INTERCEPT PHARMACEUTICALS INC
Form 424B5
April 04, 2018

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The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying base prospectus are part of an effective registration statement filed with the Securities and Exchange Commission. This preliminary prospectus supplement is not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 4, 2018

PROSPECTUS SUPPLEMENT
(To Prospectus Dated May 10, 2017)

$120,000,000

INTERCEPT PHARMACEUTICALS, INC.

Common Stock

We are offering shares of our common stock with an aggregate offering price of $120,000,000. Our common stock is listed on the Nasdaq Global Select Market under the symbol ICPT. The last reported sale price of our common stock on the Nasdaq Global Select Market on April 3, 2018 was $62.83 per share.

We have granted the underwriters a 30-day option to purchase up to $18,000,000 in additional shares of our common stock.

Pursuant to a securities purchase agreement with our largest existing shareholder, Genextra S.p.A., Samsara BioCapital, L.P. and certain other purchasers named therein (the Private Placement Purchasers), dated as of April 4, 2018 (the Private Placement Agreement), we will sell to the Private Placement Purchasers, in a private placement exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act), and at a sale price equal to the price to the public in this offering, shares of our common stock with an aggregate purchase price of approximately $92.0 million (the Concurrent Private Placement). The consummation of the Concurrent Private Placement is contingent on the closing of this offering and the satisfaction of certain other customary conditions. However, the consummation of this offering is not contingent on the consummation of the Concurrent Private Placement.

Our Chief Executive Officer and certain members of our Board of Directors have indicated an interest in purchasing an aggregate of up to approximately $1.1 million in shares of our common stock in this offering at the price offered to the public and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, these investors may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering.

Investing in our common stock involves risks. See Risk Factors beginning on page S-6 of this prospectus supplement and on page 2 of the accompanying base prospectus, as well as those risks described in our most recent Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission (the SEC).

	Price to Public	Underwriting Discounts and Commissions[(1)]	Proceeds to the Company
Per Share	$	$	$
Total	$	$	$

(1) See Underwriting for a description of compensation payable to the underwriters.

Neither the SEC, any state securities commission nor any other regulatory body has approved or disapproved of these securities or determined if this prospectus supplement and the accompanying base prospectus to which it relates are truthful and complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on or about April , 2018.

Credit Suisse **Jefferies**

The date of this prospectus supplement is April , 2018

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Prospectus Supplement

Prospectus

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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 the securities offered hereby, and also adds to and updates information contained in the accompanying base prospectus and the documents incorporated into each by reference. The second part, the accompanying base prospectus, gives more general information and disclosure. When we refer only to the prospectus, we are referring to both parts combined.

If there is any inconsistency between information in or incorporated by reference into the accompanying base prospectus and information in or incorporated by reference into this prospectus supplement, you should rely only on the information contained in or incorporated by reference into this prospectus supplement. This prospectus supplement, the accompanying base prospectus and the documents incorporated into each by reference include important information about us, the common stock being offered and other information you should know before investing. You should read this prospectus supplement and the accompanying base prospectus together with the additional information described under the heading Where You Can Find More Information before investing in our common stock.

You should rely only on the information contained in or incorporated by reference into this prospectus supplement and the accompanying base prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale thereof is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying base prospectus and the documents incorporated into each by reference is accurate only as of the respective dates of the applicable documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

When we refer to we, our, us, and the Company in this prospectus supplement, we mean Intercept Pharmaceutica Inc. and its subsidiaries.

The Intercept Pharmaceuticals® name and logo and the Ocaliva® name and logo are either registered or unregistered trademarks or trade names of the Company in the United States and/or other countries. All other trademarks, trade names and service marks appearing in this prospectus supplement, the accompanying base prospectus or the documents incorporated into each by reference are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus supplement, the accompanying base prospectus and the documents incorporated into each by reference may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights to these trademarks and trade names.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying base prospectus, including the documents incorporated into each by reference, contain forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of our clinical trials, including our clinical trials for the treatment of nonalcoholic steatohepatitis (NASH), the safety and efficacy of our approved product, Ocaliva (obeticholic acid or OCA), the potential approval of OCA in indications other than primary biliary cholangitis (PBC), the timing and potential commercial success of OCA and any other product candidates we may develop and our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act).

The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, poten should, continue, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their respective dates, and we undertake no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by our management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks. The following represent some, but not necessarily all, of the factors that could cause actual results to differ materially from historical results or those anticipated or predicted by our forward-looking statements:

our ability to successfully commercialize Ocaliva in PBC;

our ability to maintain our regulatory approval of Ocaliva in PBC in the United States, Europe, Canada and other jurisdictions in which we have or may receive marketing authorization;

the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials, including our clinical trials for the treatment of NASH;

the timing of and our ability to obtain regulatory approval of OCA in indications other than PBC and regulatory approval of any other product candidates we may develop;

conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations and/or warnings in the label of any products or product candidates;

our plans to research, develop and commercialize our products and product candidates;

our ability to obtain and maintain intellectual property protection for our products and product candidates;

our ability to successfully commercialize our products and product candidates;

the size and growth of the markets for our products and product candidates and our ability to serve those markets;

the rate and degree of market acceptance of any of our products, which may be affected by the reimbursement received from payors;

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 collaborators election to pursue research, development and commercialization activities;

our ability to attract collaborators with development, regulatory and commercialization expertise;

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our need for and ability to obtain additional financing;
our estimates regarding expenses, revenues and capital requirements and the accuracy thereof;
our use of cash and short-term investments;
our ability to attract and retain key scientific or management personnel; and

the other risks and uncertainties discussed under the caption Risk Factors herein and in the accompanying base prospectus and in our periodic filings incorporated by reference herein, including our Annual Report on Form 10-K for the year ended December 31, 2017.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights key aspects of this offering. This summary is not complete and does not contain all of the information that you should consider before investing in shares of our common stock. You should read carefully the other information included and incorporated by reference in this prospectus supplement and the accompanying base prospectus before investing in our common stock. You should pay special attention to the Risk Factors section of this prospectus supplement, the accompanying base prospectus and our Annual Report on Form 10-K for the year ended December 31, 2017, which is incorporated by reference herein, when determining whether an investment in shares of our common stock is appropriate for you.

Our Company

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases with high unmet medical need utilizing our proprietary bile acid chemistry. Our one marketed product, OCA, and portfolio of clinical product candidates have the potential to treat orphan and more prevalent liver diseases for which, currently, there are limited therapeutic solutions.

OCA was approved in the United States in May 2016 for use in patients with PBC, under the brand name Ocaliva® (obeticholic acid). 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. We believe OCA has broad liver-protective properties and may effectively counter a variety of chronic insults to the liver that cause fibrosis, or scarring, which can eventually lead to cirrhosis, liver transplant and death. We commenced sales and marketing of Ocaliva in the United States shortly after receiving marketing approval, and Ocaliva is now available to patients primarily through a network of specialty pharmacy distributors. In December 2016, the European Commission granted conditional approval for Ocaliva for the treatment of PBC and we commenced our European commercial launch in January 2017. We have submitted or are in the process of submitting dossiers to a number of reimbursement authorities in the European Union. In May 2017, Health Canada granted a conditional approval for Ocaliva in PBC and we commenced our commercial launch in July 2017. We also plan to file for marketing authorization for OCA in PBC in other target markets.

We are currently evaluating our future development strategy for OCA in other indications, including a variety of other non-viral progressive liver diseases such as NASH, primary sclerosing cholangitis (PSC) and biliary atresia.

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, a part of the National Institutes of Health. The FLINT trial was completed in late July 2014. We have an ongoing Phase 3 clinical trial in non-cirrhotic NASH patients with liver fibrosis, known as the REGENERATE trial. REGENERATE includes a pre-planned histology-based interim analysis after 72 weeks of treatment. In May 2017, we completed enrollment of the interim analysis cohort for the REGENERATE trial. We anticipate top-line results from the interim analysis in the first half of 2019. We have also completed a Phase 2 clinical trial, known as the CONTROL trial, the goal of which was to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. We announced that this trial met its primary endpoint in July 2017. We continue to work towards expanding our overall NASH development program with additional trials and studies, including our ongoing Phase 3 trial in NASH patients with compensated cirrhosis, known as the REVERSE trial.

In addition to PBC and NASH, we continue to invest in research of OCA for additional patient populations with other

liver diseases. For example, in July 2017, we announced top-line results of our Phase 2 AESOP trial in PSC which evaluated the effects of 24 weeks of treatment with varying doses of OCA compared to placebo. This trial achieved its primary endpoint, which we believe establishes a proof-of-concept of OCA in a second cholestatic liver disease. We plan to discuss these results with regulatory authorities to formulate our future development plans for OCA in PSC. OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and PSC and breakthrough therapy designation from the U.S. Food and Drug Administration (the FDA) for the treatment of NASH patients with liver fibrosis.

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Our current patents for OCA are scheduled to expire at various times through 2033. We own or have rights to develop and commercialize OCA worldwide except for China, where we have exclusively licensed OCA to Sumitomo Dainippon Pharma Co. Ltd.

Our Strategy

Our strategy is to develop and commercialize novel therapeutics for patients with progressive non-viral liver 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:

commercialize OCA in the United States, Europe, Canada 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 diseases; and
maintain infrastructure and personnel in the United States and internationally to support our product development and commercialization efforts, as well as our operations as a public company.

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 liver diseases with high unmet medical need.

Recent Developments

Quarter Ended March 31, 2018

We have previously indicated that we expect the quarter ended March 31, 2018 to be a transitional quarter for our company. In February 2018, we announced that the Ocaliva label in the United States was updated by the FDA to include a boxed warning and a dosing table that reinforce the existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis. The FDA issued an updated drug safety communication to accompany the revised label. As a result of the label update, we embarked on a significant outreach program to educate physicians, payers and thought leaders.

For the quarter ended March 31, 2018, we expect total Ocaliva prescriptions filled to be substantially consistent with total Ocaliva prescriptions filled during the quarter ended December 31, 2017. In addition, as we have previously indicated, based primarily on the impact in the first quarter of 2018 of increased gross-to-net deductions relating to the annual resetting of deductibles and the Medicare Part D coverage gap, we currently expect total gross-to-net deductions in the first quarter of 2018 to be towards the higher end of our previously announced 10% to 15% gross-to-net range. As a result, while our belief in the long-term growth opportunity for PBC in the remainder of 2018 and beyond remains unchanged, we expect that net sales of Ocaliva for the quarter ended March 31, 2018 will be slightly lower than net sales of Ocaliva for the quarter ended December 31, 2017.

The above information reflects our preliminary results based on currently available information. Our internal closing procedures with respect to the periods presented above are not complete. As a result, our final results may vary from the preliminary results presented above. Our actual results for the three months ended March 31, 2018 will not be finalized until after this offering is completed and may differ materially from the above estimates. Accordingly, you should not place undue reliance upon these preliminary results. See Risk Factors and Cautionary Statement Regarding Forward-Looking Statements.

Concurrent Private Placement

Pursuant to the Private Placement Agreement, we will sell to the Private Placement Purchasers, in a private placement exempt from the registration requirements of the Securities Act and at a sale price equal to the price to the public in this offering, shares of our common stock with an aggregate purchase price of approximately $92.0 million. The consummation of the Concurrent Private Placement is contingent on the closing of this offering and the satisfaction of certain other customary conditions. The Private Placement

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Purchasers will receive certain registration rights upon the consummation of the Concurrent Private Placement. We will not pay any underwriting discounts or commissions with respect to the shares that are sold in the Concurrent Private Placement. The closing of the Concurrent Private Placement is expected to occur on or about April , 2018. The consummation of this offering is not contingent on the consummation of the Concurrent Private Placement.

We expect that our largest existing shareholder, Genextra S.p.A. (Genextra), will purchase shares of our common stock in the Concurrent Private Placement having an aggregate purchase price of approximately $25.0 million. See Risk Factors Additional Risks Relating to our Common Stock and this Offering We have a significant stockholder, which will limit your ability to influence corporate matters and may give rise to conflicts of interest and could result in future substantial sales of shares of our common stock into the market.

Company Information

We were incorporated in the State of Delaware on September 4, 2002. Our principal executive offices are located at 10 Hudson Yards, 37th Floor, New York, New York 10001, and our telephone number is (646) 747-1000. We also have administrative offices in San Diego, California and London, United Kingdom. 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 or the accompanying base prospectus. Investors should not rely on any such information in deciding whether to invest in our common stock. We have included our website address in this prospectus supplement as an inactive textual reference only.

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The Offering

Issuer

Intercept Pharmaceuticals, Inc.

Common Stock Offered by Us

$120,000,000 in shares of our common stock.

Underwriters Option to Purchase Additional Shares of Common Stock

We have granted the underwriters an option to purchase up to $18,000,000 in additional shares of our common stock. The underwriters can exercise this option at any time within 30 days from the date of this prospectus supplement. See Underwriting.

Common Stock Sold by Us in the Concurrent Private Placement

Pursuant to the Private Placement Agreement, we will sell to the Private Placement Purchasers, in a private placement exempt from the registration requirements of the Securities Act and at a sale price equal to the price to the public in this offering, shares of our common stock with an aggregate purchase price of approximately $92.0 million. The consummation of the Concurrent Private Placement is contingent on the closing of this offering and the satisfaction of certain other customary conditions. The Private Placement Purchasers will receive certain registration rights upon the consummation of the Concurrent Private Placement. We will not pay any underwriting discounts or commissions with respect to the shares that are sold in the Concurrent Private Placement. The closing of the Concurrent Private Placement is expected to occur on or about April , 2018. The consummation of this offering is not contingent on the consummation of the Concurrent Private Placement.

Common Stock to be Outstanding After this Offering and the Concurrent Private Placement

28,546,862 shares (or 28,833,349 shares if the underwriters exercise in full their option to purchase additional shares in this offering) based on an assumed sale price of $62.83, the last reported sale price of our common stock on the Nasdaq Global Select Market on April 3, 2018.

Use of Proceeds

Assuming that we sell $120,000,000 in shares of our common stock in this offering and approximately $92.0 million in shares of our common stock in the Concurrent Private Placement, we would receive aggregate gross proceeds of approximately $212.0 million (or approximately $230.0 million if the underwriters exercise in full their option to purchase additional shares in this offering). We intend to use the net proceeds from this offering and from the Concurrent Private Placement for working capital and general corporate purposes, which may include, among other things, funding the ongoing commercialization of Ocaliva in PBC and the continued advancement of our clinical, research and development programs. See Use of Proceeds.

Risk Factors

Investing in our common stock involves risks. See Risk Factors beginning on page S-6 of this prospectus supplement and on page 2 of the accompanying base prospectus, as well as those risks described in our periodic filings incorporated by reference herein, including our Annual Report on Form 10-K for the year ended December 31, 2017.

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Nasdaq Global Select Market Symbol ICPT

The number of shares of our common stock to be outstanding immediately after this offering and the Concurrent Private Placement is based on 25,172,678 shares of our common stock outstanding as of December 31, 2017, and excludes as of that date:

1.8 million shares of common stock issuable upon the exercise of outstanding stock options, at a weighted average exercise price of $114.70 per share;

0.1 million shares of common stock issuable upon the vesting of outstanding restricted stock units;

1.9 million shares of common stock reserved for future issuance under our 2012 Equity Incentive Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under such plan pursuant to the terms thereof; and

up to 3.1 million shares of common stock issuable upon conversion of our outstanding 3.25% Convertible Senior Notes due 2023 (the Convertible Senior Notes).

The foregoing does not give effect to any issuance, exercise or settlement of stock-based awards under our equity incentive plan subsequent to December 31, 2017.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their option to purchase additional shares in this offering and assumes no exercise or settlement of the outstanding stock options or restricted stock units described above or conversion of the Convertible Senior Notes.

Our Chief Executive Officer and certain members of our Board of Directors have indicated an interest in purchasing an aggregate of up to approximately $1.1 million in shares of our common stock in this offering at the price offered to the public and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, these investors may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering.

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RISK FACTORS