INTERCEPT PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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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): May 4, 2017

INTERCEPT PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35668**	**22-3868459**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10 Hudson Yards, Floor 37 **New York, New York** **(Address of principal executive offices)**	**10001** **(Zip Code)**

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

(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

☐ 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))

Item 2.02 Results of Operations and Financial Condition.

On May 4, 2017, Intercept Pharmaceuticals, Inc. (the "Company") announced its results for the three months ended March 31, 2017 and provided other general business updates. A copy of the Company's press release (the "Press Release") containing such announcement is attached hereto as Exhibit 99.1. The information in the Press Release is incorporated by reference into this Item 2.02 of this Current Report on Form 8-K.

Except as shall be expressly set forth by specific reference, the information contained or incorporated by reference in this Item 2.02 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 7.01. Regulation FD Disclosure.

On May 4, 2017, the Company announced that it has completed enrollment of the interim analysis cohort for its Phase 3 REGENERATE trial of obeticholic acid in nonalcoholic steatohepatitis patients with liver fibrosis.

Except as shall be expressly set forth by specific reference, the information contained or incorporated by reference in this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit 99.1	Press Release of Intercept Pharmaceuticals, Inc. dated May 4, 2017

SIGNATURE

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.

Dated: May 4, 2017

/s/ Mark Pruzanski
Mark Pruzanski, M.D.
President and Chief Executive Officer

Exhibit 99.1

Intercept Pharmaceuticals Reports First Quarter 2017 Financial Results and Provides Business Update

- ***Worldwide net Ocaliva ® (obeticholic acid or OCA) 1Q 2017 sales of $20.6 million***
- ***Completed enrollment of Phase 3 REGENERATE trial interim analysis cohort: data expected in 1H 2019***

Conference call scheduled for 8:30 a.m. ET today

NEW YORK, May 4, 2017 -- 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 reported financial results for the three months ended March 31, 2017 and provided other general business updates.

“I’m very pleased with our commercial and development progress thus far in 2017, and look forward to building on the positive momentum as a leader in progressive non-viral liver disease,” said Mark Pruzanski, M.D., President and CEO of Intercept. “In the U.S., we have seen strong execution on our launch plans for Ocaliva, as evidenced by steady quarter over quarter growth. In Europe, we remain focused on market access and are enthusiastic about the rapid reimbursement decision for Ocaliva from the highly regarded UK regulatory body NICE.”

“In our NASH program, we achieved a major milestone with the completion of enrollment of our interim analysis cohort in REGENERATE, the first and largest Phase 3 trial in NASH,” added Dr. Pruzanski. “As we look to the middle of the year, we expect to announce top-line data from two additional Phase 2 trials of OCA: CONTROL, assessing combination statin therapy in NASH patients, and AESOP in primary sclerosing cholangitis."

Ocaliva Commercial Update

Intercept recorded $20.6 million of global net Ocaliva sales in the first quarter of 2017.

Net U.S. Ocaliva sales were $19.8 million for the first quarter of 2017.

Ocaliva was approved by the U.S. Food and Drug Administration (FDA) in May 2016 for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. Intercept commercially launched Ocaliva in the United States in June 2016 and in conjunction launched Interconnect ® , a comprehensive, personalized program that connects patients with dedicated care coordinators who help them understand their disease and provides treatment support and, for eligible patients, financial assistance options.

Net ex-U.S. Ocaliva sales were $0.8 million for the first quarter of 2017.

Ocaliva was granted conditional approval by the European Commission in December 2016 for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. We commenced our European commercial launch in January 2017.

Anticipated 2017 Milestones

- PBC Program
  - Ongoing U.S. Ocaliva launch
  - Launch Ocaliva in key European markets and seek regulatory approval in other target international markets
  - Continue enrollment of Phase 4 COBALT trial evaluating the effect of Ocaliva on clinical outcomes in PBC

- NASH Program
  - Report CONTROL top-line results in mid-2017
  - Initiate Phase 3 trial in NASH patients with cirrhosis during 2H 2017

- Pipeline
  - Report AESOP top-line results in mid-2017
  - Initiate Phase 2 trial for INT-767, a dual FXR/TGR5 agonist, in NASH patients with fibrosis during 2H 2017

Personnel Update

Intercept announced today that David Ford will be appointed as Chief Human Resources Officer effective May 8, 2017.

Mr. Ford brings over 25 years of experience in a variety of Human Resources roles across the United States, Europe, Latin America and New Zealand. Prior to joining Intercept, Mr. Ford spent nearly 15 years at Sanofi where most recently he served as Vice President Human Resources for the Sanofi Genzyme global business unit and, prior to that, Vice President Human Resources for the Sanofi North American businesses. Mr. Ford joined the pharmaceutical industry in 2002 as the HR Director – United Kingdom and Republic of Ireland for Sanofi-Synthelabo. Mr. Ford holds a master's degree in business administration from INSEAD, Fontainebleau (France).

Financial Results for the Three Months Ended *March 31, 2017*

For the three months ended March 31, 2017, Intercept reported a net loss of $89.9 million. GAAP operating expense for the three months ended March 31, 2017 was $105.0 million. Non-GAAP adjusted operating expense [1] for the three months ended March 31, 2017 was $90.1 million, which excludes non-cash stock-based compensation expense of $14.1 million and depreciation expense of $0.8 million.

Revenues

Intercept recognized $20.6 million of net sales of Ocaliva for the first quarter 2017. Intercept currently recognizes revenue using the sell-through method (i.e., when its specialty pharmacies dispense Ocaliva to patients, not when products are sold to the specialty pharmacies). Revenue recognition will transition from the sell-through method to the sell-in method once a sufficient period of commercial experience has occurred to enable Intercept to estimate product returns.

[1] Adjusted operating expense, as presented above and elsewhere in this press release, is a non-GAAP financial measure. Adjusted operating expense excludes stock-based compensation and other non-cash items from GAAP operating expenses. A table reconciling historical adjusted operating expense to GAAP operating expense is included below under the heading "Reconciliation of GAAP to Non-GAAP Operating Expense."

Intercept recognized $0.4 million and $0.4 million of license revenue related to the amortization of the up-front and milestone payments under the collaboration agreement with Sumitomo Dainippon for the three months ended March 31, 2017 and 2016, respectively.

Expenses

Costs of goods sold (COGS) was negligible for the first quarter of 2017. Prior to the FDA approval of Ocaliva, Intercept had expensed costs related to the manufacturing and buildup of commercial launch supplies of OCA. Therefore, COGS was only reflective of packaging and labeling costs incurred during the period. Intercept expects COGS to remain negligible until previously expensed supplies of OCA are sold.

Selling, general and administrative expenses decreased to $61.1 million for the quarter ended March 31, 2017, down from $95.9 million for the quarter ended March 31, 2016. The decrease from the prior period was primarily driven by the one-time net expense of $45.0 million attributable to the settlement of a purported securities class action lawsuit in the quarter ended March 31, 2016, offset by expenses due to an increase in Ocaliva commercialization activities and additional personnel-related costs.

Research and development expenses increased to $43.8 million for the quarter ended March 31, 2017, up from $32.0 million for the quarter ended March 31, 2016. The increase over the prior period was primarily driven by increases in clinical development programs for OCA and infrastructure to support such programs.

Interest expense for the quarter ended March 31, 2017 was $7.2 million. The interest expense is related to the 3.25% convertible senior notes due 2023 issued in July 2016.

Cash Position

As of March 31, 2017, Intercept had cash, cash equivalents and investment securities available for sale of approximately $608.0 million, compared to $689.4 million as of December 31, 2016.

Financial guidance

Intercept continues to project non-GAAP adjusted operating expenses of $380 million to $420 million for the fiscal year ending December 31, 2017. This guidance excludes non-cash items such as stock-based compensation and depreciation. These expenses are planned to support the continued commercialization of Ocaliva in PBC in the United States and other markets, continued clinical development for OCA in PBC and NASH and the continued development of INT-767 and other pipeline programs.

Intercept anticipates that stock-based compensation expense will represent the most significant non- cash item that will be excluded in adjusted operating expenses as compared to operating expenses under GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. A reconciliation of projected operating expense calculated in accordance with GAAP to non- GAAP adjusted operating expense 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.

Conference Call on May 4 th at 8:30 a.m. ET

Intercept will hold its first quarter 2017 financial results conference call and webcast on Thursday, May 4 th at 8:30 a.m. ET. The live event will be available on the investor page of the Intercept 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 the Intercept 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 non-viral, progressive liver diseases, including primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. Founded in 2002 in New York, Intercept now has operations in the United States, Europe and Canada.

Non-GAAP Financial Measures

This press release presents adjusted operating expense, which is a non-GAAP measure, both on a historical and projected basis. Adjusted operating expense should be considered in addition to, but not as a substitute for, operating expense that Intercept prepares and announces in accordance with GAAP. Intercept excludes certain items from adjusted operating expense, such as stock-based compensation and depreciation, that management does not believe affect Intercept's basic operations and that do not meet the GAAP definition of unusual or nonrecurring items. For the quarter ended March 31, 2016, adjusted operating expense also excludes the one-time $45 million net expense for the settlement of the purported class action lawsuit.

A table reconciling historical GAAP operating expense to non-GAAP adjusted operating expense is included below under the heading "Reconciliation of GAAP to Non-GAAP Operating Expense." A reconciliation of projected operating expense calculated in accordance with GAAP to non-GAAP adjusted operating expense 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 Intercept's business. Other companies may define this measure in different ways. Intercept believes 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.

About Ocaliva ® (obeticholic acid)

Ocaliva is indicated in the United States for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP), as a surrogate endpoint which is reasonably likely to predict clinical benefit, including an improvement in liver transplant free-survival. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Intercept is currently enrolling COBALT, a Phase 4 clinical outcomes trial of Ocaliva in patients with PBC with the goal of confirming clinical benefit on a post-marketing basis.

In December 2016, Ocaliva received conditional marketing authorization in Europe for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA, conditional to the company providing further data post-approval to confirm benefit. For detailed safety information for Ocaliva (obeticholic acid) 5 mg and 10 mg tablets including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European Summary of Product Characteristics that can be found on www.ema.europa.eu.

U.S. IMPORTANT SAFETY INFORMATION

Contraindications

Ocaliva is contraindicated in patients with complete biliary obstruction.

Warnings and Precautions

Liver-Related Adverse Reactions

In two 3-month, placebo-controlled clinical trials a dose-response relationship was observed for the occurrence of liver-related adverse reactions including jaundice, ascites and primary biliary cholangitis flare with dosages of Ocaliva of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with Ocaliva.

In a pooled analysis of three placebo-controlled trials in patients with PBC, the exposure-adjusted incidence rates for all serious and otherwise clinically significant liver-related adverse reactions, and isolated elevations in liver biochemical tests, per 100 patient exposure years (PEY) were: 5.2 in the Ocaliva 10 mg group (highest recommended dosage), 19.8 in the Ocaliva 25 mg group (2.5 times the highest recommended dosage) and 54.5 in the Ocaliva 50 mg group (5 times the highest recommended dosage) compared to 2.4 in the placebo group.

Monitor patients during treatment with Ocaliva for elevations in liver biochemical tests and for the development of liver-related adverse reactions. Weigh the potential risks against the benefits of continuing treatment with Ocaliva in patients who have experienced clinically significant liver-related adverse reactions. The maximum recommended dosage of Ocaliva is 10 mg once daily. Adjust the dosage for patients with moderate or severe hepatic impairment.

Discontinue Ocaliva in patients who develop complete biliary obstruction.

Severe Pruritus

Severe pruritus was reported in 23% of patients in the Ocaliva 10 mg arm, 19% of patients in the Ocaliva titration arm and 7% of patients in the placebo arm in the POISE trial, a 12-month double- blind randomized controlled trial of 216 patients. Severe pruritus was defined as intense or widespread itching, interfering with activities of daily living, or causing severe sleep disturbance, or intolerable discomfort, and typically requiring medical interventions. In the subgroup of patients in the Ocaliva titration arm who increased their dosage from 5 mg once daily to 10 mg once daily after 6 months of treatment (n=33), the incidence of severe pruritus was 0% from months 0 to 6 and 15% from months 6 to 12. The median time to onset of severe pruritus was 11, 158 and 75 days for patients in the Ocaliva 10 mg, Ocaliva titration and placebo arms, respectively.

Management strategies include the addition of bile acid resins or antihistamines, Ocaliva dosage reduction and/or temporary interruption of Ocaliva dosing.

Reduction in HDL-C

Patients with PBC generally exhibit hyperlipidemia characterized by a significant elevation in total cholesterol primarily due to increased levels of high density lipoprotein-cholesterol (HDLC). In the POISE trial, dose-dependent reductions from baseline in mean HDL-C levels were observed at 2 weeks in Ocaliva-treated patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. At month 12, the reduction from baseline in mean HDL-C level was 19% in the Ocaliva 10 mg arm, 12% in the Ocaliva titration arm and 2% in the placebo arm. Nine patients in the Ocaliva 10 mg arm and six patients in the Ocaliva titration arm, versus three patients in the placebo arm had reductions in HDL-C to less than 40 mg/dL.

Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to Ocaliva after one year at the highest recommended dosage that can be tolerated (maximum of 10 mg once daily), and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.

Adverse Reactions

The most common adverse reactions from subjects taking Ocaliva (≥5%) were pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality and eczema.

Drug Interaction

Bile Acid Binding Resins
Bile acid binding resins such as cholestyramine, colestipol or colesevelam absorb and reduce bile acid absorption and may reduce the absorption, systemic exposure and efficacy of Ocaliva. If taking bile acid binding resins, take Ocaliva at least 4 hours before or 4 hours after (or at as great an interval as possible) taking a bile acid binding resin.

Please see the U.S. Full Prescribing Information for Ocaliva (obeticholic acid) 5 mg and 10 mg tablets.

Safe Harbor Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Intercept's financial position, including expected adjusted operating expenses; the activities anticipated to be undertaken by Intercept, including the anticipated progression of the U.S. and EU launches of Ocaliva ® in PBC; the potential approval of OCA in PBC by regulatory bodies outside of the United States and the European Union and the timelines related thereto; the timelines for access to OCA for the treatment of PBC in Europe and other jurisdictions outside the United States and timelines related thereto; the initiation, enrollment, conduct and completion of clinical trials and the timelines related thereto, including the full enrollment of the interim analysis cohort for the Phase 3 REGENERATE trial of OCA in NASH patients with liver fibrosis; the anticipated regulatory process and timetable with respect to Intercept's product candidates; the continued development of OCA and Intercept's other product candidates; and Intercept's strategic directives under the caption "About Intercept." These "forward- looking statements" are based on management's current expectations of future events and are subject to a number of important risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: Intercept's ability to successfully commercialize Ocaliva in PBC, and Intercept's ability to maintain its regulatory approval in jurisdictions in which Ocaliva is approved for use in PBC; the initiation, cost, timing, progress and results of Intercept's development activities, preclinical studies and clinical trials, including Intercept's development program in NASH; the timing of and Intercept's ability to obtain and maintain regulatory approval of OCA in PBC in countries outside the ones in which it is approved and in indications other than PBC and any other product candidates it may develop such as INT-767; conditions that may be imposed by regulatory authorities on Intercept's marketing approvals for its 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 approved products and product candidates; Intercept's plans to research, develop and commercialize its product candidates; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates; Intercept's ability to successfully commercialize OCA in indications other than PBC and its other product candidates; the size and growth of the markets for Intercept's products and product candidates and its ability to serve those markets; the rate and degree of market acceptance of any of Intercept's products, which may be affected by the reimbursement that it may receive for its products from payors; the success of competing drugs that are or become available; the election by Intercept's collaborators to pursue research, development and commercialization activities; Intercept's ability to attract collaborators with development, regulatory and commercialization expertise; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; Intercept's use of cash, short-term investments and the proceeds from the offering; Intercept's ability to attract and retain key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in our annual report on Form 10-K for the year ended December 31, 2016 filed on March 1, 2017 as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Intercept undertakes no duty to update this information unless required by law.

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Intercept Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2017	**2016**
Revenue:		
Product revenue, net	$ 20,603	$ -
Licensing revenue	445	445
Total revenue	21,048	445
Operating expenses:		
Cost of sales	97	-
Selling, general and administrative	61,082	95,865
Research and development	43,832	31,980
Total operating expenses	105,011	127,845
Operating loss	(83,963)	(127,400)
Other income (expense):		
Interest expense	(7,207)	-
Other income, net	1,240	726
	(5,967)	726
Net loss	$ (89,930)	$ (126,674)
Net loss per common and potential common share:		
Basic and diluted	$ (3.61)	$ (5.17)
Weighted average common and potential common shares outstanding:		
Basic and diluted	24,931	24,495

Condensed Consolidated Balance Sheet Information
(Unaudited)
(In thousands)

	March 31, 2017	**December 31, 2016**
Cash, cash equivalents and investment securities	$ 608,013	$ 689,385
Total assets	$ 668,020	$ 739,253
Deferred revenue, total	$ 10,028	$ 10,147
Total liabilities	$ 427,782	$ 424,321
Stockholders' equity	$ 240,238	$ 314,932

Reconciliation of GAAP to Non-GAAP Operating Expense
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2017	**2016**
Total operating expense	$ 105,011	$ 127,845
Adjustments:		
Stock based compensation	14,061	10,244
Depreciation	802	684
Litigation settlement	-	45,000
Adjusted operating expense	$ 90,148	$ 71,917