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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): February 19, 2019

Intercept Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35668**	**22-3868459**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10 Hudson Yards, 37th Floor
New York, NY 10001
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: **(646) 747-1000**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On February 19, 2019, Intercept Pharmaceuticals, Inc. issued a press release announcing topline results from its pivotal Phase 3 REGENERATE study. A copy of such press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press Release issued February 19, 2019

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued February 19, 2019

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INTERCEPT PHARMACEUTICALS, INC.

By: /s/ Sandip Kapadia
Name: Sandip Kapadia
Title: Chief Financial Officer and Treasurer

Date: February 25, 2019

Exhibit 99.1

Intercept Announces Positive Topline Results from Pivotal Phase 3 REGENERATE Study of Obeticholic Acid in Patients with Liver Fibrosis Due to NASH

First and largest successful pivotal Phase 3 study in patients with liver fibrosis due to NASH

OCA achieves primary endpoint demonstrating statistically significant improvement in liver fibrosis without worsening of NASH at 18 months (p=0.0002)

Intercept intends to file for regulatory approval in the U.S. and Europe in the second half of 2019

Results to be presented at European Association for the Study of the Liver 2019 International Liver Congress

Intercept to host conference call at 8:00 a.m. ET

NEW YORK, Feb. 19, 2019 – Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced positive results from its pivotal Phase 3 REGENERATE study of obeticholic acid (OCA) in patients with liver fibrosis due to nonalcoholic steatohepatitis (NASH). In the primary efficacy analysis, once-daily OCA 25 mg met the primary endpoint of fibrosis improvement (≥1 stage) with no worsening of NASH at the planned 18-month interim analysis (p=0.0002 vs. placebo). In the primary efficacy analysis, a numerically greater proportion of patients in both OCA treatment arms compared to placebo achieved the primary endpoint of NASH resolution with no worsening of liver fibrosis, but this did not reach statistical significance. As agreed with the U.S. Food and Drug Administration (FDA), in order for the primary objective to be met, the study was required to achieve one of the two primary endpoints.

“We are thrilled to report the first positive registrational Phase 3 study results in patients with NASH, a devastating disease that is on track to become a leading cause of liver transplant in coming years,” said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. “The topline REGENERATE data we are reporting today support our belief that OCA will become the first approved medicine for those living with liver fibrosis due to NASH. We are deeply grateful to the patients, investigators and study staff whose ongoing participation in REGENERATE has brought us one step closer to delivering a much-needed therapeutic option to address the enormous unmet medical need in this population.”

Based on these results, Intercept intends to file for approval in the U.S. and Europe in the second half of 2019. OCA remains the only investigational drug to have received Breakthrough Therapy designation from the FDA for NASH with fibrosis. REGENERATE results will be presented at the European Association for the Study of the Liver (EASL): The International Liver Congress™ 2019.

“Patients with significant fibrosis due to NASH are at the greatest risk of progression to severe liver-related complications, such as liver failure and death, and fibrosis is considered the strongest predictor of liver-related mortality in this population,” said Zobair M. Younossi, M.D., Professor and Chairman of the Department of Medicine at Inova Fairfax Medical Campus, Professor of Medicine at Virginia Commonwealth University, Inova Campus and the Chair of the REGENERATE Steering Committee. “I am very encouraged by these results that demonstrate OCA’s ability to significantly improve fibrosis in patients with advanced disease. As the first successful pivotal trial in NASH, REGENERATE is an important advancement for the liver community.”

Efficacy Results

The primary efficacy analysis (Intent-to-Treat or ITT) assessed efficacy at 18 months in 931 patients with stage 2 or 3 liver fibrosis due to NASH. Overall study discontinuations in the primary efficacy analysis population were balanced across treatment arms: 16% in placebo, 17% in OCA 10 mg and 15% in OCA 25 mg.

An additional pre-specified full efficacy analysis at 18 months added an exploratory cohort of 287 NASH patients with stage 1 liver fibrosis and additional risk factors who were at increased risk of progression to cirrhosis (N=1,218).

Patients with biopsy proven NASH with fibrosis were randomized 1:1:1 to receive placebo, OCA 10 mg or OCA 25 mg once daily. A repeat biopsy was conducted after 18 months for histologic endpoint assessment. Patients without a repeat biopsy due to study discontinuation or other reason were treated as non-responders in the primary and full efficacy analyses.

Fibrosis Improvement at Month 18

Primary Efficacy Analysis (ITT population: NASH with stage 2 and 3 liver fibrosis)	**Placebo n=311**	**OCA 10 mg n=312**	**OCA 25 mg n=308**
Fibrosis improvement (≥1 stage) with no worsening of NASH*	**11.9%**	**17.6% p=0.0446**	**23.1% p=0.0002****
Additional Full Efficacy Analysis (ITT population plus stage 1 liver fibrosis patients)	Placebo n=407	OCA 10 mg n=407	OCA 25 mg n=404
Fibrosis improvement (≥1 stage) with no worsening of NASH*	10.6%	15.7% p=0.0286	21.0% p<0.0001
**Defined as no worsening of hepatocellular ballooning, no worsening of lobular inflammation and no worsening of steatosis* ***Statistically significant in accordance with the statistical analysis plan agreed with the FDA*			

NASH Resolution at Month 18

Primary Efficacy Analysis (ITT population: NASH with stage 2 and 3 liver fibrosis)	**Placebo n=311**	**OCA 10 mg n=312**	**OCA 25 mg n=308**
NASH resolution‡ with no worsening of liver fibrosis stage	**8.0%**	**11.2% p=0.1814**	**11.7% p=0.1268**
Additional Full Efficacy Analysis (ITT population plus stage 1 liver fibrosis patients)	Placebo n=407	OCA 10 mg n=407	OCA 25 mg n=404
NASH resolution‡ with no worsening of liver fibrosis stage	7.9%	11.3% p=0.0903	14.9% p=0.0013
‡*Defined as the overall histopathologic interpretation of (i) no fatty liver disease or (ii) fatty liver disease (simple or isolated steatosis) without steatohepatitis AND a nonalcoholic fatty liver disease (NAFLD) activity score of 0 for ballooning and 0-1 for inflammation*			

Safety and Tolerability

The safety population in this planned 18-month analysis of REGENERATE included 1,968 randomized patients who received at least one dose of investigational product (OCA or placebo).

Adverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA. The frequency of serious adverse events was similar across treatment arms (11% in placebo, 11% in OCA 10 mg and 14% in OCA 25 mg) and no serious adverse event occurred in >1% of patients in any treatment arm. There were 3 deaths in the study (2 in placebo: bone cancer and cardiac arrest, 1 in OCA 25 mg: glioblastoma) and none were considered related to treatment.

The most common adverse event reported was dose-related pruritus (19% in placebo, 28% in OCA 10 mg and 51% in OCA 25 mg). The large majority of pruritus events were mild to moderate, with severe pruritus occurring in a small number of patients (<1% in placebo, <1% in OCA 10 mg and 5% in OCA 25 mg). A higher incidence of pruritus associated treatment discontinuation was observed for OCA 25 mg (<1% in placebo, <1% in OCA 10 mg and 9% in OCA 25 mg). According to the clinical study protocol, investigator assessed severe pruritus mandated treatment discontinuation.

Consistent with observations from previous NASH studies, OCA treatment was associated with an increase in LDL cholesterol, with a peak increase of 22.6 mg/dL at 4 weeks and subsequently reversing and approaching baseline at month 18 (4.0 mg/dL increase from baseline). Triglycerides rapidly and continually decreased in the OCA treatment arms through month 18. There were few and varied serious cardiovascular events and incidence was balanced across the three treatment arms (2% in placebo, 1% in OCA 10 mg and 2% in OCA 25 mg).

With respect to hepatobiliary events, more patients (3%) on OCA 25 mg experienced gallstones or cholecystitis compared to <1% on placebo and 1% on OCA 10 mg. While numerically higher in the OCA 25 mg treatment arm, serious hepatic adverse events were uncommon with <1% incidence in each of the three treatment arms.

About Liver Fibrosis due to NASH

Nonalcoholic steatohepatitis (NASH) is a serious progressive liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. Advanced fibrosis is associated with a substantially higher risk of liver-related morbidity and mortality in patients with NASH, and as early as 2020, the disease is projected to become the leading cause of liver transplants in the United States. There are currently no medications approved for the treatment of NASH.

About the REGENERATE Study

The Phase 3 REGENERATE study is a randomized, double-blind, placebo-controlled, multicenter study assessing the safety and efficacy of obeticholic acid (OCA) on liver-related clinical outcomes in patents with liver fibrosis due to NASH. An 18-month analysis was conducted to assess the effect of OCA in liver histology comparing month 18 biopsy with baseline. REGENERATE is targeted to enroll more than 2,000 adult NASH patients with stage 2 and 3 fibrosis across 339 qualified centers worldwide. A smaller exploratory cohort of 287 patients with high-risk early fibrosis (defined as stage 1 fibrosis and metabolic syndrome) were also enrolled in REGENERATE, but were not included in the primary efficacy analysis. These patients were included in the full efficacy analysis and safety analysis. REGENERATE is planned to continue through clinical outcomes in order to confirm clinical benefit. The end-of-study analysis will evaluate the effect of OCA on mortality and liver-related clinical outcomes, as well as its long-term safety.

About the REVERSE Study

The Phase 3 REVERSE study is a randomized, double-blind, placebo-controlled, multicenter trial evaluating the safety and efficacy of OCA in histological improvement in fibrosis with no worsening of NASH in NASH patients with compensated cirrhosis.

Conference Call at 8:00 a.m. ET

Intercept will hold a conference call to discuss the topline results of the Phase 3 REGENERATE study in patients with liver fibrosis due to NASH today at 8:00 a.m. ET. The live event will be available on the investor page of Intercept's website at http://ir.interceptpharma.com or by calling (855) 232-3919 (toll-free domestic) or (315) 625-6894 (international) five minutes prior to the start time (no passcode is required). A replay of the call will be available on Intercept's website approximately two hours after the completion of the call and will be archived for two weeks.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, including primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH). Founded in 2002 in New York, Intercept has operations in the United States, Europe and Canada. For more information, please visit www.interceptpharma.com or connect with the company on Twitter and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains 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") for primary biliary cholangitis ("PBC"), and our product development candidates, including OCA for NASH, the timing and acceptance of our potential regulatory filings and potential approval of OCA for NASH or any other indications in addition to 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, financial guidance, 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 of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "possible," "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 the date of this release, 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 for PBC; our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization; the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients, meeting specific endpoints in the jurisdictions in which we intend to seek approval or completing and timely reporting the results of our NASH or PBC clinical trials; our ability to timely and cost-effectively file for and obtain regulatory approval of our product candidates, including OCA for NASH, in the United States, Europe and our other target markets; 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 contained in the label of any of our products or product candidates; any potential side effects associated with Ocaliva for PBC, OCA for NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions or otherwise limit the sale of such product or product candidate; our ability to establish and maintain relationships with, and the performance of, third-party manufacturers, contract research organizations and other vendors upon whom we are substantially dependent for, among other things, the manufacture and supply of our products, including Ocaliva for PBC and, if approved, OCA for NASH, and our clinical trial activities; our ability to identify, develop and successfully commercialize our products and product candidates, including our ability to timely and successfully launch OCA for NASH, if approved; our ability to obtain and maintain intellectual property protection for our products and product candidates, including our ability to cost-effectively file, prosecute, defend and enforce any patent claims or other intellectual property rights; the size and growth of the markets for our products and product candidates and our ability to serve those markets; the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for NASH or our other product candidates among physicians, patients and healthcare payors; the availability of adequate coverage and reimbursement from governmental and private healthcare payors for our products, including Ocaliva for PBC and, if approved, OCA for NASH, and our ability to obtain adequate pricing for such products; our ability to establish and maintain effective sales, marketing and distribution capabilities, either directly or through collaborations with third parties; competition from existing drugs or new drugs that become available; our ability to prevent system failures, data breaches or violations of data protection laws; costs and outcomes relating to any disputes, governmental inquiries or investigations, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation; our collaborators' election to pursue research, development and commercialization activities; our ability to establish and maintain relationships with collaborators with development, regulatory and commercialization expertise; our need for and ability to generate or 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 acquire, license and invest in businesses, technologies, product candidates and products; our ability to attract and retain key personnel to manage our business effectively; our ability to manage the growth of our operations, infrastructure, personnel, systems and controls; our ability to obtain and maintain adequate insurance coverage; the impact of general U.S. and foreign economic, industry, market, regulatory or political conditions; and the other risks and uncertainties identified in our periodic filings filed with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2017.

Contact

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