are enrolling or have initiated trials in certain subpopulations of NASH patients based on different endpoints from the one used in the FLINT trial. Although the FDA acknowledged at recent workshops the possibility of granting accelerated approval for NASH therapies using surrogate endpoints, with potential examples including histological improvement, using the NAS or another scoring system, histological resolution of NASH, or improvements in fibrosis in pre-cirrhotic patients with NASH, the FDA did not provide any formal regulatory guidance on approvable endpoints and may not accept a surrogate endpoint for OCA for the treatment of NASH.

The FDA generally requires two pivotal clinical trials to approve an NDA. Therefore, even if we achieve favorable results in a single Phase 3 clinical trial, the FDA may not accept this one trial as an adequate basis for approval and require that we conduct and complete a second Phase 3 clinical trial before considering an NDA for any of the indications for which we may seek marketing approval for our product candidates. Our NDA for OCA for the treatment of PBC patients who have an inadequate response to or are intolerant of ursodiol will be based on the results of three clinical trials – the POISE trial and two Phase 2 trials. It is possible that our final NDA submission for regulatory approval will not be accepted by the FDA for review or, even if it is accepted for review, that there may be delays in the FDA’s review process and that the FDA may determine that our NDA does not merit the approval of OCA for the treatment of PBC, in particular because we have only conducted a single Phase 3 clinical trial of OCA for the treatment of PBC, in which case the FDA may require that we conduct and/or complete additional clinical trials and preclinical studies before it will reconsider our application for approval. A similar risk applies if we seek marketing approval of OCA for NASH based on a single Phase 3 pivotal trial. Our regulatory pathway for OCA for the treatment of NASH will depend upon our discussions with the FDA and EMA. As a result, we may face difficulty in designing an acceptable registration strategy around the design of any follow-on trials to the FLINT trial. In addition, it is likely that the primary and possibly other endpoints in future clinical trials of OCA for NASH will be different from those of the FLINT trial. The use of different endpoints, or other trial design changes, would increase the risk that the results of these future trials would differ from the FLINT results.

The EMA and regulatory authorities in other countries in which we may seek approval for, and market, OCA or our other product candidates may require additional preclinical studies and/or clinical trials prior to granting approval. It may be expensive and time consuming to conduct and complete additional preclinical studies and clinical trials that the FDA, EMA and other regulatory authorities may require us to perform. As such, any requirement by the FDA, EMA or other regulatory authorities that we conduct additional preclinical studies or clinical trials could materially and adversely affect our business, financial condition and results of operations. Furthermore, even if we receive regulatory approval of OCA for the treatment of any of our targeted indications, the labeling for our product candidates in the United States, Europe or other countries in which we seek approval may include limitations that could impact the commercial success of our product candidates.

### **Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for OCA and our other product candidates.**

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We initiated our clinical outcomes confirmatory trial in PBC in December 2014. We also initiated our Phase 2 trial in PSC in December 2014. We anticipate that we will need to conduct at least one Phase 3 clinical trial prior to applying for marketing approval for NASH. We are planning for the finalization of the design of our Phase 3 clinical program in NASH in the second quarter of 2015, subject to the

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and

completion of our regulatory discussions with the FDA and EMA. The results from these trials may not be available when we expect or we may be required to conduct additional clinical trials or preclinical studies not currently planned to receive approval for OCA as a treatment for the related indication, in which case we would require additional funding. In addition, our clinical programs are subject to a number of variables and contingencies, such as the results of other trials or regulatory interactions that may result in a change in timing. As such, we do not know whether any future trials or studies of our other product candidates, including our clinical outcomes trial of OCA, will begin on time or will be completed on schedule, if at all.

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The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
  - inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
  - clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
  - discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
  - inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
  - the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;
  - inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
  - severe or unexpected drug-related adverse effects experienced by patients or any determination that a clinical trial presents unacceptable health risks;
  - a breach of the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, including Sumitomo Dainippon and Servier or investigators leading clinical trials on our product candidates;
  - inability to timely manufacture sufficient quantities of the product candidate required for a clinical trial;
  - difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our trial, the risks of procedures that may be required as part of the trial, such as a liver biopsy, and competition from other clinical trial programs for the same indications as our product candidates; and
  - inability to retain enrolled patients after a clinical trial is underway.
- For example, in the past, we experienced delays in our Phase 2 clinical trial of OCA given as a monotherapy to patients with PBC because we were unable to find and enroll a sufficient number of trial patients who met the specific enrollment criteria in accordance with our anticipated trial schedule. Our plan to finalize the design of our Phase 3 program for OCA in NASH in the second quarter of 2015 is dependent upon our successfully completing regulatory discussions.

Changes in regulatory requirements and guidance may also occur and we or any of our collaborators may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us or any of our collaborators to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, if we or any of our collaborators are required to conduct additional clinical trials or other preclinical studies of our product candidates beyond those contemplated, our ability to obtain regulatory approval of these product candidates and generate revenue from their sales would be similarly harmed.



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**Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we, Sumitomo Dainippon, Servier or our potential future collaborators advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.**

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials and at other stages of clinical development, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If OCA or our other product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them, the prospects for approval of OCA would be materially and adversely affected and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes or differences in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

We believe that the results of our POISE trial and our long-term safety extension trials in PBC patients, which include patients who currently have been on OCA therapy for more than four years, demonstrate that OCA produces a durable therapeutic response. Based on these results, we currently expect to complete our filing for marketing approval of OCA in PBC in the United States and the European Union during the first half of 2015. We cannot assure you that our POISE trial results will result in our receiving marketing approval for OCA in PBC or that our planned clinical outcomes confirmatory trial of OCA in PBC will demonstrate a correlation of biochemical therapeutic response in patients taking OCA with a significant reduction in adverse clinical events over time.

In December 2014, we received comprehensive datasets from the FLINT trial. The Phase 2 trial in NASH currently being conducted in Japan by our collaborator Sumitomo Dainippon involves different doses of OCA being administered to the trial subjects than those utilized in FLINT. As a result, the positive efficacy results seen in FLINT may not be replicated in the Japanese trial or any future trial we may conduct in NASH. While we continue to work towards finalizing the design of our Phase 3 clinical program in NASH in the second quarter of 2015, this remains subject to the completion of our regulatory discussions with the FDA and EMA. We currently believe that we will

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily

conduct at least one Phase 3 clinical trial of OCA in NASH patients. We expect the trial design for any such Phase 3 trial would incorporate an interim surrogate endpoint that may serve as the basis for filing for accelerated approval in the United States and approval in Europe. Even though OCA has been granted breakthrough therapy designation by the FDA, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. As a result, it may take longer than anticipated to complete the design and initiation of our Phase 3 program in NASH.

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**Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require our product candidates to be taken off the market, require them to include safety warnings or otherwise limit their sales.**

A substance that binds to a receptor of a cell and triggers a response by that cell is called an agonist. OCA has been shown to be a potent agonist of the farnesoid X receptor, or FXR. With the exception of the endogenous human bile acid CDCA, which has been approved to treat cholesterol gallstone dissolution and a rare lipid storage disease, there are no approved FXR agonists and the adverse effects from long-term exposure to this drug class are unknown.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed.

The most common side effects observed in clinical trials of OCA in PBC were pruritus, or itching, fatigue, headaches, nausea, constipation and diarrhea. In our Phase 2 PBC clinical trial of OCA in combination with ursodiol, approximately 8% of the patients enrolled in the 10 mg and 25 mg dose groups withdrew from the trial due to severe pruritus. At the 50 mg dose, approximately 25% of the patients withdrew from the trial due to severe pruritus. In our POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 68% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group (5 mgs to 10 mgs). Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) patients were in the 10 mg OCA group and one (1%) patient was in the OCA titration group (in a patient who had titrated up to 10 mg). Pruritus also has been observed in other clinical trials of OCA.

Based on information in the manuscript for the FLINT trial published in November 2014, pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%,  $p < 0.001$ ) and at a higher grade (predominately moderate pruritus), but resulted in only one patient discontinuation in the OCA treatment group.

In the FLINT trial, OCA treatment was associated with changes in serum lipid levels, including increases in total cholesterol and LDL cholesterol and a decrease in HDL cholesterol, that were observed within 12 weeks of initiating treatment, peaked and then decreased in magnitude while on treatment, and reversed further during the 24-week post-treatment period. As previously disclosed, these changes in cholesterol levels, along with achieving the pre-defined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of FLINT, and the publication of the FLINT results has noted the need for further study of these changes. We intend to initiate a Phase 2 trial characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients in 2015. There were two patient deaths in the FLINT trial that were previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013, and neither death was considered related to OCA treatment.

Additional or unforeseen side effects from these or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. If new side effects are found during the development of OCA for any indication, if known side effects are shown to be more severe than previously observed or if OCA is found to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH, PSC, biliary atresia and other potential indications.

The range and potential severity of possible side effects from systemic therapies is significant. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with

Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if ap

restrictive label warnings.

In addition, our drug candidates are being developed as potential treatments for severe, life threatening diseases and, as a result, our trials will necessarily be conducted in a patient population that will be more prone than the general population to exhibit certain disease states or adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials were due to our drug candidates or placebo, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drug candidates. We further cannot assure you that additional or more severe adverse side effects with respect to OCA will not develop in future clinical trials, which could delay or preclude regulatory approval of OCA or limit its commercial use.

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If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;  
we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;  
we may be subject to limitations on how we may promote the product;  
sales of the product may decrease significantly;  
regulatory authorities may require us to take our approved product off the market;  
we may be subject to litigation or product liability claims; and  
our reputation may suffer.

Any of these events could prevent us, Sumitomo Dainippon, Servier or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

**Breakthrough therapy designation for OCA may not lead to faster development or regulatory processes nor does it increase the likelihood that OCA will receive marketing approval for NASH.**

If a drug is intended for the treatment of a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development, the FDA may grant a breakthrough therapy designation. Breakthrough therapy designation is intended to facilitate the development, and expedite the review of such drugs, but the breakthrough therapy designation does not assure any such qualification or ultimate marketing approval by the FDA.

In January 2015, we received breakthrough therapy designation for OCA in the treatment of NASH patients with fibrosis. There is no guarantee that the receipt of breakthrough therapy designation will result in a faster development process, review or approval for OCA in fibrotic NASH patients or increase the likelihood that OCA will be granted marketing approval for fibrotic NASH patients. Likewise, any future breakthrough therapy designation for any other potential indication of OCA neither guarantees a faster development process, review or approval nor improves the likelihood of the grant of marketing approval by FDA for any such potential indication of OCA compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw any breakthrough therapy designation at any time. We may seek a breakthrough therapy designation for other of our product candidates, but the FDA may not grant this status to any of our proposed product candidates.

**We may not be able to obtain or maintain orphan drug exclusivity for our product candidates, if approved, which would cause our revenues to suffer.**

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation

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was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. In addition, it is possible that orphan drug designation in Europe will not be maintained following approval if the EMA determines that the product does not satisfy the requisite criteria including demonstration of significant clinical benefit.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

**Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of our product candidates, if approved. If there is not sufficient reimbursement for our products or they are not covered at all, it is less likely that they will be widely used.**

Market acceptance and sales of OCA or any other product candidates that we develop, if approved, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for OCA or any other product candidates that we develop. Also, reimbursement policies could reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize OCA or any other product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of OCA and any other products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in

general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of OCA or any future product candidates. In addition, although the United States Supreme Court upheld the constitutionality of most of the ACA, some states have indicated that they intend to not implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us.

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**If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.**

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as fraud and abuse laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions such as Europe have similar laws. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

**If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production on a timely basis or at all, we may not be able to commercialize any of our product candidates or commercialization of our product candidates could be delayed.**

We do not intend to manufacture the pharmaceutical products that we plan to sell. We currently have agreements with a contract manufacturer for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for the confirmatory outcomes trial and the long-term safety extension phase of the POISE trial for OCA in PBC, our Phase 3 NASH program for OCA and the other trials and preclinical studies that we plan to conduct prior to seeking regulatory approval. If our contract manufacturer should cease to provide services to us for any reason, we likely would experience delays in advancing our clinical trials while we identify and qualify one or more replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us.

We do not have agreements for commercial supplies of OCA or any of our other product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize OCA if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture OCA or any of our other product candidates must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls.

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Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates, including:

the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our product candidates;

the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

**Even if our product candidates receive regulatory approval, we will still be subject to strict regulatory requirements governing manufacturing and marketing of our products and, as a result, we could face future development and regulatory difficulties.**

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers facilities are required to comply with extensive FDA and EMA requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMPs. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs.

Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

issue warning letters;

mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

require us or our collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for

Even if our product candidates receive regulatory approval, we will still be subject to strict regulatory requirements g

noncompliance;

impose other administrative or judicial civil or criminal penalties;  
withdraw regulatory approval;

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refuse to approve pending applications or supplements to approved applications filed by us, Sumitomo Dainippon, Servier or our potential future collaborators;

impose restrictions on operations, including costly new manufacturing requirements; or  
seize or detain products.

## **Risks Related to the Commercialization of Our Products**

**Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from their sales may be limited.**

If we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States and certain European countries in 2016. The commercial success of OCA or our other product candidates, if approved, will depend upon their acceptance among the medical community, including physicians, health care payors and patients. For PBC, the current standard of care is ursodeoxycholic acid, which is available generically as ursodiol. In order for OCA to be commercially successful, we will need to demonstrate that it is safe and effective for the treatment of patients who have an inadequate response to or who are unable to tolerate ursodiol, referred to as second line treatment, and is more effective than any other alternatives that may be developed as a second line treatment for PBC, particularly given the much higher price that we anticipate charging for OCA compared to the price of generically available ursodiol. In NASH and PSC, since there are currently no approved therapies, we do not know the degree to which OCA will be accepted as a therapy, even if approved.

The degree of market acceptance of our product candidates will depend on a number of factors, including:

limitations or warnings contained in our product candidates FDA or EMA-approved labeling;  
changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for any of our product candidates, such as ursodiol for the treatment of PBC;

limitations in the approved clinical indications for our product candidates;  
demonstrated clinical safety and efficacy compared to other products;

lack of significant adverse side effects;  
sales, marketing and distribution support;

availability of reimbursement from managed care plans and other third-party payors;  
timing of market introduction and perceived effectiveness of competitive products;

the degree of cost-effectiveness;

availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;  
the extent to which our product candidates are approved for inclusion on formularies of hospitals and managed care organizations;

whether our product candidates are designated under physician treatment guidelines for the treatment of the indications for which we have received regulatory approval;

adverse publicity about our product candidates or favorable publicity about competitive products;  
convenience and ease of administration of our product candidates; and

potential product liability claims.

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If our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and healthcare payors, sufficient revenue may not be generated from these products and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

**We have no sales, marketing or distribution experience and we will have to invest significant additional resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.**

We have no sales, marketing or distribution experience and have only recently started the initial phases of developing an internal commercial organization. We plan to establish our own sales and marketing capabilities and promote OCA for PBC in the United States and Europe with a targeted sales force if and when it is approved and may utilize the services of third-party collaborators in certain jurisdictions. To develop internal sales, distribution and marketing capabilities, we will have to invest significant additional amounts of financial and management resources, some of which will be committed prior to any confirmation that OCA or any of our other product candidates will be approved.

For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. For product candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including:

we or our third-party sales collaborators may not be able to attract and build an effective marketing or sales force; the cost of securing or establishing a marketing or sales force may exceed the revenues generated by any products; and

our direct sales and marketing efforts may not be successful.

We have entered into an agreement with Sumitomo Dainippon for the development and commercialization of OCA in Japan, China, South Korea and potentially other Asian countries, if approved, and have entered into an agreement with Servier to assist in the development and commercialization of certain of our earlier stage agonists of a dedicated bile acid receptor called TGR5 outside of the United States and Japan, if approved, and may elect to seek additional strategic collaborators for our product candidates. We may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

**If any of our current strategic collaborators fails to perform its obligations or terminates its agreement with us, the development and commercialization of the product candidates under such agreement could be delayed or terminated and our business could be substantially harmed.**

We currently have strategic collaborations in place relating to certain of our product candidates. We entered into an exclusive license agreement with Sumitomo Dainippon regarding the development and commercialization of OCA for PBC and NASH in Japan, China and South Korea and provided Sumitomo Dainippon with an option to extend its exclusive license to different indications as well as certain other Asian countries. We entered into a strategic collaboration with Servier initially focused on the identification and optimization of novel TGR5 agonists for the treatment of type-2 diabetes and other associated disorders. These strategic collaborations may not be scientifically or commercially successful due to a number of important factors, including the following:

Sumitomo Dainippon and Servier have significant discretion in determining the efforts and resources that each will apply to their strategic collaboration with us. The timing and amount of any cash payments, milestones and royalties

Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients and

that we may receive under such agreements will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of our product candidates by Sumitomo Dainippon and Servier under their respective agreements;

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Our agreement with Servier provides it with wide discretion in deciding which novel compounds to advance through the preclinical and clinical development process. It is possible for Servier to reject certain compounds at any point in the research, development and clinical trial process without triggering a termination of their agreement with us. In the event of any such decision, our business and prospects may be adversely affected due to our inability to progress such compounds ourselves;

Our agreement with Sumitomo Dainippon restricts it from developing or commercializing any FXR agonist to treat PBC or NASH during the term of the agreement other than pursuant to the Sumitomo Dainippon agreement and our agreement with Servier restricts it from developing or commercializing any TGR5 receptor agonist during the term of the agreement other than pursuant to the Servier agreement. Subject to these restrictions, it is possible that Sumitomo Dainippon or Servier may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that they license from us;

Sumitomo Dainippon or Servier may change the focus of their development and commercialization efforts or pursue higher-priority programs;

Sumitomo Dainippon or Servier may, under specified circumstances, terminate their strategic collaborations with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities;

Sumitomo Dainippon and Servier have, under certain circumstances, the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our strategic collaborators do not, our ability to do so may be compromised by our strategic collaborators' acts or omissions;

Sumitomo Dainippon or Servier may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability; and

Sumitomo Dainippon or Servier may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.

If either Sumitomo Dainippon or Servier fails to develop or effectively commercialize OCA or any TGR5 compounds, respectively, we may not be able to replace them with another collaborator. We may also be unable to obtain, on terms acceptable to us, a license from such strategic collaborator to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a product candidate. Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

### **We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.**

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, expanding manufacturing capabilities and marketing approved products are expensive, we have entered into, and may seek to enter into, collaborations with companies that have more experience and resources than we have. For example, we have entered into collaborations with Sumitomo Dainippon for OCA and Servier for our earlier stage TGR5 program. We may establish additional collaborations for development and commercialization of OCA in territories outside of those licensed by Sumitomo Dainippon or for our earlier stage TGR5 program in the United States or Japan and for other product candidates and research programs, including INT-767 and INT-777. Additionally, if any of our product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to our unlicensed territories. If we are unable to maintain our existing arrangements or enter into any new such arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements

We may not be successful in establishing and maintaining development and commercialization collaborations, which



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complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates.

When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For example, Sumitomo Dainippon has the exclusive rights to OCA in Japan, China and South Korea and a right of first refusal to license OCA in several other Asian countries. Our collaboration partner may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into, including our collaborations with Sumitomo Dainippon and Servier, may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our product candidates, we would face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them and we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition will be materially and adversely affected.

### **If we fail to develop OCA for additional indications, our commercial opportunity will be limited.**

To date, we have focused the majority of our development efforts on the development of OCA for the second line treatment of PBC. One of our strategies is to pursue clinical development of OCA for other orphan and more common indications, to the extent that we have sufficient funding.

PBC is a rare disease for which we plan to seek marketing approval for OCA as a second-line treatment and, as a result, the market size for treatments of PBC is limited. Furthermore, because a significant proportion of PBC patients do not exhibit any symptoms at the time of diagnosis, PBC may be left undiagnosed for a significant period of time.

Due to these factors, our ability to grow revenues will be dependent on our ability to successfully develop and commercialize OCA for the treatment of additional indications, including NASH. In particular, we believe that our future success will depend in large part on the results of our development of OCA for the treatment of NASH.

Although NASH is believed to be one of the most prevalent chronic liver diseases worldwide, NASH may be left undiagnosed for a long time and a definitive diagnosis of NASH is currently based on a histological assessment of a liver biopsy, which impacts the ability to easily identify patients. Furthermore, even if we are successful in developing and obtaining marketing approval of OCA for the treatment of NASH, we may not be able to commercialize OCA successfully.

The completion of development, securing of approval and commercialization of OCA for additional indications will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully advance any of these indications through the development process. Even if we receive FDA or EMA approval to market OCA for the treatment of any of these additional indications, we cannot assure you that any such additional indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize OCA for these additional indications, our commercial opportunity will be limited and our business prospects will suffer.

## **Risks Related to Our Business and Strategy**

**We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.**

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty

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pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products.

These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA or EMA approval or discovering, developing and commercializing drugs for the chronic liver and other diseases that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Some of the pharmaceutical and biotechnology companies we expect to compete with include Astellas Pharma US, Inc., AstraZeneca, Bristol-Myers Squibb Company, Conatus Pharmaceuticals Inc., Dr. Falk Pharma GmbH, Eli Lilly, Exelixis, Inc., Galectin Therapeutics Inc., Galmed Medical Research Ltd., Genfit SA, Gilead Sciences, Inc., GlaxoSmithKline, Immuron Ltd., Kadmon Corporation LLC, La Jolla Pharmaceutical Company, Lumena Pharmaceuticals, Inc. (now part of Shire PLC), Mochida Pharmaceutical Co., Ltd., NasVax Ltd., NovImmune SA., Novo Nordisk A/S, Raptor Pharmaceutical Corp., Salix Pharmaceuticals, Inc., Takeda Pharmaceutical Co Ltd, Tioga Pharmaceuticals, Inc. and Tobira Therapeutics. Each of Gilead Sciences, Inc. and Genfit SA has publicly stated its intention to announce Phase 2 clinical trial results for the treatment of NASH in 2015. In addition, many universities and private and public research institutes may become active in our target disease areas. The results from our POISE and FLINT trials have brought more attention to our targeted indications and bile acid chemistry. As a result, we believe that additional companies and organizations may seek to compete with us in the future. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than OCA or any other product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

Off-label uses of other potential treatments may limit the commercial potential of our product candidates, especially given the anticipated pricing for our product candidates. For example, off-label use of fibrate drugs has been reported in PBC, though many fibrates are specifically contraindicated for use in PBC due to potential concerns over acute and long-term safety in this patient population. In NASH, a number of treatments, including vitamin E (an antioxidant), insulin sensitizers (such as metformin), antihyperlipidemic agents (such as gemfibrozil), pentoxifylline and ursodiol, are used off-label. Although none of these treatments have been clearly shown in clinical trials to alter the course of the disease, in a previous study conducted by the NASH Clinical Research Network, similar improvements to those observed with OCA in the FLINT trial in certain histological measures of NASH were reported with vitamin E and pioglitazone. Various other treatments, both approved and unapproved, have been used in the other indications we are targeting.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our and our strategic collaborators' clinical trials and preclinical studies;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals, if any;

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if

our ability to commercialize and market any of our product candidates that receive regulatory approval;

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the price of our products;  
adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;  
our ability to protect intellectual property rights related to our products;  
our ability to manufacture and sell commercial quantities of any approved products to the market; and  
acceptance of our product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

**We depend on third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves.**

We outsource and plan to continue to outsource substantial portions of our operations to third-party service providers, including the conduct of preclinical studies and clinical trials, collection and analysis of data and manufacturing. We will likely use the services of third-party vendors in relation to our commercialization activities, including product sales, marketing and distribution. Our agreements with third-party service providers are on a study-by-study and/or project-by-project basis. Typically, we may terminate the agreements with notice and are responsible for the supplier's previously incurred costs. In addition, a number of third-party service providers that we retain will be subject to the FDA's and EMA's regulatory requirements and similar standards outside of the United States and Europe and we do not have control over compliance with these regulations by these providers. Consequently, if these providers do not adhere to applicable governing practices and standards, the development and commercialization of our product candidates could be delayed or stopped, which could severely harm our business and financial condition.

Because we have relied on third parties, our internal capacity to perform these functions is limited to management oversight. Outsourcing these functions involves the risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. Several years ago, we experienced difficulties with a third-party contract manufacturer for OCA, including delays in receiving adequate clinical trial supplies as requested within the requested time periods. We subsequently replaced this manufacturer with other third-party contract manufacturers for OCA. It is possible that we could experience similar difficulties in the future. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There are a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor third-party service providers. To the extent we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. We may further be subject to the imposition of civil or criminal penalties if their conduct of clinical trials violates applicable law.

Our third-party service providers generally are not prohibited from providing their services to other biopharmaceutical companies, including companies that currently or may in the future compete with us. For example, certain of our third-party service providers and consultants may be able to develop intellectual property to which we are not entitled

We depend on third-party contractors for a substantial portion of our operations and may not be able to control their

under our agreements which may eventually be used to develop products that compete with our products. Although we generally have confidentiality and non-disclosure agreements in place with our third-party service providers and consultants, such third parties may be able to provide services to other companies without violating the terms of our agreements. In addition, although we may seek to enter

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into non-compete arrangements with our key third-party service providers, such arrangements are difficult to negotiate and we may be unable to successfully enter into such arrangements.

**A variety of risks associated with our international business operations and our planned international business relationships could materially adversely affect our business.**

We have recently formed a wholly-owned subsidiary in the United Kingdom which we anticipate will serve as our headquarters for our operations in Europe and anticipate building out our European operations. We also currently have an Italian subsidiary that acts as our legal representative for our clinical trials in the European Union to satisfy European Union regulatory requirements. In addition, we have entered into an agreement with Sumitomo Dainippon for the development of OCA and with Servier for our earlier stage TGR5 program, and we may enter into agreements with other third parties for the development and commercialization of OCA or our other product candidates in international markets. Our international operations and business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- the potential for so-called parallel importing, which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

**We have been significantly expanding our operations and the size of our company and will need to continue our expansion. We may experience difficulties in managing our significant growth.**

From December 31, 2013 to December 31, 2014, our employee base has grown from 40 to 136 employees. Of the 136 employees as of December 31, 2014, 92 employees are in our development group, 18 employees are in our commercial group and 26 employees are in our corporate group. At December 31, 2014, one employee was based in Europe. As we advance our programs for OCA in PBC, NASH and PSC and seek regulatory approval in the United States and elsewhere, increase the number of ongoing product development programs and advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. We will also need to grow our commercial capabilities, which will require us to hire additional personnel, both for our ongoing pre-commercial activities and for the launch and ongoing marketing and sale of any product candidate for which we obtain marketing approval. In addition, to

A variety of risks associated with our international business operations and our planned international business relationships



meet our obligations as a public company and to support the anticipated growth in the other functions at our company, we will need to increase our general and administrative capabilities. We are also expanding our operations geographically and have recently formed a wholly-owned subsidiary in the United Kingdom which we anticipate will serve as our

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headquarters for our operations in Europe and anticipate building out our European operations. Our management, personnel and systems currently in place may not be adequate to support this future growth.

Our need to effectively manage our operations, growth and various projects requires that we:

successfully attract and recruit new employees or consultants with the expertise and experience we will require in the United States and Europe;

manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites across the world, and advance our other development efforts;

develop and expand our marketing and sales infrastructure; and

continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

**We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.**

We may not be able to attract or retain qualified personnel and consultants across our organization due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercial objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Mark Pruzanski, our co-founder and president and chief executive officer; David Shapiro, our chief medical officer; Barbara Duncan, our chief financial officer and treasurer; Daniel Regan, our chief commercial officer; Luciano Adorini, our chief scientific officer; Rachel McMinn, our chief strategy officer; and our other key employees and consultants, such as Lisa Bright, our head of Europe, and Professor Roberto Pellicciari, our co-founder who provides ongoing consulting services to us. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants.

We have scientific and clinical advisors and consultants, such as our co-founder Professor Roberto Pellicciari, who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

**Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.**

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing

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and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting expense and expend significant management efforts. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner so as to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner each year, we could be subject to sanctions or investigations by the Securities and Exchange Commission, the NASDAQ Stock Market or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

**Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.**

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations in the United States and abroad intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

**We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.**

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

withdrawal of clinical trial participants;  
termination of clinical trial sites or entire trial programs;  
costs of related litigation;  
substantial monetary awards to patients or other claimants;  
decreased demand for our product candidates and loss of revenues;  
impairment of our business reputation;

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diversion of management and scientific resources from our business operations; and  
the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials in the United States and in selected other jurisdictions where we are conducting clinical trials. Our product liability insurance coverage for clinical trials in the United States is currently limited to an aggregate of \$10 million and outside of the United States we have coverage for amounts that vary by country. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business.

**Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.**

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers compensation, products liability and directors and officers insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. Furthermore, our significant increase in stock price and increased volatility may result in us being required to pay substantially higher premiums for our directors and officers insurance than those to which we are currently subject, and may even lead a large number of underwriters to be unwilling to cover us.

**If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.**

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
  - incur substantial debt that may place strains on our operations;
  - spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
  - assume substantial actual or contingent liabilities;
  - reprioritize our development programs and even cease development and commercialization of our product candidates; or
  - merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash and/or shares of the other company on terms that certain of our stockholders may not deem desirable.
- Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we

have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

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If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adv

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### **Our business and operations would suffer in the event of system failures.**

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

## **Risks Related to Our Intellectual Property**

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

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

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

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

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

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



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

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

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

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

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

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

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

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As of December 31, 2014, we were the owner of record of over 110 issued or granted U.S. and non-U.S. patents relating to OCA with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds, and methods of using these compounds in various indications. We were also the owner at that date of record of 28 pending U.S. and non-U.S. patent applications relating to OCA in these areas.

In addition, as of December 31, 2014, we were the owner of record of over 145 issued or granted U.S. and non-U.S. patents relating to our product candidates other than OCA, with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds and methods of using these compounds in various indications. We were also the owner of record of over 40 pending U.S. and non-U.S. patent applications relating to such other product candidates in these areas.

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

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

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

### **If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.**

Depending upon the timing, duration and specifics of FDA marketing approval of OCA and our other product candidates, if any, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by e

patent expiration, and our revenue could be reduced, possibly materially. In the event that we are unable to obtain any patent term extensions, the issued composition of matter patents for OCA are expected to expire in 2022 assuming they withstand any challenge. We expect that the other patents and patent applications for the OCA portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2022 to 2033.

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**We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.**

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office, or USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

**We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.**

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we fail to obtain a license, develop or obtain non-infringing technology or defend an infringement action successfully, or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

some patent applications in the United States may be maintained in secrecy until the patents are issued;

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patent applications in the United States are typically not published until 18 months after the priority date; and publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and such patent applications may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

### **Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.**

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

### **We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.**

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these

claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is

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not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

### **We have not yet registered all of our trademarks and failure to secure those registrations could adversely affect our business.**

We have applied for a number of trademarks and service marks to further protect the proprietary position of our products. We have approximately ten pending trademark and service mark applications in the United States. Our trademark applications may not be allowed for registration or our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms. We cannot provide any assurances that any trademarks or service marks will be sufficient to prevent competitors from adopting similar names. The adoption of similar names by competitors could impede our ability to build brand identity and lead to customer confusion, which could adversely affect our sales or profitability.

In addition, we have not yet received approval from regulatory authorities for a proprietary name for any of our product candidates, including OCA, in any jurisdiction. Any proprietary name we propose to use with OCA in the United States and Europe must be approved by the FDA and EMA, respectively, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA and EMA typically conduct a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or EMA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

## **Risks Related to Ownership of Our Common Stock and this Offering**

### **An active trading market in our common stock may not be maintained.**

The trading market in our common stock has been extremely volatile. The quotation of our common stock on The NASDAQ Global Select Market does not assure that a meaningful, consistent and liquid trading market will exist. We cannot predict whether an active market for our common stock will be maintained in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices



in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of December 31, 2014, approximately 39.6% of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5% or more of our securities (other than FMR LLC, Carmignac Gestion and their respective affiliates) and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

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**We are currently subject to securities class action litigation and may be subject to similar or other litigation in the future, which may divert management's attention.**

On February 21, 2014 and February 28, 2014, purported shareholder class actions, styled *Scot H. Atwood v. Intercept Pharmaceuticals, Inc. et al.* and *George Burton v. Intercept Pharmaceuticals, Inc. et al.*, respectively, were filed in the United States District Court for the Southern District of New York, naming us and certain of our officers as defendants. These lawsuits were filed by stockholders who claim to be suing on behalf of anyone who purchased or otherwise acquired our securities between January 9, 2014 and January 10, 2014. The plaintiffs seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. The lawsuits allege that we made material misrepresentations and/or omissions of material fact in our public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to our January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that our January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. On August 14, 2014, the defendants filed a motion to dismiss the complaint, which has been opposed by the lead plaintiff. Oral arguments on the motion to dismiss have been scheduled for February 24, 2015. The lead plaintiff seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees.

While we believe we have meritorious defenses, we cannot predict the outcome of these lawsuits. There may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability fully to focus our internal resources on our business activities, and we cannot predict how long it may take to resolve these matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance, coverage could be denied or prove to be insufficient. We are not currently able to estimate the possible cost to us from these lawsuits, as they are currently at an early stage, and we cannot be certain how long it may take to resolve these lawsuits or the possible amount of any damages that we may be required to pay. We have not established any reserves for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgment or enter into settlement of claims for monetary damages. A decision adverse to our interests on either of these lawsuits could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition. In addition, the uncertainty of the currently pending lawsuits could lead to more volatility in our stock price.

**Our stock price has been and may in the future be volatile, which could cause purchasers of our common stock to incur substantial losses.**

The trading price of our stock price has been, and is likely to continue to be, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering which occurred in October 2012, the price of our common stock on The NASDAQ Global Select Market has ranged from \$17.96 per share to \$497.00 per share. In addition to the other factors discussed in this Risk Factors section, these factors include:

We are currently subject to securities class action litigation and may be subject to similar or other litigation in the future.

adverse results or delays in our clinical trials;  
inability to obtain additional funding;  
any delay in filing an IND, NDA, MAA or comparable submission for any of our product candidates and any adverse development or perceived adverse development with respect to the regulatory review of such submission;  
failure to successfully develop and commercialize OCA and any of our other product candidates;  
failure to maintain our existing strategic alliances or enter into new alliances;

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inability to obtain adequate product supply for OCA and our future product candidates or the inability to do so at acceptable prices;

    results of clinical trials of our competitors' products;

    regulatory actions with respect to our products or our competitors' products;

    changes in laws or regulations applicable to our future products;

    failure to meet or exceed financial projections we may provide to the public;

    failure to meet or exceed the estimates and projections of the investment community;

    actual or anticipated fluctuations in our financial condition and operating results;

    actual or anticipated changes in our growth rate relative to our competitors;

actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;

    competition from existing products or new products that may emerge;

announcements by us, our collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;

    issuance of new or updated research or reports by securities analysts;

    fluctuations in the valuation of companies perceived by investors to be comparable to us;

    share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

    additions or departures of key management or scientific personnel;

disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

    announcement or expectation of additional financing efforts;

    significant lawsuits, including patent or stockholder litigation, involving us;

    sales of our common stock by us, our insiders or our other stockholders;

failure to adopt appropriate information security systems, including any systems that may be required to support our growing and changing business requirements;

    market conditions for biopharmaceutical stocks in general; and

    general economic, industry and market conditions.

Furthermore, the stock markets in general and the market for biotechnology companies in particular have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations may negatively impact the market price of shares of our common stock, regardless of our actual operating performance. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are currently subject to class action securities lawsuits and may be the target of this type of litigation in the future, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. As a result of this volatility, our stockholders could incur substantial losses.

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**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 December 31, 2014, Genextra owned 6,454,953 shares of our common stock. The shares of common stock owned by Genextra represented approximately 30.1% of our outstanding common stock as of December 31, 2014. Following this offering, we anticipate that the shares of common stock owned by Genextra will represent approximately 27.8% of our outstanding common stock (assuming no exercise by the underwriters of their option to purchase additional shares). 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 within the meaning of the NASDAQ Listing Rules. Under the NASDAQ Listing Rules, a company of which more than 50% of the voting power is held by another person or group of persons acting together is a controlled company and may elect not to comply with certain NASDAQ Listing Rules regarding corporate governance, 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 nine directors, including two affiliated with Genextra, has the power to set the number of directors on our board from time to time.

**Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.**

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly,

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

because of the inherent limitations in our control system, misstatements or insufficient disclosure due to error or fraud may occur and not be detected.

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**You may experience future dilution as a result of future equity offerings.**

In the future, we may offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock in order to raise additional capital. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share you paid for our shares. Investors purchasing shares or other securities in the future could have rights, preferences or privileges senior to those of existing stockholders and you may experience dilution. You may incur additional dilution upon the exercise of any outstanding stock options or vesting of restricted stock units or awards.

**Future sales of shares of our common stock, including by us or our directors, executive officers and beneficial owners of 5% or more of our securities (other than FMR LLC and Carmignac Gestion) and their respective affiliates following expiration or early release of the lock-up or shares issued upon the exercise of currently outstanding options could cause the market price of our common stock to drop significantly, even if our business is doing well.**

A substantial portion of our outstanding common stock can be traded without restriction at any time. Some of these shares are currently restricted from resale as a result of securities laws, but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options. The exercise of these options and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. In connection with this offering, we and our directors, executive officers and beneficial owners of 5% or more of our securities (other than FMR LLC and Carmignac Gestion) and their respective affiliates have entered into lock-up agreements for a period of 45-days following this offering. We and our directors, executive officers and beneficial owners of 5% or more of our securities (other than FMR LLC and Carmignac Gestion) and their respective affiliates may be released from lock-up prior to the expiration of the lock-up period at the sole discretion of Citigroup Global Markets Inc. and RBC Capital Markets, LLC. Upon expiration or earlier release of the lock-up agreements described in the Underwriting section of this prospectus supplement, we and our directors, executive officers and beneficial owners of 5% or more of our securities (other than FMR LLC and Carmignac Gestion) and their respective affiliates may sell securities into the market, which could adversely affect the market price of shares of our common stock. In addition, during the lock-up period and thereafter, sales of shares of common stock held by our directors and executive officers are permitted under trading plans, as in effect as of the date of the applicable lock-up agreement, established pursuant to Rule 10b5-1 of the Exchange Act. We cannot predict the size of future issuances or the effect, if any, that this offering or any future issuances may have on the market price for our common stock.

In addition, as of December 31, 2014, holders of an aggregate of 8,423,533 shares of our common stock 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. See the section entitled Description of Capital Stock Registration Rights contained in the accompanying prospectus.

**Our management will have broad discretion over the use of the proceeds we receive from this offering and may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return, if any.**

Our management will have broad discretion over the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. You may not agree with the manner in which our management chooses to allocate and spend these net proceeds. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately.

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The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce significant income or investments that lose value.

**Because we do not anticipate paying cash dividends on our common stock for the foreseeable future, investors in this offering may never receive a return on their investment.**

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations.

Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not invest in our common stock.

**If securities or industry analysts cease publishing research or reports about us, our business or our market, or if they publish inaccurate or unfavorable reports about our stock, the price of our stock and trading volume could decline.**

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about our company. We do not have any control over these analysts, and there can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of the analysts covering us fail to regularly publish reports on us, demand for our common stock could decline, which could cause our stock price and trading volume to decline.

**Anti-takeover provisions in our restated certificate of incorporation and our restated by-laws, as well as provisions of Delaware law, might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.**

Provisions in our restated certificate of incorporation and restated by-laws, as well as provisions of Delaware law, contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Our corporate governance documents include provisions:

authorizing the issuance of blank check convertible preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders, to the extent that no stockholder, together with its affiliates, holds more than 50% of our voting stock;

eliminating the ability of stockholders to call a special meeting of stockholders;

Because we do not anticipate paying cash dividends on our common stock for the foreseeable future, investors in th

permitting our board of directors to accelerate the vesting of outstanding equity awards upon certain transactions that result in a change of control; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, as a Delaware corporation, we are subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, or DGCL, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock. Any provision of our restated certificate of incorporation or restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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The existence of the foregoing provisions and anti-takeover measures may also frustrate or prevent any attempts by our stockholders to replace or remove our current management or members of our board of directors and could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

**Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.**

As permitted by Section 102(b)(7) of the DGCL, our restated certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the DGCL, our restated certificate of incorporation and restated bylaws provide that we shall indemnify, to the fullest extent authorized by the DGCL, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of our company 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 bylaws authorize the claimant to bring an action against us and prescribe what constitutes a defense to such action.

Section 145 of the DGCL 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 above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Although we have increased the coverage under our directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder

coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against our company.

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**Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.**

As of December 31, 2013 and September 30, 2014, we had net operating loss carryforwards, or NOLs, for federal income tax purposes of \$108.2 million and \$179.2 million, respectively, which expire from 2024 through 2033. Our ability to utilize our NOLs may be limited under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382 of the Internal Revenue Code, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). We have assessed whether one or more ownership changes as defined under Section 382 of the Internal Revenue Code have occurred since our inception and have determined that there have been at least two such changes. Accordingly, although we believe that these ownership changes have not resulted in material limitations on our ability to use these NOLs, our ability to utilize the aforementioned carryforwards may be limited due to other reasons. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation.

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## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of 800,000 shares of our common stock in this offering will be approximately \$142.6 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and based on an assumed public offering price of \$188.66 per share, the last sale price of our common stock on February 2, 2015, as reported on The NASDAQ Global Select Market. If the underwriters exercise in full their option to purchase additional shares, we estimate that net proceeds to us will be approximately \$164.1 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from the sale by us of common stock offered under this prospectus, together with our existing cash, cash equivalents and short-term investments, to fund:

expansion of our clinical, regulatory, medical affairs and commercial infrastructure in the United States and Europe;  
continued clinical development of OCA in PBC, NASH and PSC;  
expansion of OCA manufacturing activities;  
advancement of INT-767 and other preclinical pipeline programs; and  
preparation for and potential initiation of the commercial launch of OCA in PBC in the United States and certain European countries in 2016.

The balance, if any, will be used for general corporate purposes, including general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property.

We have not determined the exact amounts we plan to spend on any of the items listed above or the timing of these expenditures. Our expected use of the net proceeds from this offering represents our current intentions based upon our present plans and business conditions. We currently project adjusted operating expenses in the range of \$180 million to \$200 million in the fiscal year ending December 31, 2015, which excludes stock-based compensation and other non-cash items. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. See **Non-GAAP Financial Measures** for more information.

Due to the many variables inherent to the development and commercialization of novel therapies, such as the risks described in the **Risk Factors** section of this prospectus supplement, and our rapid growth and expansion, we currently cannot accurately or precisely predict the duration beyond 2015 over which we expect our cash and cash equivalents, together with the net proceeds from this offering, to last. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the relative success and cost of our clinical development programs, the willingness of the FDA and EMA to accept our POISE trial data, as well as our other completed and planned clinical trials and preclinical studies and other work, as the basis for review and marketing approval of OCA for PBC; the outcome of our discussions with the FDA and EMA regarding the clinical and regulatory requirements to advance OCA for the treatment of NASH; the pre-commercialization activities in which we engage for OCA in PBC and the timing of such activities; the amount and timing of additional revenues, if any, received from our collaborations with Sumitomo Dainippon and Servier, whether we are able to enter into future collaborations; and any unforeseen cash needs.

Our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue clinical trials or preclinical activities if the net proceeds from this offering and the other sources of cash are less than expected. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies.

Pending our use of the net proceeds from this offering, we expect to invest the proceeds in short-term, interest-bearing, investment-grade securities.

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Our common stock is listed on The NASDAQ Global Select Market and trades under the symbol ICPT. The following table sets forth, for the quarterly periods indicated, the high and low sale price per share of our common stock as reported on The NASDAQ Global Select Market:

	High	Low
Year ended December 31, 2013		
First Quarter	\$ 42.67	\$ 33.45
Second Quarter	\$ 45.00	\$ 30.38
Third Quarter	\$ 72.64	\$ 42.41
Fourth Quarter	\$ 77.53	\$ 46.81
Year ended December 31, 2014		
First Quarter	\$ 497.00	\$ 65.22
Second Quarter	\$ 339.67	\$ 209.00
Third Quarter	\$ 349.08	\$ 208.00
Fourth Quarter	\$ 264.92	\$ 128.50
Year ended December 31, 2015		
First Quarter (through February 2, 2015)	\$ 210.00	\$ 144.79

On February 2, 2015, the last sale price of our common stock, as reported on The NASDAQ Global Select Market, was \$188.66 per share.

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## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

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TABLE OF CONTENTS**CAPITALIZATION**

The following table shows our cash, cash equivalents and investment securities as well as capitalization as of September 30, 2014:

on an actual basis; and

on an as adjusted basis to give effect to the sale by us of 800,000 shares of our common stock in this offering at an assumed public offering price of \$188.66 per share, the last sale price of our common stock on February 2, 2015, as reported on The NASDAQ Global Select Market, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the information contained in our consolidated financial statements and condensed consolidated financial statements and related notes incorporated by reference in this prospectus supplement and the accompanying prospectus.

	As of September 30, 2014	
	Actual	As Adjusted <sup>(1)</sup>
	(unaudited, in thousands, except par value data)	
Cash, cash equivalents and investment securities	\$272,806	\$415,436
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 5,000,000 shares authorized, no shares issued and outstanding, actual and as adjusted		
Common stock, par value \$0.001 per share; 35,000,000 shares authorized, 21,323,549 shares issued and outstanding, respectively, actual; 35,000,000 shares authorized, 22,123,549 shares issued and outstanding, respectively, as adjusted	21	22
Additional paid-in capital	695,622	838,250
Accumulated other comprehensive income (loss), net	(203 )	(203 )
Accumulated deficit	(434,378)	(434,378)
Total stockholders' equity	261,062	403,691
Total capitalization	\$261,062	\$403,691

- (1) Each \$10.00 increase (decrease) in the assumed public offering price of \$188.66 per share, the last reported sale price of our common stock on the NASDAQ Global Select Market on February 2, 2015, would increase (decrease) the as adjusted amount of cash and cash equivalents and investment securities, total stockholders' equity and total capitalization by approximately \$7.6 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus supplement, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 50,000 shares in the number of shares offered by us would increase (decrease) the as adjusted amount of cash and cash equivalents and investment securities, total stockholders' equity and total capitalization by approximately \$8.9 million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative

only and will be based on the actual public offering price and other terms of this offering determined at pricing.

The number of shares of common stock reflected in the table above is based on 21,323,549 shares of our common stock outstanding of September 30, 2014, and excludes as of such date:

1,342,833 shares of common stock issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$63.05 per share;

restricted stock units for 70,543 shares of our common stock that were unvested; and

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918,479 shares of common stock reserved for future issuance under our 2012 Plan.

**DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering.

Our net tangible book value as of September 30, 2014 was \$261.1 million, or \$12.24 per share of our common stock, based on approximately 21,323,549 shares of our common stock then outstanding. After giving effect to the sale by us of 800,000 shares of our common stock in this offering at an assumed public offering price of \$188.66 per share, the last sale price of our common stock on February 2, 2015, as reported on The NASDAQ Global Select Market, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value at September 30, 2014 would have been \$403.7 million, or \$18.25 per share. This represents an immediate increase in net tangible book value of \$6.00 per share to existing stockholders and an immediate dilution of \$170.41 per share to investors in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share	\$188.66
Net tangible book value per share as of September 30, 2014	\$12.24
Increase per share attributable to new investors purchasing shares in this offering	\$6.00
Net tangible book value per share after this offering	\$18.25
Dilution per share to new investors	\$170.41

Each \$10.00 increase (decrease) in the assumed public offering price of \$188.66 per share would increase (decrease) our pro forma net tangible book value after this offering by approximately \$7.6 million, or approximately \$0.34 per share, and the dilution per share to new investors by approximately \$9.66 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus supplement, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 50,000 shares in the number of shares offered by us would increase (decrease) our pro forma net tangible book value after this offering by approximately \$8.9 million, or \$0.36 per share, and decrease (increase) the dilution per share to new investors by approximately \$0.36 per share, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering determined at pricing.

The foregoing table and calculations are based on 21,323,549 shares of our common stock outstanding of September 30, 2014, and exclude as of such date:

1,342,833 shares of common stock issuable upon the exercise of outstanding stock options at a weighted-average exercise price of \$63.05 per share;

restricted stock units for 70,543 shares of our common stock that were unvested; and  
918,479 shares of common stock reserved for future issuance under our 2012 Plan.

If the underwriters exercise their option to purchase additional shares of our common stock or if any additional shares are issued in connection with outstanding options, there will be further dilution to new investors.



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## **MATERIAL U.S. TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK**

The following is a general discussion of material U.S. federal income and estate tax considerations relating to the ownership and disposition of our common stock issued pursuant to this offering 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.

An individual may be treated as a resident instead of a nonresident of the United States in any calendar year for U.S. federal income tax purposes if the individual was present in the United States for at least 31 days in that calendar year and for an aggregate of at least 183 days during the three-year period ending with the current calendar year. For purposes of this calculation, all of the days present in the current year, one-third of the days present in the immediately preceding year and one-sixth of the days present in the second preceding year are counted. Residents are taxed for U.S. federal income tax purposes as if they were U.S. citizens.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as 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 supplement 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, including the alternative minimum tax and the Medicare contribution tax, 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 U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

insurance companies;  
tax-exempt organizations;  
financial institutions;  
brokers or dealers in securities;  
regulated investment companies;  
pension plans;  
controlled foreign corporations;  
passive foreign investment companies;  
owners that have a functional currency other than the U.S. dollar;

owners deemed to sell our common stock under the constructive sale provisions of the Code;

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owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and

certain U.S. expatriates.

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

***This discussion is for general information only and it is not tax advice. 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. Any such distribution would also be subject to the discussion below under the section titled The Foreign Account Tax Compliance Act.

As discussed in the Dividend Policy section of this prospectus, we do not expect to pay cash dividends to holders of our common stock in the foreseeable future. In the event we pay dividends, 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.

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 provides a properly executed IRS Form W-8ECI and satisfies applicable certification and disclosure requirements. 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 generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (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.





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## Gain on Disposition of Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other disposition of our common stock unless:

the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons (as defined in the Code), and if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

the non-U.S. holder is a non-resident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-U.S. holder will be subject to a 30% tax (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) on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States, provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses); or we are or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a U.S. real property holding corporation unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a U.S. real property holding corporation for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rule described above.

## 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 W-8-BEN-E (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under "Dividends," will generally be exempt U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption.

Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker.

However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through

a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

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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 that an appropriate claim is timely filed with the IRS.

## **The Foreign Account Tax Compliance Act**

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax at a rate of 30% on payments of dividends on, and gross from the sale or other disposition of, our common stock if paid to a foreign entity unless (i) if the foreign entity is a foreign financial institution, the foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a foreign financial institution, the foreign entity identifies certain of its U.S. investors, or (iii) the foreign entity is otherwise exempt under FATCA.

Under applicable U.S. Treasury regulations, withholding under FATCA will only apply (1) to payments of dividends on our common stock made after June 30, 2014 and (2) to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2016. Under certain circumstances, a non-US holder may be eligible for refunds or credits of the tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

## **Federal Estate Tax**

Common stock owned or treated as owned by an individual who is not a citizen or resident of the United States (as specially defined for U.S. federal estate tax purposes) at the time of death are considered U.S. situs assets and 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.**

TABLE OF CONTENTS**UNDERWRITING**

Citigroup Global Markets Inc. and RBC Capital Markets, LLC are acting as joint book-running managers of the offering and as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
Citigroup Global Markets Inc.	
RBC Capital Markets, LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement (other than those covered by the underwriters' option to purchase additional shares described below) if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

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

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

**Commissions and Discounts**

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus supplement 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 us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to Intercept	\$	\$	\$

The expenses of the offering, not including the underwriting discount, are estimated at \$550,000 and are payable by us. The underwriters have agreed to reimburse us for certain expenses related to this offering.

## **Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus supplement, to purchase up to 120,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

## **No Sales of Similar Securities**

We, our executive officers and directors and certain beneficial owners of 5% or more of our securities have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for,

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exercisable for, or repayable with common stock, for 45 days after the date of this prospectus supplement without first obtaining the written consent of the representatives. Specifically, we and these other persons have agreed, with certain limited 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,  
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.

The restrictions described above do not apply to:

sales of common stock by certain of our executive officers and directors under trading plans established prior to the date of the lock-up agreement pursuant to Rule 10b5-1 under the Exchange Act; and  
upon the vesting of restricted stock units, the withholding of common stock issuable pursuant to the restricted stock unit in satisfaction of any tax withholding obligation, provided that common stock issued upon the vesting of such restricted stock units continues to be subject to the restrictions described above.

The representatives in their sole discretion may release the common stock and other securities subject to the lock-up agreements described above at any time without notice.

Notwithstanding the foregoing, if (i) during the last 17 days of the 45-day restricted period, we issue an earnings release or material news or a material event relating to our company occurs; or (ii) prior to the expiration of the 45-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 45-day restricted period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event; provided, however, that such extension of the 45-day restricted period shall not apply if, (i) at the expiration of the 45-day restricted period, our shares of common stock are actively traded securities (as defined in Regulation M) and (ii) we meet the applicable requirements of paragraph (a)(1) of Rule 139 under the Securities Act in the manner contemplated by NASD Rule 2711(f)(4) of the FINRA Manual.

## **Nasdaq Global Select Market Listing**

The shares are listed on the Nasdaq Global Select Market under the symbol ICPT.

## **Price Stabilization, Short Positions**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives 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 underwriters 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

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by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their 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 underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. Naked short sales are sales in excess of such option. The underwriters 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 underwriters are 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 underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate 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 underwriters may conduct these transactions on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make 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 nor any of the underwriters make any representation that the representatives 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, underwriters and selling group members may engage in passive market making transactions in the 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 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 underwriters 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 underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

## **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial

activities and services. Some of the underwriters and their 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.

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In addition, in the ordinary course of their business activities, the underwriters and their 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 underwriters and their 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 (each, a Relevant Member State ), 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 representatives; 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 representatives 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 who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that 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. 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 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 representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

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 any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters 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 underwriters 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.

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## **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 (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 ( 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 ( 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 supplement relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ( DFSA ). This prospectus supplement 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 Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for the prospectus supplement. The shares to which this prospectus supplement 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 supplement 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 the shares 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 the shares without disclosure to investors under Chapter 6D of the Corporations Act.

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The shares 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 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 securities 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 securities 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 securities 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 securities 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.

### **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 Non-CIS Securities may not be circulated or distributed, nor may the Non-CIS Securities 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 Non-CIS Securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which (a) 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

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- (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 Non-CIS Securities 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 under this prospectus by us will be passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP. The underwriters are being represented in connection with this offering by Orrick, Herrington & Sutcliffe LLP.

## EXPERTS

The consolidated financial statements of Intercept Pharmaceuticals, Inc. (a development stage enterprise) as of December 31, 2012 and December 31, 2013 and for each of the years in the three-year period ended December 31, 2013 and the information included in the cumulative from inception presentation for the period September 4, 2002 (inception) to December 31, 2013, incorporated by reference in this prospectus from Intercept Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013 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 file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). Copies of certain information filed by us with the SEC are also available on our website at [www.interceptpharma.com](http://www.interceptpharma.com). Our website is not a part of this prospectus and is not incorporated by reference in this prospectus. You may also read and copy any document we file at the SEC's Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

This prospectus is part of a registration statement we filed with the SEC. This prospectus supplement and the accompany prospectus omit some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information on us and our consolidated subsidiaries and the securities we are offering. Statements in this prospectus supplement and the accompany prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements. You can obtain a copy of the registration statement from the SEC at the address listed above or from the SEC's Internet site.

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## **INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference in this prospectus supplement and the accompanying prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference in this prospectus is considered to be part of this prospectus. Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below (File No. 001- 35668) and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act (in each case, other than those documents or the portions of those documents not deemed to be filed) until the offering of the securities under the registration statement is terminated or completed:

Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the SEC on March 14, 2014, as amended by the Amendment to Form 10-K on Form 10-K/A filed with the SEC on April 30, 2014;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 filed on May 9, 2014;

our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 filed on August 11, 2014;

our Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 filed on November 6, 2014;

Current Reports on Form 8-K and 8-K/A filed with the SEC on January 2, 2014, January 10, 2014 (solely with respect to Item 8.01), February 18, 2014 (solely with respect to Item 5.02), March 17, 2014 (solely with respect to Item 8.01), March 26, 2014, April 4, 2014, April 17, 2014, May 7, 2014 (solely with respect to Item 1.01), May 28, 2014 (solely with respect to Item 8.01), and July 22, 2014; and

The description of our common stock contained in our Registration Statement on Form 8-A as filed with the SEC on September 27, 2012, including any amendments or reports filed for the purpose of updating such description.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or phone number:

Intercept Pharmaceuticals, Inc.  
450 W. 15<sup>th</sup> Street, Suite 505  
New York, New York 10011  
Attn: Investor Relations  
Phone: (646) 747-1000

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# PROSPECTUS

## Debt Securities Common Stock Preferred Stock Depositary Shares Purchase Contracts Purchase Units Warrants

We may issue securities from time to time in one or more offerings. This prospectus describes the general terms of these securities and the general manner in which these securities will be offered. We will provide the specific terms of these securities in supplements to this prospectus. The prospectus supplements will also describe the specific manner in which these securities will be offered and may also supplement, update or amend information contained in this document. This prospectus may be used to offer shares of our common stock for the account of persons other than us, whom we refer to in this prospectus as selling stockholders. You should read this prospectus and any applicable prospectus supplement carefully before you invest.

We or any selling stockholders may offer these securities in amounts, at prices and on terms determined at the time of offering. The securities may be sold directly to you, through agents, or through underwriters and dealers. If agents, underwriters or dealers are used to sell the securities, we will name them and describe their compensation in a prospectus supplement. Unless otherwise set forth in a prospectus supplement, we will not receive any proceeds from the sale of common stock by any selling stockholders.

Our common stock trades on The NASDAQ Global Select Market under the symbol ICPT.

**Investing in these securities involves significant risks. See Risk Factors included in any accompanying prospectus supplement and in the documents incorporated by reference in this prospectus for a discussion of the factors you should carefully consider before deciding to purchase these securities.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is April 1, 2014

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## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, which we refer to as the SEC, utilizing a shelf registration process. Under this shelf registration process, we may from time to time sell any combination of the securities described in this prospectus in one or more offerings, and selling stockholders may from time to time sell shares of common stock described in this prospectus in one or more offerings.

This prospectus provides you with a general description of the securities we or selling stockholders may offer. Each time we or selling stockholders sell securities, we will provide one or more prospectus supplements that will contain specific information about the terms of the offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and the accompanying prospectus supplement together with the additional information described under the heading **Where You Can Find More Information** beginning on page 2 of this prospectus.

We have not authorized anyone to provide you with information different from that contained in this prospectus, any accompanying prospectus supplement or in any related free writing prospectus filed by us with the SEC. We do not take any responsibility for, and cannot provide any assurance as to the reliability of, any information other than the information in this prospectus, any accompanying prospectus supplement or in any related free writing prospectus filed by us with the SEC. This prospectus and the accompanying prospectus supplement do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in the accompanying prospectus supplement or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, any prospectus supplement, the documents incorporated by reference and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

Unless the context otherwise indicates, references in this prospectus to we, our, us and the Company refer, collectively, to Intercept Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

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## **RISK FACTORS**

Investing in our securities involves significant risks. You should carefully consider the risks and uncertainties described in this prospectus and any accompanying prospectus supplement, including the risk factors set forth in our filings with the SEC that are incorporated by reference herein, including the risk factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, before making an investment decision pursuant to this prospectus and any accompanying prospectus supplement relating to a specific offering.

Our business, financial condition and results of operations could be materially and adversely affected by any or all of these risks or by additional risks and uncertainties not presently known to us or that we currently deem immaterial that may adversely affect us in the future.

## **WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. Copies of certain information filed by us with the SEC are also available on our website at <http://www.interceptpharma.com>. Our website is not a part of this prospectus and is not incorporated by reference in this prospectus. You may also read and copy any document we file at the SEC's Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

This prospectus is part of a registration statement we filed with the SEC. This prospectus omits some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information on us and our consolidated subsidiaries and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

## **INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference in this prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference in this prospectus is considered to be part of this prospectus. Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below (File No. 001-35668) and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act (in each case, other than those documents or the portions of those documents not deemed to be filed) until the offering of the securities under the registration statement is terminated or completed:

Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the SEC on March 14, 2014;  
Definitive Proxy Statement on Schedule 14A, as filed with the SEC on April 12, 2013 (excluding those portions that are not incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2012);





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Current Reports on Form 8-K and 8-K/A as filed with the SEC on April 15, 2013, May 13, 2013 (solely with respect to Item 5.02), January 2, 2014, January 10, 2014 (solely with respect to Item 8.01), February 18, 2014 (solely with respect to Item 5.02), March 17, 2014 (solely with respect to Item 8.01) and March 26, 2014; and  
The description of our common stock contained in our Registration Statement on Form 8-A as filed with the SEC on September 27, 2012, including any amendments or reports filed for the purpose of updating such description.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or phone number:

Intercept Pharmaceuticals, Inc.  
450 W. 15<sup>th</sup> Street, Suite 505  
New York, New York 10011  
Attn: Investor Relations  
Phone: (646) 747-1000

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## **FORWARD-LOOKING STATEMENTS**

This prospectus and the information incorporated by reference in this prospectus include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. All statements contained or incorporated by reference herein, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, other than statements of historical facts, are forward-looking statements.

The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, potential, should, continue, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward-looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward-looking statements we make. These important factors include our critical accounting estimates described in Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates of our most recent Annual Report on Form 10-K and the factors set forth under the caption Risk Factors in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

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## INTERCEPT PHARMACEUTICALS, INC.

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

Our principal executive offices are located at 450 W. 15<sup>th</sup> Street, Suite 505, New York, New York 10011, and our telephone number is (646) 747-1000.

### CONSOLIDATED RATIOS OF EARNINGS TO FIXED CHARGES

The following table sets forth our ratio of earnings to fixed charges and preferred stock dividends for each of the periods indicated. For purposes of calculating the ratios in the table below, earnings consist of net loss plus fixed charges. Fixed charges include interest expense and an estimate of the interest portion of rent expense which is deemed to be representative of the interest factor.

You should read this table in conjunction with the consolidated financial statements and notes incorporated by reference in this prospectus.

	Fiscal Year Ended December 31,			
	2010	2011	2012	2013
Consolidated ratios of earnings to fixed charges <sup>(1)(2)</sup>	N/A	N/A	N/A	N/A
Consolidated ratios of earnings to fixed charges and preferred dividends <sup>(1)(3)</sup>	N/A	N/A	N/A	N/A

(1) Due to our losses for the years ended December 31, 2010, 2011, 2012 and 2013, the ratio coverage was less than 1:1.

(2) We would have needed to generate additional earnings of \$15.1 million, \$12.7 million, \$43.6 million and \$67.8 million for the years ended December 31, 2010, 2011, 2012 and 2013, respectively, to cover our fixed charges in those periods.

(3) We would have needed to generate additional earnings of \$18.0 million, \$15.7 million, \$46.3 million and \$67.8 million for the years ended December 31, 2010, 2011, 2012 and 2013, respectively, to cover our fixed charges and accrued preferred dividends in those periods. We did not have any preferred stock outstanding after the completion of our initial public offering in October 2012.

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## **USE OF PROCEEDS**

We intend to use the net proceeds from the sale of any securities offered under this prospectus for general corporate purposes unless otherwise indicated in the applicable prospectus supplement. General corporate purposes may include the acquisition of products, technologies or businesses, repayment and refinancing of debt, working capital and capital expenditures. We may temporarily invest the net proceeds in investment-grade, interest-bearing securities until they are used for their stated purpose. We have not determined the amount of net proceeds to be used specifically for such purposes. As a result, management will retain broad discretion over the allocation of net proceeds.

Unless otherwise set forth in a prospectus supplement, we will not receive any proceeds from the sale of common stock by any selling stockholders.

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## **SELLING STOCKHOLDERS**

In addition to covering the offering of the securities by us, this prospectus covers the offering for resale of common stock by selling stockholders. Information about selling stockholders, if any, will be set forth in a prospectus supplement, in an amendment to the registration statement of which this prospectus is a part or in other filings we make with the SEC under the Exchange Act, which are incorporated by reference.

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## DESCRIPTION OF DEBT SECURITIES

We may offer debt securities which may be senior or subordinated. We refer to the senior debt securities and the subordinated debt securities collectively as debt securities. The following description summarizes the general terms and provisions of the debt securities. We will describe the specific terms of the debt securities and the extent, if any, to which the general provisions summarized below apply to any series of debt securities in the prospectus supplement relating to the series and any applicable free writing prospectus that we authorize to be delivered. When we refer to the Company, we, our, and us in this section, we mean Intercept Pharmaceuticals, Inc. excluding, unless the context otherwise requires or as otherwise expressly stated, our subsidiaries.

We may issue senior debt securities from time to time, in one or more series under a senior indenture to be entered into between us and a senior trustee to be named in a prospectus supplement, which we refer to as the senior trustee. We may issue subordinated debt securities from time to time, in one or more series under a subordinated indenture to be entered into between us and a subordinated trustee to be named in a prospectus supplement, which we refer to as the subordinated trustee. The forms of senior indenture and subordinated indenture are filed as exhibits to the registration statement of which this prospectus forms a part. Together, the senior indenture and the subordinated indenture are referred to as the indentures and, together, the senior trustee and the subordinated trustee are referred to as the trustees. This prospectus briefly outlines some of the provisions of the indentures. The following summary of the material provisions of the indentures is qualified in its entirety by the provisions of the indentures, including definitions of certain terms used in the indentures. Wherever we refer to particular sections or defined terms of the indentures, those sections or defined terms are incorporated by reference in this prospectus or the applicable prospectus supplement. You should review the indentures that are filed as exhibits to the registration statement of which this prospectus forms a part for additional information.

None of the indentures will limit the amount of debt securities that we may issue. The applicable indenture will provide that debt securities may be issued up to an aggregate principal amount authorized from time to time by us and may be payable in any currency or currency unit designated by us or in amounts determined by reference to an index.

### General

The senior debt securities will constitute our unsubordinated general obligations and will rank pari passu with our other unsubordinated obligations. The subordinated debt securities will constitute our subordinated general obligations and will be junior in right of payment to our senior indebtedness (including senior debt securities), as described under the heading Certain Terms of the Subordinated Debt Securities Subordination.

The debt securities will be our unsecured obligations unless otherwise specified in the applicable prospectus supplement. Any secured debt or other secured obligations will be effectively senior to the debt securities to the extent of the value of the assets securing such debt or other obligations.

The applicable prospectus supplement and any free writing prospectus will include any additional or different terms of the debt securities of any series being offered, including the following terms:

- the title and type of the debt securities;
- whether the debt securities will be senior or subordinated debt securities, and, with respect to debt securities issued under the subordinated indenture the terms on which they are subordinated;
- the aggregate principal amount of the debt securities;

the price or prices at which we will sell the debt securities;  
the maturity date or dates of the debt securities and the right, if any, to extend such date or dates;  
the rate or rates, if any, per year, at which the debt securities will bear interest, or the method of determining such rate or rates;

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the date or dates from which such interest will accrue, the interest payment dates on which such interest will be payable or the manner of determination of such interest payment dates and the related record dates;  
the right, if any, to extend the interest payment periods and the duration of that extension;  
the manner of paying principal and interest and the place or places where principal and interest will be payable;  
provisions for a sinking fund, purchase fund or other analogous fund, if any;  
any redemption dates, prices, obligations and restrictions on the debt securities;  
the currency, currencies or currency units in which the debt securities will be denominated and the currency, currencies or currency units in which principal and interest, if any, on the debt securities may be payable;  
any conversion or exchange features of the debt securities;  
whether and upon what terms the debt securities may be defeased;  
any events of default or covenants in addition to or in lieu of those set forth in the indenture;  
whether the debt securities will be issued in definitive or global form or in definitive form only upon satisfaction of certain conditions;  
whether the debt securities will be guaranteed as to payment or performance;  
if the debt securities of the series or, if applicable, any guarantees will be secured by any collateral and, if so, a general description of the collateral and the terms and provisions of such collateral security, pledge or other agreements; and  
any other material terms of the debt securities.

The applicable prospectus supplement will also describe any applicable material U.S. federal income tax consequences.

When we refer to principal in this section with reference to the debt securities, we are also referring to premium, if any.

We may from time to time, without notice to or the consent of the holders of any series of debt securities, create and issue further debt securities of any such series ranking equally with the debt securities of such series in all respects (or in all respects other than (1) the payment of interest accruing prior to the issue date of such further debt securities or (2) the first payment of interest following the issue date of such further debt securities). Such further debt securities may be consolidated and form a single series with the debt securities of such series and have the same terms as to status, redemption or otherwise as the debt securities of such series.

You may present debt securities for exchange and you may present debt securities for transfer in the manner, at the places and subject to the restrictions set forth in the debt securities and the applicable prospectus supplement. We will provide you those services without charge, although you may have to pay any tax or other governmental charge payable in connection with any exchange or transfer, as set forth in the indenture.

Debt securities may bear interest at a fixed rate or a floating rate. Debt securities bearing no interest or interest at a rate that at the time of issuance is below the prevailing market rate (original issue discount securities) may be sold at a discount below their stated principal amount.

We may issue debt securities with the principal amount payable on any principal payment date, or the amount of interest payable on any interest payment date, to be determined by reference to one or more currency exchange rates, securities or baskets of securities, commodity prices or indices. You may receive a payment of principal on any principal payment date, or a payment of interest on any interest payment date, that is greater than or less than the amount of principal or interest otherwise payable on such dates, depending



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on the value on such dates of the applicable currency, security or basket of securities, commodity or index. Information as to the methods for determining the amount of principal or interest payable on any date, the currencies, securities or baskets of securities, commodities or indices to which the amount payable on such date is linked.

## **Certain Terms of the Senior Debt Securities**

*Covenants.* Unless we indicate otherwise in a prospectus supplement, the senior debt securities will not contain any financial or restrictive covenants, including covenants restricting either us or any of our subsidiaries from incurring, issuing, assuming or guaranteeing any indebtedness secured by a lien on any of our or our subsidiaries' property or capital stock, or restricting either us or any of our subsidiaries from entering into sale and leaseback transactions.

*Consolidation, Merger and Sale of Assets.* Unless we indicate otherwise in a prospectus supplement, we may not consolidate with or merge into any other person, in a transaction in which we are not the surviving corporation, or convey, transfer or lease our properties and assets substantially as an entirety to any person, in either case, unless:

the successor entity, if any, is a U.S. corporation, limited liability company, partnership or trust (subject to certain exceptions provided for in the senior indenture);

the successor entity assumes our obligations on the senior debt securities and under the senior indenture; immediately after giving effect to the transaction, no default or event of default shall have occurred and be continuing; and

certain other conditions are met.

*No Protection in the Event of a Change in Control.* Unless we indicate otherwise in a prospectus supplement with respect to a particular series of senior debt securities, the senior debt securities will not contain any provisions that may afford holders of the senior debt securities protection in the event we have a change in control or in the event of a highly leveraged transaction (whether or not such transaction results in a change in control).

*Events of Default.* Unless we indicate otherwise in a prospectus supplement with respect to a particular series of senior debt securities, the following are events of default under the senior indenture for any series of senior debt securities:

failure to pay interest on any senior debt securities of such series when due and payable, if that default continues for a period of 90 days (or such other period as may be specified for such series);

failure to pay principal on the senior debt securities of such series when due and payable whether at maturity, upon redemption, by declaration or otherwise (and, if specified for such series, the continuance of such failure for a specified period);

default in the performance of or breach of any of our covenants or agreements in the senior indenture applicable to senior debt securities of such series, other than a covenant breach which is specifically dealt with elsewhere in the senior indenture, and that default or breach continues for a period of 90 days after we receive written notice from the trustee or from the holders of 25% or more in aggregate principal amount of the senior debt securities of such series;

certain events of bankruptcy or insolvency, whether or not voluntary; and

any other event of default provided for in such series of senior debt securities as may be specified in the applicable prospectus supplement.

Unless we indicate otherwise in a prospectus supplement, the default by us under any other debt, including any other series of debt securities, is not a default under the senior indenture.



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If an event of default other than an event of default specified in the fourth bullet point above occurs with respect to a series of senior debt securities and is continuing under the senior indenture, then, and in each such case, either the trustee or the holders of not less than 25% in aggregate principal amount of such series then outstanding under the senior indenture (each such series voting as a separate class) by written notice to us and to the trustee, if such notice is given by the holders, may, and the trustee at the request of such holders shall, declare the principal amount of and accrued interest on such series of senior debt securities to be immediately due and payable, and upon this declaration, the same shall become immediately due and payable.

If an event of default specified in the fourth bullet point above occurs with respect to us and is continuing, the entire principal amount of and accrued interest, if any, on each series of senior debt securities then outstanding shall become immediately due and payable.

Unless otherwise specified in the prospectus supplement relating to a series of senior debt securities originally issued at a discount, the amount due upon acceleration shall include only the original issue price of the senior debt securities, the amount of original issue discount accrued to the date of acceleration and accrued interest, if any.

Upon certain conditions, declarations of acceleration may be rescinded and annulled and past defaults may be waived by the holders of a majority in aggregate principal amount of all the senior debt securities of such series affected by the default, each series voting as a separate class. Furthermore, prior to a declaration of acceleration and subject to various provisions in the senior indenture, the holders of a majority in aggregate principal amount of a series of senior debt securities, by notice to the trustee, may waive an existing default or event of default with respect to such senior debt securities and its consequences, except a default in the payment of principal of or interest on such senior debt securities or in respect of a covenant or provision of the senior indenture which cannot be modified or amended without the consent of the holders of each such senior debt security. Upon any such waiver, such default shall cease to exist, and any event of default with respect to such senior debt securities shall be deemed to have been cured, for every purpose of the senior indenture; but no such waiver shall extend to any subsequent or other default or event of default or impair any right consequent thereto. For information as to the waiver of defaults, see Modification and Waiver.

The holders of a majority in aggregate principal amount of a series of senior debt securities may direct the time, method and place of conducting any proceeding for any remedy available to the trustee or exercising any trust or power conferred on the trustee with respect to such senior debt securities. However, the trustee may refuse to follow any direction that conflicts with law or the senior indenture, that may involve the trustee in personal liability or that the trustee determines in good faith may be unduly prejudicial to the rights of holders of such series of senior debt securities not joining in the giving of such direction and may take any other action it deems proper that is not inconsistent with any such direction received from holders of such series of senior debt securities. A holder may not pursue any remedy with respect to the senior indenture or any series of senior debt securities unless:

- the holder gives the trustee written notice of a continuing event of default;
- the holders of at least 25% in aggregate principal amount of such series of senior debt securities make a written request to the trustee to pursue the remedy in respect of such event of default;
- the requesting holder or holders offer the trustee indemnity satisfactory to the trustee against any costs, liability or expense;
- the trustee does not comply with the request within 60 days after receipt of the request and the offer of indemnity; and during such 60-day period, the holders of a majority in aggregate principal amount of such series of senior debt securities do not give the trustee a direction that is inconsistent with the request.

These limitations, however, do not apply to the right of any holder of a senior debt security to receive payment of the principal of and interest, if any, on such senior debt security in accordance with the terms of such debt security, or to

bring suit for the enforcement of any such payment in accordance with the terms of such debt security, on or after the due date for the senior debt securities, which right shall not be impaired or affected without the consent of the holder.

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The senior indenture requires certain of our officers to certify, on or before a fixed date in each year in which any senior debt security is outstanding, as to their knowledge of our compliance with all covenants, agreements and conditions under the senior indenture.

*Satisfaction and Discharge.* We can satisfy and discharge our obligations to holders of any series of senior debt securities if:

we pay or cause to be paid, as and when due and payable, the principal of and any interest on all senior debt securities of such series outstanding under the senior indenture; or all senior debt securities of such series have become due and payable or will become due and payable within one year (or are to be called for redemption within one year) and we deposit in trust a combination of cash and U.S. government or U.S. government agency obligations that will generate enough cash to make interest, principal and any other payments on the debt securities of that series on their various due dates.

Under current U.S. federal income tax law, the deposit and our legal release from the senior debt securities would be treated as a taxable event, and beneficial owners of such debt securities would generally recognize any gain or loss on such senior debt securities. Purchasers of the senior debt securities should consult their own advisers with respect to the tax consequences to them of such deposit and discharge, including the applicability and effect of tax laws other than the U.S. federal income tax law.

*Defeasance.* Unless the applicable prospectus supplement provides otherwise, the following discussion of legal defeasance and discharge and covenant defeasance will apply to any senior series of senior debt securities issued under the indentures.

*Legal Defeasance.* We can legally release ourselves from any payment or other obligations on the senior debt securities of any series (called legal defeasance ) if certain conditions are met, including the following:

We deposit in trust for your benefit and the benefit of all other direct holders of the senior debt securities of the same series a combination of cash and U.S. government or U.S. government agency obligations that will generate enough cash to make interest, principal and any other payments on the senior debt securities of that series on their various due dates.

There is a change in current U.S. federal income tax law or an IRS ruling that lets us make the above deposit without causing you to be taxed on the senior debt securities any differently than if we did not make the deposit and instead repaid the senior debt securities ourselves when due.

We deliver to the trustee a legal opinion of our counsel confirming the tax law change or ruling described above.

If we ever did accomplish legal defeasance, as described above, you would have to rely solely on the trust deposit for repayment of the debt securities. You could not look to us for repayment in the event of any shortfall.

*Covenant Defeasance.* Without any change of current U.S. federal tax law, we can make the same type of deposit described above and be released from some of the covenants in the senior debt securities (called covenant defeasance ).

In that event, you would lose the protection of those covenants but would gain the protection of having money and securities set aside in trust to repay the debt senior securities. In order to achieve covenant defeasance, we must do the following (among other things):

We must deposit in trust for your benefit and the benefit of all other direct holders of the senior debt securities of the same series a combination of cash and U.S. government or U.S. government agency obligations that will generate enough cash to make interest, principal and any other payments on the senior debt securities of that series on their various due dates.





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We must deliver to the trustee a legal opinion of our counsel confirming that under current U.S. federal income tax law we may make the above deposit without causing you to be taxed on the senior debt securities any differently than if we did not make the deposit and instead repaid the debt securities ourselves when due.

If we accomplish covenant defeasance, you can still look to us for repayment of the senior debt securities if there were a shortfall in the trust deposit. In fact, if one of the events of default occurred (such as our bankruptcy) and the debt securities become immediately due and payable, there may be such a shortfall. Depending on the events causing the default, you may not be able to obtain payment of the shortfall.

*Modification and Waiver.* We and the trustee may amend or supplement the senior indenture or the senior debt securities without the consent of any holder:

to convey, transfer, assign, mortgage or pledge any assets as security for the senior debt securities of one or more series;

to evidence the succession of a corporation, limited liability company, partnership or trust to us, and the assumption by such successor of our covenants, agreements and obligations under the senior indenture;

to comply with the requirements of the SEC in order to effect or maintain the qualification of the indenture under the Trust Indenture Act of 1939, as amended;

to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, and to make the occurrence, or the occurrence and continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default;

to cure any ambiguity, defect or inconsistency in the senior indenture or in any supplemental indenture or to conform the senior indenture or the senior debt securities to the description of senior debt securities of such series set forth in this prospectus or any applicable prospectus supplement;

to provide for or add guarantors with respect to the senior debt securities of any series;

to establish the form or forms or terms of the senior debt securities as permitted by the senior indenture;

to evidence and provide for the acceptance of appointment under the senior indenture by a successor trustee, or to make such changes as shall be necessary to provide for or facilitate the administration of the trusts in the senior indenture by more than one trustee;

to add to, delete from or revise the conditions, limitations and restrictions on the authorized amount, terms, purposes of issue, authentication and delivery of any series of senior debt securities;

to make any change to the senior debt securities of any series so long as no senior debt securities of such series are outstanding; or

to make any change that does not adversely affect the rights of any holder in any material respect.

Other amendments and modifications of the senior indenture or the senior debt securities issued may be made, and our compliance with any provision of the senior indenture with respect to any series of senior debt securities may be waived, with the consent of the holders of a majority of the aggregate principal amount of the outstanding senior debt securities of all series affected by the amendment or modification (voting together as a single class); provided, however, that each affected holder must consent to any modification, amendment or waiver that:

extends the final maturity of any senior debt securities of such series;

reduces the principal amount of on any senior debt securities of such series;

reduces the rate or extends the time of payment of interest on any senior debt securities of such series;

reduces the amount payable upon the redemption of any senior debt securities of such series;

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changes the currency of payment of principal of or interest on any senior debt securities of such series; reduces the principal amount of original issue discount securities payable upon acceleration of maturity or the amount provable in bankruptcy;

waives a default in the payment of principal of or interest on the senior debt securities; changes the provisions relating to the waiver of past defaults or changes or impairs the right of holders to receive payment or to institute suit for the enforcement of any payment or conversion of any senior debt securities of such series on or after the due date therefor; modifies any of the provisions of these restrictions on amendments and modifications, except to increase any required percentage or to provide that certain other provisions cannot be modified or waived without the consent of the holder of each senior debt security of such series affected by the modification; or reduces the above-stated percentage of outstanding senior debt securities of such series whose holders must consent to a supplemental indenture or to modify or amend or to waive certain provisions of or defaults under the senior indenture.

It shall not be necessary for the holders to approve the particular form of any proposed amendment, supplement or waiver, but it shall be sufficient if the holders' consent approves the substance thereof. After an amendment, supplement or waiver of the senior indenture in accordance with the provisions described in this section becomes effective, the trustee must give to the holders affected thereby certain notice briefly describing the amendment, supplement or waiver. Any failure by the trustee to give such notice, or any defect therein, shall not, however, in any way impair or affect the validity of any such amendment, supplemental indenture or waiver.

*No Personal Liability of Incorporators, Stockholders, Officers, Directors.* The senior indenture provides that no recourse shall be had under any obligation, covenant or agreement of ours in the senior indenture or any supplemental indenture, or in any of the senior debt securities or because of the creation of any indebtedness represented thereby, against any of our incorporators, stockholders, officers or directors, past, present or future, or of any predecessor or successor entity thereof under any law, statute or constitutional provision or by the enforcement of any assessment or by any legal or equitable proceeding or otherwise. Each holder, by accepting the senior debt securities, waives and releases all such liability.

*Concerning the Trustee.* The senior indenture provides that, except during the continuance of an event of default, the trustee will not be liable except for the performance of such duties as are specifically set forth in the senior indenture. If an event of default has occurred and is continuing, the trustee will exercise such rights and powers vested in it under the senior indenture and will use the same degree of care and skill in its exercise as a prudent person would exercise under the circumstances in the conduct of such person's own affairs.

The senior indenture and the provisions of the Trust Indenture Act of 1939, or Trust Indenture Act, incorporated by reference therein contain limitations on the rights of the trustee thereunder, should it become a creditor of ours or any of our subsidiaries, to obtain payment of claims in certain cases or to realize on certain property received by it in respect of any such claims, as security or otherwise. The trustee is permitted to engage in other transactions, provided that if it acquires any conflicting interest (as defined in the Trust Indenture Act), it must eliminate such conflict or resign.

We may have normal banking relationships with the senior trustee in the ordinary course of business.

*Unclaimed Funds.* All funds deposited with the trustee or any paying agent for the payment of principal, premium, interest or additional amounts in respect of the senior debt securities that remain unclaimed for two years after the date upon which such principal, premium or interest became due and payable will be repaid to us. Thereafter, any right of any holder of senior debt securities to such funds shall be enforceable only against us, and the trustee and paying agents will have no liability therefor.



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*Governing Law.* The senior indenture and the senior debt securities will be governed by, and construed in accordance with, the internal laws of the State of New York.

## **Certain Terms of the Subordinated Debt Securities**

Other than the terms of the subordinated indenture and subordinated debt securities relating to subordination or otherwise as described in the prospectus supplement relating to a particular series of subordinated debt securities, the terms of the subordinated indenture and subordinated debt securities are identical in all material respects to the terms of the senior indenture and senior debt securities.

Additional or different subordination terms may be specified in the prospectus supplement applicable to a particular series.

*Subordination.* The indebtedness evidenced by the subordinated debt securities is subordinate to the prior payment in full of all of our senior indebtedness, as defined in the subordinated indenture. During the continuance beyond any applicable grace period of any default in the payment of principal, premium, interest or any other payment due on any of our senior indebtedness, we may not make any payment of principal of or interest on the subordinated debt securities (except for certain sinking fund payments). In addition, upon any payment or distribution of our assets upon any dissolution, winding-up, liquidation or reorganization, the payment of the principal of and interest on the subordinated debt securities will be subordinated to the extent provided in the subordinated indenture in right of payment to the prior payment in full of all our senior indebtedness. Because of this subordination, if we dissolve or otherwise liquidate, holders of our subordinated debt securities may receive less, ratably, than holders of our senior indebtedness. The subordination provisions do not prevent the occurrence of an event of default under the subordinated indenture.

The term *senior indebtedness* of a person means with respect to such person the principal of, premium, if any, interest on, and any other payment due pursuant to any of the following, whether outstanding on the date of the subordinated indenture or incurred by that person in the future:

- all of the indebtedness of that person for money borrowed;
- all of the indebtedness of that person evidenced by notes, debentures, bonds or other securities sold by that person for money;
- all of the lease obligations which are capitalized on the books of that person in accordance with generally accepted accounting principles;
  - all indebtedness of others of the kinds described in the first two bullet points above and all lease obligations of others of the kind described in the third bullet point above that the person, in any manner, assumes or guarantees or that the person in effect guarantees through an agreement to purchase, whether that agreement is contingent or otherwise; and
- all renewals, extensions or refundings of indebtedness of the kinds described in the first, second or fourth bullet point above and all renewals or extensions of leases of the kinds described in the third or fourth bullet point above;
  - unless, in the case of any particular indebtedness, renewal, extension or refunding, the instrument creating or evidencing it or the assumption or guarantee relating to it expressly provides that such indebtedness, renewal, extension or refunding is not superior in right of payment to the subordinated debt securities. Our senior debt securities constitute senior indebtedness for purposes of the subordinated debt indenture.



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## DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is intended as a summary only. This description is based upon, and is qualified by reference to, our restated certificate of incorporation, our restated by-laws and applicable provisions of Delaware corporate law. This summary is not complete. You should read our restated certificate of incorporation and restated by-laws, which are filed as exhibits to the registration statement of which this prospectus forms a part, for the provisions that are important to you.

Our authorized capital stock consists of 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 February 28, 2014, 19,519,657 shares of common stock were outstanding, and no shares of preferred stock were outstanding. In addition, as of February 28, 2014, we also had outstanding options to purchase 1,522,818 shares of our common stock, restricted stock units to purchase 104,941 shares of our common stock and warrants to purchase 865,381 shares of our common stock.

### Common Stock

*Annual Meeting.* Annual meetings of our stockholders are held on the date designated in accordance with our restated by-laws. Written notice must be mailed to each stockholder entitled to vote not less than ten nor more than 60 days before the date of the meeting. The presence in person or by proxy of the holders of record of a majority of our issued and outstanding shares entitled to vote at such meeting constitutes a quorum for the transaction of business at meetings of the stockholders. Special meetings of the stockholders may be called for any purpose only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors. Except as may be otherwise provided by applicable law, our restated certificate of incorporation or our restated by-laws, all elections shall be decided by a plurality, and all other questions shall be decided by a majority, of the votes cast by stockholders entitled to vote thereon at a duly held meeting of stockholders at which a quorum is present.

*Voting Rights.* 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.

*Dividends.* 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.

*Liquidation and Dissolution.* 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.

*Other Rights.* 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.

*Transfer Agent and Registrar.* VStock Transfer, LLC is transfer agent and registrar for the common stock.

*NASDAQ Global Select Market.* Our common stock is listed on The NASDAQ Global Select Market under the symbol ICPT.

## Preferred Stock

As of February 28, 2014, no shares of preferred stock were outstanding. Other terms of any series of preferred stock will be described in the prospectus supplement relating to that series of preferred stock. The terms of any series of preferred stock may differ from the terms described below. Certain provisions of the preferred stock described below and in any applicable prospectus supplement are not complete.

We are authorized to issue blank check preferred stock, which may be issued in one or more series upon authorization of our board of directors. Our board of directors is authorized to fix the designation of the series, the number of authorized shares of the series, dividend rights and terms, conversion rights, voting rights, redemption rights and terms, liquidation preferences and any other rights, powers, preferences and

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limitations applicable to each series of preferred stock. The authorized shares of our preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. If the approval of our stockholders is not required for the issuance of shares of our preferred stock, our board may determine not to seek stockholder approval. The specific terms of any series of preferred stock offered pursuant to this prospectus will be described in the prospectus supplement relating to that series of preferred stock.

A series of our preferred stock could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt. Our board of directors will make any determination to issue such shares based upon its judgment as to the best interests of our stockholders. Our directors, in so acting, could issue preferred stock having terms that could discourage an acquisition attempt through which an acquirer may be able to change the composition of our board of directors, including a tender offer or other transaction that some, or a majority, of our stockholders might believe to be in their best interests or in which stockholders might receive a premium for their stock over the then-current market price of the stock.

The preferred stock has the terms described below unless otherwise provided in the prospectus supplement relating to a particular series of preferred stock. You should read the prospectus supplement relating to the particular series of preferred stock being offered for specific terms, including:

the designation and stated value per share of the preferred stock and the number of shares offered;

the amount of liquidation preference per share;

the price at which the preferred stock will be issued;

the dividend rate, or method of calculation of dividends, the dates on which dividends will be payable, whether dividends will be cumulative or noncumulative and, if cumulative, the dates from which dividends will commence to accumulate;

any redemption or sinking fund provisions;

if other than the currency of the United States, the currency or currencies including composite currencies in which the preferred stock is denominated and/or in which payments will or may be payable;

any conversion provisions;

whether we have elected to offer depositary shares as described below under Description of Depositary Shares; and any other rights, preferences, privileges, limitations and restrictions on the preferred stock.

The preferred stock will, when issued, be fully paid and nonassessable. Unless otherwise specified in the prospectus supplement, each series of preferred stock will rank equally as to dividends and liquidation rights in all respects with each other series of preferred stock. The rights of holders of shares of each series of preferred stock will be subordinate to those of our general creditors.

As described under Description of Depositary Shares, we may, at our option, with respect to any series of preferred stock, elect to offer fractional interests in shares of preferred stock, and provide for the issuance of depositary receipts representing depositary shares, each of which will represent a fractional interest in a share of the series of preferred stock. The fractional interest will be specified in the prospectus supplement relating to a particular series of preferred stock.

*Rank.* Unless otherwise specified in the prospectus supplement, the preferred stock will, with respect to dividend rights and rights upon our liquidation, dissolution or winding up of its affairs, rank:

senior to our common stock and to all equity securities ranking junior to such preferred stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs;



on a parity with all equity securities issued by us, the terms of which specifically provide that such equity securities rank on a parity with the preferred stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs; and

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junior to all equity securities issued by us, the terms of which specifically provide that such equity securities rank senior to the preferred stock with respect to dividend rights or rights upon our liquidation, dissolution or winding up of our affairs.

The term equity securities does not include convertible debt securities.

*Dividends.* Holders of the preferred stock of each series will be entitled to receive, when, as and if declared by our board of directors, cash dividends at such rates and on such dates described in the prospectus supplement. Different series of preferred stock may be entitled to dividends at different rates or based on different methods of calculation. The dividend rate may be fixed or variable or both. Dividends will be payable to the holders of record as they appear on our stock books on record dates fixed by our board of directors, as specified in the applicable prospectus supplement.

Dividends on any series of preferred stock may be cumulative or noncumulative, as described in the applicable prospectus supplement. If our board of directors does not declare a dividend payable on a dividend payment date on any series of noncumulative preferred stock, then the holders of that noncumulative preferred stock will have no right to receive a dividend for that dividend payment date, and we will have no obligation to pay the dividend accrued for that period, whether or not dividends on that series are declared payable on any future dividend payment dates. Dividends on any series of cumulative preferred stock will accrue from the date we initially issue shares of such series or such other date specified in the applicable prospectus supplement.

No dividends may be declared or paid or funds set apart for the payment of any dividends on any parity securities unless full dividends have been paid or set apart for payment on the preferred stock. If full dividends are not paid, the preferred stock will share dividends pro rata with the parity securities.

No dividends may be declared or paid or funds set apart for the payment of dividends on any junior securities unless full dividends for all dividend periods terminating on or prior to the date of the declaration or payment will have been paid or declared and a sum sufficient for the payment set apart for payment on the preferred stock.

*Liquidation Preference.* Upon any voluntary or involuntary liquidation, dissolution or winding up of our affairs, then, before we make any distribution or payment to the holders of any common stock or any other class or series of our capital stock ranking junior to the preferred stock in the distribution of assets upon any liquidation, dissolution or winding up of our affairs, the holders of each series of preferred stock shall be entitled to receive out of assets legally available for distribution to stockholders, liquidating distributions in the amount of the liquidation preference per share set forth in the prospectus supplement, plus any accrued and unpaid dividends thereon. Such dividends will not include any accumulation in respect of unpaid noncumulative dividends for prior dividend periods. Unless otherwise specified in the prospectus supplement, after payment of the full amount of their liquidating distributions, the holders of preferred stock will have no right or claim to any of our remaining assets. Upon any such voluntary or involuntary liquidation, dissolution or winding up, if our available assets are insufficient to pay the amount of the liquidating distributions on all outstanding preferred stock and the corresponding amounts payable on all other classes or series of our capital stock ranking on parity with the preferred stock and all other such classes or series of shares of capital stock ranking on parity with the preferred stock in the distribution of assets, then the holders of the preferred stock and all other such classes or series of capital stock will share ratably in any such distribution of assets in proportion to the full liquidating distributions to which they would otherwise be entitled.

Upon any such liquidation, dissolution or winding up and if we have made liquidating distributions in full to all holders of preferred stock, we will distribute our remaining assets among the holders of any other classes or series of capital stock ranking junior to the preferred stock according to their respective rights and preferences and, in each case, according to their respective number of shares. For such purposes, our consolidation or merger with or into any

other corporation, trust or entity, or the sale, lease or conveyance of all or substantially all of our property or assets will not be deemed to constitute a liquidation, dissolution or winding up of our affairs.

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*Redemption.* If so provided in the applicable prospectus supplement, the preferred stock will be subject to mandatory redemption or redemption at our option, as a whole or in part, in each case upon the terms, at the times and at the redemption prices set forth in such prospectus supplement.

The prospectus supplement relating to a series of preferred stock that is subject to mandatory redemption will specify the number of shares of preferred stock that shall be redeemed by us in each year commencing after a date to be specified, at a redemption price per share to be specified, together with an amount equal to all accrued and unpaid dividends thereon to the date of redemption. Unless the shares have a cumulative dividend, such accrued dividends will not include any accumulation in respect of unpaid dividends for prior dividend periods. We may pay the redemption price in cash or other property, as specified in the applicable prospectus supplement. If the redemption price for preferred stock of any series is payable only from the net proceeds of the issuance of shares of our capital stock, the terms of such preferred stock may provide that, if no such shares of our capital stock shall have been issued or to the extent the net proceeds from any issuance are insufficient to pay in full the aggregate redemption price then due, such preferred stock shall automatically and mandatorily be converted into the applicable shares of our capital stock pursuant to conversion provisions specified in the applicable prospectus supplement. Notwithstanding the foregoing, we will not redeem any preferred stock of a series unless:

if that series of preferred stock has a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full cumulative dividends on the preferred stock for all past dividend periods and the then current dividend period; or

if such series of preferred stock does not have a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full dividends for the then current dividend period.

In addition, we will not acquire any preferred stock of a series unless:

if that series of preferred stock has a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full cumulative dividends on all outstanding shares of such series of preferred stock for all past dividend periods and the then current dividend period; or

if that series of preferred stock does not have a cumulative dividend, we have declared and paid or contemporaneously declare and pay or set aside funds to pay full dividends on the preferred stock of such series for the then current dividend period.

However, at any time we may purchase or acquire preferred stock of that series (1) pursuant to a purchase or exchange offer made on the same terms to holders of all outstanding preferred stock of such series or (2) by conversion into or exchange for shares of our capital stock ranking junior to the preferred stock of such series as to dividends and upon liquidation.

If fewer than all of the outstanding shares of preferred stock of any series are to be redeemed, we will determine the number of shares that may be redeemed pro rata from the holders of record of such shares in proportion to the number of such shares held or for which redemption is requested by such holder or by any other equitable manner that we determine. Such determination will reflect adjustments to avoid redemption of fractional shares.

Unless otherwise specified in the prospectus supplement, we will mail notice of redemption at least 30 days but not more than 60 days before the redemption date to each holder of record of preferred stock to be redeemed at the address shown on our stock transfer books. Each notice shall state:

the redemption date;  
the number of shares and series of preferred stock to be redeemed;  
the redemption price;

the place or places where certificates for such preferred stock are to be surrendered for payment of the redemption price;  
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that dividends on the shares to be redeemed will cease to accrue on such redemption date; the date on which the holder's conversion rights, if any, as to such shares shall terminate; and the specific number of shares to be redeemed from each such holder if fewer than all the shares of any series are to be redeemed.

If notice of redemption has been given and we have set aside the funds necessary for such redemption in trust for the benefit of the holders of any shares called for redemption, then from and after the redemption date, dividends will cease to accrue on such shares, and all rights of the holders of such shares will terminate, except the right to receive the redemption price.

*Voting Rights.* Holders of preferred stock will not have any voting rights, except as required by law or as indicated in the applicable prospectus supplement.

Unless otherwise provided for under the terms of any series of preferred stock, no consent or vote of the holders of shares of preferred stock or any series thereof shall be required for any amendment to our restated certificate of incorporation that would increase the number of authorized shares of preferred stock or the number of authorized shares of any series thereof or decrease the number of authorized shares of preferred stock or the number of authorized shares of any series thereof (but not below the number of authorized shares of preferred stock or such series, as the case may be, then outstanding).

*Conversion Rights.* The terms and conditions, if any, upon which any series of preferred stock is convertible into our common stock will be set forth in the applicable prospectus supplement relating thereto. Such terms will include the number of shares of common stock into which the shares of preferred stock are convertible, the conversion price, rate or manner of calculation thereof, the conversion period, provisions as to whether conversion will be at our option or at the option of the holders of the preferred stock, the events requiring an adjustment of the conversion price and provisions affecting conversion in the event of the redemption.

*Transfer Agent and Registrar.* The transfer agent and registrar for the preferred stock will be set forth in the applicable prospectus supplement.

## **Warrants**

As of February 28, 2014, we had outstanding warrants to purchase 865,381 of shares of our common stock, at an exercise price of \$10.40 per share, which expire on January 25, 2015. The warrants have 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 number 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. The warrants also contain provisions for the adjustment of the exercise price in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations and 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 the exercise price is adjusted as a result of a lower-priced issuance, 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.

## **Registration Rights**

We have entered into a third amended and restated stockholders agreement, dated August 9, 2012, which we refer to as the stockholders agreement, with certain existing holders of our common stock and the holders of warrants to

purchase our common stock described above. As of February 28, 2014, holders of an aggregate of up to 8,363,728 shares of our common stock, including shares of our common stock issuable upon exercise of outstanding warrants, having rights under the stockholders agreement, which we refer to as registrable shares, have the right to require us to register such shares under the Securities Act under specified circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. If not otherwise exercised, the rights described below will expire on the earliest to occur of (a) October 16, 2015, (b) the date on which no stockholder holds any registrable shares or (c) the sale of all or substantially all of our assets or business by merger, sale of assets or otherwise. The

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summary of the registration rights below is qualified by reference to the stockholders agreement, a copy of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

*Demand Registration Rights.* Subject to specified limitations set forth in the stockholders agreement, at any time, each holder having rights under the stockholders agreement and holding at least 1,500,000 shares of our common stock or the holders of at least 30% of the then outstanding registrable shares, acting together, may request in writing that we register all or a portion of the registrable shares under the Securities Act so long as the total amount of registrable shares registered have an aggregate value of at least \$25.0 million based on the then current market price or fair value. We are not obligated to file a registration statement pursuant to this provision on more than three occasions, and prior to the date of this prospectus, we have filed one registration statement upon demand by certain holders of registrable shares.

*Form S-3 Registration Rights.* In addition, provided that we are eligible for the use of Form S-3, or any successor form, the holders of registrable shares may make unlimited requests that we register all or a portion of their registrable shares on Form S-3, or any successor form, so long as registrable shares held by such holders have an aggregate value of at least \$5.0 million based on the then current market price or fair value. Subject to specified limitations set forth in the stockholders agreement, we are obligated to use our commercially reasonable efforts to file a Form S-3, or any successor form, as soon as practicable, and in any event within 30 days, after the request for such registration.

Upon receipt of any request for demand or Form S-3 registration, we are required to promptly provide written notice of such proposed registration to all other holders of registrable shares, and subject to specified exceptions in the case of an underwritten public offering, such other holders will be entitled to elect to have their registrable shares included in such demand or Form S-3 registration.

*Incidental Registration Rights.* If we propose to file a registration statement under the Securities Act either for our own account or for the account of other stockholders (other than in connection with 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 registrable shares will be entitled to notice of the registration and, subject to specified exceptions, we will be required to use our commercially reasonable efforts to register all or a portion of any registrable shares then held by such holders that they request that we register. In the event that any registration in which the holders of registrable shares participate pursuant to our stockholders agreement is an underwritten public offering, we agree to enter into an underwriting agreement containing customary representation and warranties and covenants, including without limitation customary provisions with respect to indemnification by us of the underwriters of such offering.

### **Other Provisions.**

In the event that any registration in which the holders of registrable shares participate pursuant to the stockholders agreement is an underwritten public offering, the number of registrable shares to be included may, in specified circumstances, be limited due to market conditions.

We are required to pay all registration expenses, including registration and filing fees, exchange listing fees, printing expenses and accounting fees and the fees and expenses of one counsel to represent the selling stockholders, other than any underwriting discounts and commissions, related to any registration effected in accordance with the stockholders agreement. The stockholders agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.



## **Effects of Authorized but Unissued Stock**

We have shares of common stock and preferred stock available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of The NASDAQ Global Select Market. We may utilize these additional shares for a variety of corporate purposes, including for future public offerings to raise additional capital, or facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that

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could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a controlling interest in our company by means of a merger, tender offer, proxy contest or otherwise. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock, and the likelihood that such holders will receive dividend payments and payments upon liquidation.

## **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 Business Combination Statute.* We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which we refer to as the DGCL. With some exception, Section 203 of the DGCL 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 by the board of directors and the holders of at least two-thirds of the outstanding voting stock of the corporation. The shares held by the interested stockholder are not counted as outstanding when calculating the two-thirds of the outstanding voting stock needed for approval. For purposes of Section 203 of the DGCL, 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 outstanding 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, a 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 annual meeting date; *provided*, that if the date of the annual meeting is more than 30 days before or more than 30 days after the anniversary of the previous year's annual meeting date, such stockholder's notice must be delivered not earlier than the close of business on the 120<sup>th</sup> day prior to such annual meeting and not later than the close of business on the later of the 90<sup>th</sup> day prior to such annual meeting or the close of business on the 10<sup>th</sup> day following the day on which public announcement of the date of such meeting is first made by us. For a special meeting, the notice must generally be delivered not earlier than the 90<sup>th</sup> day prior to the meeting and not later than the later of (1) the 60<sup>th</sup> day prior to the meeting or (2) the 10<sup>th</sup> 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.

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*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, our restated certificate of incorporation provides 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.

*Board of Directors.* We do not have a classified board of directors. All of our directors are elected annually. The number of directors comprising our board of directors is fixed from time to time by the board of directors.

*Removal of Directors by Stockholders.* Our restated bylaws provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 80% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and our restated certificate of incorporation and restated bylaws provide that any vacancy on our board of directors, including a vacancy resulting from an increase in the size of our board of directors, may be filled only by vote of a majority of our directors then in office.

*Super Majority Stockholder Vote Required for Certain Actions.* The DGCL 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 the 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. The affirmative vote of at least 80% of our outstanding voting stock 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.

## **Directors Liability**

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.

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## **DESCRIPTION OF DEPOSITARY SHARES**

### **General**

We may, at our option, elect to offer fractional shares of preferred stock, which we call depositary shares, rather than full shares of preferred stock. If we do, we will issue to the public receipts, called depositary receipts, for depositary shares, each of which will represent a fraction, to be described in the applicable prospectus supplement, of a share of a particular series of preferred stock. Unless otherwise provided in the prospectus supplement, each owner of a depositary share will be entitled, in proportion to the applicable fractional interest in a share of preferred stock represented by the depositary share, to all the rights and preferences of the preferred stock represented by the depositary share. Those rights include dividend, voting, redemption, conversion and liquidation rights.

The shares of preferred stock underlying the depositary shares will be deposited with a bank or trust company selected by us to act as depositary under a deposit agreement between us, the depositary and the holders of the depositary receipts. The depositary will be the transfer agent, registrar and dividend disbursing agent for the depositary shares.

The depositary shares will be evidenced by depositary receipts issued pursuant to the deposit agreement. Holders of depositary receipts agree to be bound by the deposit agreement, which requires holders to take certain actions such as filing proof of residence and paying certain charges.

The summary of terms of the depositary shares contained in this prospectus is not a complete description of the terms of the depositary shares. You should refer to the form of the deposit agreement, our certificate of incorporation and the certificate of designation for the applicable series of preferred stock that are, or will be, filed with the SEC.

### **Dividends and Other Distributions**

The depositary will distribute all cash dividends or other cash distributions, if any, received in respect of the preferred stock underlying the depositary shares to the record holders of depositary shares in proportion to the numbers of depositary shares owned by those holders on the relevant record date. The relevant record date for depositary shares will be the same date as the record date for the underlying preferred stock.

If there is a distribution other than in cash, the depositary will distribute property (including securities) received by it to the record holders of depositary shares, unless the depositary determines that it is not feasible to make the distribution. If this occurs, the depositary may, with our approval, adopt another method for the distribution, including selling the property and distributing the net proceeds from the sale to the holders.

### **Liquidation Preference**

If a series of preferred stock underlying the depositary shares has a liquidation preference, in the event of the voluntary or involuntary liquidation, dissolution or winding up of us, holders of depositary shares will be entitled to receive the fraction of the liquidation preference accorded each share of the applicable series of preferred stock, as set forth in the applicable prospectus supplement.

## **Withdrawal of Stock**

Unless the related depositary shares have been previously called for redemption, upon surrender of the depositary receipts at the office of the depositary, the holder of the depositary shares will be entitled to delivery, at the office of the depositary to or upon his or her order, of the number of whole shares of the preferred stock and any money or other property represented by the depositary shares. If the depositary receipts delivered by the holder evidence a number of depositary shares in excess of the number of depositary shares representing the number of whole shares of preferred stock to be withdrawn, the depositary will deliver to the holder at the same time a new depositary receipt evidencing the excess number of depositary shares. In no event will the depositary deliver fractional shares of preferred stock upon surrender of depositary receipts. Holders of preferred stock thus withdrawn may not thereafter deposit those shares under the deposit agreement or receive depositary receipts evidencing depositary shares therefor.

## **Redemption of Depositary Shares**

Whenever we redeem shares of preferred stock held by the depositary, the depositary will redeem as of the same redemption date the number of depositary shares representing shares of the preferred stock so

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redeemed, so long as we have paid in full to the depositary the redemption price of the preferred stock to be redeemed plus an amount equal to any accumulated and unpaid dividends on the preferred stock to the date fixed for redemption. The redemption price per depositary share will be equal to the redemption price and any other amounts per share payable on the preferred stock multiplied by the fraction of a share of preferred stock represented by one depositary share. If less than all the depositary shares are to be redeemed, the depositary shares to be redeemed will be selected by lot or pro rata or by any other equitable method as may be determined by the depositary.

After the date fixed for redemption, depositary shares called for redemption will no longer be deemed to be outstanding and all rights of the holders of depositary shares will cease, except the right to receive the monies payable upon redemption and any money or other property to which the holders of the depositary shares were entitled upon redemption upon surrender to the depositary of the depositary receipts evidencing the depositary shares.

## **Voting the Preferred Stock**

Upon receipt of notice of any meeting at which the holders of the preferred stock are entitled to vote, the depositary will mail the information contained in the notice of meeting to the record holders of the depositary receipts relating to that preferred stock. The record date for the depositary receipts relating to the preferred stock will be the same date as the record date for the preferred stock. Each record holder of the depositary shares on the record date will be entitled to instruct the depositary as to the exercise of the voting rights pertaining to the number of shares of preferred stock represented by that holder's depositary shares. The depositary will endeavor, insofar as practicable, to vote the number of shares of preferred stock represented by the depositary shares in accordance with those instructions, and we will agree to take all action that may be deemed necessary by the depositary in order to enable the depositary to do so. The depositary will not vote any shares of preferred stock except to the extent it receives specific instructions from the holders of depositary shares representing that number of shares of preferred stock.

## **Charges of Depositary**

We will pay all transfer and other taxes and governmental charges arising solely from the existence of the depositary arrangements. We will pay charges of the depositary in connection with the initial deposit of the preferred stock and any redemption of the preferred stock. Holders of depositary receipts will pay transfer, income and other taxes and governmental charges and such other charges (including those in connection with the receipt and distribution of dividends, the sale or exercise of rights, the withdrawal of the preferred stock and the transferring, splitting or grouping of depositary receipts) as are expressly provided in the deposit agreement to be for their accounts. If these charges have not been paid by the holders of depositary receipts, the depositary may refuse to transfer depositary shares, withhold dividends and distributions and sell the depositary shares evidenced by the depositary receipt.

## **Amendment and Termination of the Deposit Agreement**

The form of depositary receipt evidencing the depositary shares and any provision of the deposit agreement may be amended by agreement between us and the depositary. However, any amendment that materially and adversely alters the rights of the holders of depositary shares, other than fee changes, will not be effective unless the amendment has been approved by the holders of a majority of the outstanding depositary shares. The deposit agreement may be terminated by the depositary or us only if:

all outstanding depositary shares have been redeemed; or

there has been a final distribution of the preferred stock in connection with our dissolution and such distribution has been made to all the holders of depositary shares.

## **Resignation and Removal of Depositary**

The depositary may resign at any time by delivering to us notice of its election to do so, and we may remove the depositary at any time. Any resignation or removal of the depositary will take effect upon our appointment of a successor depositary and its acceptance of such appointment. The successor depositary must be appointed within 60 days after delivery of the notice of resignation or removal and must be a bank or trust company having its principal office in the United States and having the requisite combined capital and surplus as set forth in the applicable agreement.



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## **Notices**

The depositary will forward to holders of depositary receipts all notices, reports and other communications, including proxy solicitation materials received from us, that are delivered to the depositary and that we are required to furnish to the holders of the preferred stock. In addition, the depositary will make available for inspection by holders of depositary receipts at the principal office of the depositary, and at such other places as it may from time to time deem advisable, any reports and communications we deliver to the depositary as the holder of preferred stock.

## **Limitation of Liability**

Neither we nor the depositary will be liable if either we or it is prevented or delayed by law or any circumstance beyond its control in performing its obligations. Our obligations and those of the depositary will be limited to performance in good faith of our and their duties thereunder. We and the depositary will not be obligated to prosecute or defend any legal proceeding in respect of any depositary shares or preferred stock unless satisfactory indemnity is furnished. We and the depositary may rely upon written advice of counsel or accountants, on information provided by persons presenting preferred stock for deposit, holders of depositary receipts or other persons believed to be competent to give such information and on documents believed to be genuine and to have been signed or presented by the proper party or parties.

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## **DESCRIPTION OF PURCHASE CONTRACTS AND PURCHASE UNITS**

We may issue purchase contracts, including contracts obligating holders to purchase from or sell to us, and obligating us to sell to or purchase from the holders, a specified number of shares of our common stock, preferred stock or depositary shares at a future date or dates, which we refer to in this prospectus as purchase contracts. The price per share of common stock, preferred stock or depositary shares and the number of shares of each may be fixed at the time the purchase contracts are issued or may be determined by reference to a specific formula set forth in the purchase contracts. The purchase contracts may be issued separately or as part of units, often known as purchase units, consisting of one or more purchase contracts and beneficial interests in debt securities or any other securities described in the applicable prospectus supplement or any combination of the foregoing, securing the holders obligations to purchase the common stock, preferred stock or depositary shares under the purchase contracts.

The purchase contracts may require us to make periodic payments to the holders of the purchase units or vice versa, and these payments may be unsecured or prefunded on some basis. The purchase contracts may require holders to secure their obligations under those contracts in a specified manner, including pledging their interest in another purchase contract.

The applicable prospectus supplement will describe the terms of the purchase contracts and purchase units, including, if applicable, collateral or depositary arrangements.

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## DESCRIPTION OF WARRANTS

We may issue warrants to purchase debt securities, common stock, preferred stock or depositary shares. We may offer warrants separately or together with one or more additional warrants, debt securities, common stock, preferred stock or depositary shares, or any combination of those securities in the form of units, as described in the applicable prospectus supplement. If we issue warrants as part of a unit, the accompanying prospectus supplement will specify whether those warrants may be separated from the other securities in the unit prior to the expiration date of the warrants. The applicable prospectus supplement will also describe the following terms of any warrants:

- the specific designation and aggregate number of, and the offering price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;
- whether the warrants are to be sold separately or with other securities as parts of units;
- whether the warrants will be issued in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
- any applicable material U.S. federal income tax consequences;
- the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;
- the proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;
- the designation and terms of any equity securities purchasable upon exercise of the warrants;
- the designation, aggregate principal amount, currency and terms of any debt securities that may be purchased upon exercise of the warrants;
- if applicable, the designation and terms of the debt securities, common stock, preferred stock or depositary shares with which the warrants are issued and, the number of warrants issued with each security;
- if applicable, the date from and after which any warrants issued as part of a unit and the related debt securities, common stock, preferred stock or depositary shares will be separately transferable;
- the number of shares of common stock, the number of shares of preferred stock or the number of depositary shares purchasable upon exercise of a warrant and the price at which those shares may be purchased;
- if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;
- information with respect to book-entry procedures, if any;
- the antidilution provisions of, and other provisions for changes to or adjustment in the exercise price of, the warrants, if any;
- any redemption or call provisions; and
- any additional terms of the warrants, including terms, procedures and limitations relating to the exchange or exercise of the warrants.

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## **FORMS OF SECURITIES**

Each debt security, depositary share, purchase contract, purchase unit and warrant will be represented either by a certificate issued in definitive form to a particular investor or by one or more global securities representing the entire issuance of securities. Unless the applicable prospectus supplement provides otherwise, certificated securities will be issued in definitive form and global securities will be issued in registered form. Definitive securities name you or your nominee as the owner of the security, and in order to transfer or exchange these securities or to receive payments other than interest or other interim payments, you or your nominee must physically deliver the securities to the trustee, registrar, paying agent or other agent, as applicable. Global securities name a depositary or its nominee as the owner of the debt securities, depositary shares, purchase contracts, purchase units or warrants represented by these global securities. The depositary maintains a computerized system that will reflect each investor's beneficial ownership of the securities through an account maintained by the investor with its broker/dealer, bank, trust company or other representative, as we explain more fully below.

### **Registered Global Securities**

We may issue the registered debt securities, depositary shares, purchase contracts, purchase units and warrants in the form of one or more fully registered global securities that will be deposited with a depositary or its nominee identified in the applicable prospectus supplement and registered in the name of that depositary or nominee. In those cases, one or more registered global securities will be issued in a denomination or aggregate denominations equal to the portion of the aggregate principal or face amount of the securities to be represented by registered global securities. Unless and until it is exchanged in whole for securities in definitive registered form, a registered global security may not be transferred except as a whole by and among the depositary for the registered global security, the nominees of the depositary or any successors of the depositary or those nominees.

If not described below, any specific terms of the depositary arrangement with respect to any securities to be represented by a registered global security will be described in the prospectus supplement relating to those securities. We anticipate that the following provisions will apply to all depositary arrangements.

Ownership of beneficial interests in a registered global security will be limited to persons, called participants, that have accounts with the depositary or persons that may hold interests through participants. Upon the issuance of a registered global security, the depositary will credit, on its book-entry registration and transfer system, the participants accounts with the respective principal or face amounts of the securities beneficially owned by the participants. Any dealers, underwriters or agents participating in the distribution of the securities will designate the accounts to be credited. Ownership of beneficial interests in a registered global security will be shown on, and the transfer of ownership interests will be effected only through, records maintained by the depositary, with respect to interests of participants, and on the records of participants, with respect to interests of persons holding through participants. The laws of some states may require that some purchasers of securities take physical delivery of these securities in definitive form. These laws may impair your ability to own, transfer or pledge beneficial interests in registered global securities.

So long as the depositary, or its nominee, is the registered owner of a registered global security, that depositary or its nominee, as the case may be, will be considered the sole owner or holder of the securities represented by the registered global security for all purposes under the applicable indenture, deposit agreement, purchase contract, warrant agreement or purchase unit agreement. Except as described below, owners of beneficial interests in a registered global security will not be entitled to have the securities represented by the registered global security registered in their

names, will not receive or be entitled to receive physical delivery of the securities in definitive form and will not be considered the owners or holders of the securities under the applicable indenture, deposit agreement, purchase contract, purchase unit agreement or warrant agreement. Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depositary for that registered global security and, if that person is not a participant, on the procedures of the participant through which the person owns its interest, to exercise any rights of a holder under the applicable indenture, deposit agreement, purchase contract, purchase unit agreement or warrant agreement. We understand that under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security desires to give or take

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any action that a holder is entitled to give or take under the applicable indenture, deposit agreement, purchase contract, purchase unit agreement or warrant agreement, the depositary for the registered global security would authorize the participants holding the relevant beneficial interests to give or take that action, and the participants would authorize beneficial owners owning through them to give or take that action or would otherwise act upon the instructions of beneficial owners holding through them.

Principal, premium, if any, and interest payments on debt securities, and any payments to holders with respect to depositary shares, warrants, purchase agreements or purchase units, represented by a registered global security registered in the name of a depositary or its nominee will be made to the depositary or its nominee, as the case may be, as the registered owner of the registered global security. None of us, the trustees, the warrant agents, the unit agents or any other agent of ours, agent of the trustees or agent of the warrant agents or unit agents will have any responsibility or liability for any aspect of the records relating to payments made on account of beneficial ownership interests in the registered global security or for maintaining, supervising or reviewing any records relating to those beneficial ownership interests.

We expect that the depositary for any of the securities represented by a registered global security, upon receipt of any payment to holders of principal, premium, interest or other distribution of underlying securities or other property on that registered global security, will immediately credit participants' accounts in amounts proportionate to their respective beneficial interests in that registered global security as shown on the records of the depositary. We also expect that payments by participants to owners of beneficial interests in a registered global security held through participants will be governed by standing customer instructions and customary practices, as is now the case with the securities held for the accounts of customers or registered in street name, and will be the responsibility of those participants.

If the depositary for any of the securities represented by a registered global security is at any time unwilling or unable to continue as depositary or ceases to be a clearing agency registered under the Exchange Act, and a successor depositary registered as a clearing agency under the Exchange Act is not appointed by us within 90 days, we will issue securities in definitive form in exchange for the registered global security that had been held by the depositary. Any securities issued in definitive form in exchange for a registered global security will be registered in the name or names that the depositary gives to the relevant trustee, warrant agent, unit agent or other relevant agent of ours or theirs. It is expected that the depositary's instructions will be based upon directions received by the depositary from participants with respect to ownership of beneficial interests in the registered global security that had been held by the depositary.

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## **PLAN OF DISTRIBUTION**

We or a selling stockholder may sell securities:

to or through underwriters, brokers or dealers;  
through agents;

directly to one or more purchasers in negotiated sales or competitively bid transactions;  
through a block trade in which the broker or dealer engaged to handle the block trade will attempt to sell the securities as agent, but may position and resell a portion of the block as principal to facilitate the transaction; or  
through a combination of any of the above methods of sale.

In addition, we may issue the securities as a dividend or distribution or in a subscription rights offering to our existing security holders.

We or any selling stockholder may directly solicit offers to purchase securities, or agents may be designated to solicit such offers. We will, in the prospectus supplement relating to such offering, name any agent that could be viewed as an underwriter under the Securities Act, and describe any commissions that we must pay. Any such agent will be acting on a best efforts basis for the period of its appointment or, if indicated in the applicable prospectus supplement, on a firm commitment basis. This prospectus may be used in connection with any offering of our securities through any of these methods or other methods described in the applicable prospectus supplement.

The distribution of the securities may be effected from time to time in one or more transactions:

at a fixed price, or prices, which may be changed from time to time;  
at market prices prevailing at the time of sale;  
at prices related to such prevailing market prices; or  
at negotiated prices.

Each prospectus supplement will describe the method of distribution of the securities and any applicable restrictions.

The prospectus supplement with respect to the securities of a particular series will describe the terms of the offering of the securities, including the following:

the name of the agent or any underwriters;  
the public offering or purchase price and the proceeds we will receive from the sales of securities;  
any discounts and commissions to be allowed or paid to the agent or underwriters;  
all other items constituting underwriting compensation;  
any discounts and commissions to be allowed or re-allowed or paid to dealers; and  
any exchanges on which the securities will be listed.

If any underwriters or agents are utilized in the sale of the securities in respect of which this prospectus is delivered, we will enter into an underwriting agreement or other agreement with them at the time of sale to them, and we will set forth in the prospectus supplement relating to such offering the names of the underwriters or agents and the terms of the related agreement with them.

If a dealer is utilized in the sale of the securities in respect of which the prospectus is delivered, we or any selling stockholder will sell such securities to the dealer, as principal. The dealer may then resell such securities to the public at varying prices to be determined by such dealer at the time of resale.

If we offer securities in a subscription rights offering to our existing security holders, we may enter into a standby underwriting agreement with dealers, acting as standby underwriters. We may pay the standby



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underwriters a commitment fee for the securities they commit to purchase on a standby basis. If we do not enter into a standby underwriting arrangement, we may retain a dealer-manager to manage a subscription rights offering for us.

Remarketing firms, agents, underwriters, dealers and other persons may be entitled under agreements which they may enter into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

We may pay expenses incurred with respect to the registration of the shares of common stock owned by any selling stockholders.

If so indicated in the applicable prospectus supplement, we or any selling stockholder will authorize underwriters or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in the prospectus supplement. Each contract will be for an amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in the prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will not be subject to any conditions except that:

the purchase by an institution of the securities covered under that contract shall not at the time of delivery be prohibited under the laws of the jurisdiction to which that institution is subject; and  
if the securities are also being sold to underwriters acting as principals for their own account, the underwriters shall have purchased such securities not sold for delayed delivery. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of delayed delivery contracts.

Certain agents, underwriters and dealers, and their associates and affiliates may be customers of, have borrowing relationships with, engage in other transactions with, or perform services, including investment banking services, for us or one or more of our respective affiliates or any selling stockholder in the ordinary course of business.

In order to facilitate the offering of the securities, any underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the securities or any other securities the prices of which may be used to determine payments on such securities. Specifically, any underwriters may overallocate in connection with the offering, creating a short position for their own accounts. In addition, to cover overallocations or to stabilize the price of the securities or of any such other securities, the underwriters may bid for, and purchase, the securities or any such other securities in the open market. Finally, in any offering of the securities through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the securities above independent market levels. Any such underwriters are not required to engage in these activities and may end any of these activities at any time.

Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in three business days, unless the parties to any such trade expressly agree otherwise. The applicable prospectus supplement may provide that the original issue date for your securities may be more than three scheduled business days after the trade date for your securities. Accordingly, in such a case, if you wish to trade securities on any date prior to the third business day before the original issue date for your securities, you will be required, by virtue of the fact that your securities initially are expected to settle in more than three scheduled business days after the trade date for your securities, to make alternative settlement arrangements to prevent a failed settlement.



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To comply with the securities laws of some states, if applicable, the securities may be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the securities may not be sold unless they have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

The securities may be new issues of securities and may have no established trading market. The securities may or may not be listed on a national securities exchange. We can make no assurance as to the liquidity of or the existence of trading markets for any of the securities.

In compliance with the guidelines of the Financial Industry Regulatory Authority, or FINRA, the aggregate maximum discount, commission or agency fees or other items constituting underwriting compensation to be received by any FINRA member or independent broker-dealer will not exceed 8% of the proceeds from any offering pursuant to this prospectus and any applicable prospectus supplement.

## **LEGAL MATTERS**

Unless the applicable prospectus supplement indicates otherwise, the validity of the securities in respect of which this prospectus is being delivered will be passed upon by Wilmer Cutler Pickering Hale and Dorr LLP.

## **EXPERTS**

The consolidated financial statements of Intercept Pharmaceuticals, Inc. (a development stage enterprise) as of December 31, 2012 and December 31, 2013 and for each of the years in the three-year period ended December 31, 2013 and the information included in the cumulative from inception presentation for the period September 4, 2002 (inception) to December 31, 2013, incorporated by reference in this prospectus from Intercept Pharmaceuticals, Inc. s Annual Report on Form 10-K for the year ended December 31, 2013, 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.

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**800,000 Shares**

Common Stock

**Citigroup**

**RBC Capital Markets**

February , 2015