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): July 31, 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		**10001**
(Address of principal executive offices)		**(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))

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 2.02 Results of Operations and Financial Condition.

On July 31, 2017, Intercept Pharmaceuticals, Inc. (the "Company") announced its financial results for the three and six months ended June 30, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Bifurcation of Role of David Shapiro, M.D.

On July 31, 2017, the Company announced that the role of David Shapiro, M.D., the Company's Chief Medical Officer and Executive Vice President, Development, will be bifurcated into two separate roles. Dr. Shapiro will remain with the Company and continue to serve as its Chief Medical Officer. Until the Company has filled the position of head of research and development, Dr. Shapiro will continue to lead the Company's research and development organization.

Item 7.01. Regulation FD Disclosure.

On July 31, 2017, the Company announced top-line results from the Phase 2 AESOP trial in primary sclerosing cholangitis ("PSC") which evaluated the effects of 24 weeks of treatment with varying doses of obeticholic acid ("OCA") compared to placebo. This trial achieved its primary endpoint, which the Company believes establishes a proof-of-concept of OCA in a second cholestatic liver disease. The press release is attached hereto as Exhibit 99.2.

On July 31, 2017, the Company announced top-line results from the CONTROL trial which characterized the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in nonalcoholic steatohepatitis patients. This trial achieved its primary endpoint. The press release is attached hereto as Exhibit 99.3.

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. on financial results dated July 31, 2017
Exhibit 99.2	Press Release of Intercept Pharmaceuticals, Inc. on AESOP trial dated July 31, 2017
Exhibit 99.2	Press Release of Intercept Pharmaceuticals, Inc. on CONTROL trial dated July 31, 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: July 31, 2017

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

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

- ***Worldwide net Ocaliva ® (obeticholic acid or OCA) 2Q 2017 sales of $30.4 million***
- ***AESOP Phase 2 trial in patients with PSC met its primary endpoint***
- ***CONTROL trial met its objective, confirming statin co-administration with OCA reduces LDL to below baseline levels in patients with NASH***

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

NEW YORK, July 31, 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 June 30, 2017, and provided other general business updates.

"I'm very pleased with our commercial performance to date and continued 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 in the first year of our Ocaliva launch, with steady quarter over quarter growth. In Europe and Canada, we remain focused on securing reimbursement and are pleased with initial uptake in our early access markets."

"Today we also announced exciting topline results from two important Phase 2 trials," added Dr. Pruzanski. "In AESOP, our Phase 2 trial in primary sclerosing cholangitis (PSC), OCA met the primary endpoint of statistically significant reduction in alkaline phosphatase (ALP), a clinically important biomarker in this aggressive cholestatic liver disease. And in CONTROL, we achieved our objective in demonstrating that the lowest available dose of atorvastatin rapidly reverses OCA associated LDL changes to below baseline levels in nonalcoholic steatohepatitis (NASH) patients with fibrosis or cirrhosis."

Ocaliva Commercial Update

Intercept recorded $30.4 million of worldwide net Ocaliva sales in the second quarter of 2017.

Net U.S. Ocaliva sales were $27.9 million for the second 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. international Ocaliva sales were $2.5 million for the second 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. Ocaliva was granted conditional approval by Health Canada in May 2017.

Anticipated 2017 Milestones

- PBC Program
  - Continue growth in ongoing U.S. Ocaliva launch
  - Launch Ocaliva in key European markets and seek regulatory approval in other target international markets
  - Continue enrolling COBALT (Phase 4 confirmatory trial in PBC)
- NASH Program
  - Continue enrolling clinical outcomes cohort in REGENERATE (Phase 3 trial in NASH patients with fibrosis)
  - Initiate Phase 3 trial in NASH patients with cirrhosis during 2H 2017
- Pipeline
  - Define path forward for OCA in PSC
  - Initiate Phase 2 trial of INT-767 in NASH patients with fibrosis during 2H 2017

Financial Results

Three Months Ended June 30, 2017

For the three months ended June 30, 2017, Intercept reported a net loss of $86.6 million. GAAP operating expense for the three months ended June 30, 2017 was $111.4 million. Non-GAAP adjusted operating expense [1] for the three months ended June 30, 2017 was $96.0 million, which excludes non-cash stock-based compensation expense of $14.3 million and depreciation expense of $1.1 million.

Revenues

Intercept recognized $30.4 million of net sales of Ocaliva for the second 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 $5.4 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 June 30, 2017 and 2016, respectively.

Expenses

Costs of goods sold (COGS) was negligible for the second 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 increased to $66.9 million for the quarter ended June 30, 2017, up from $48.7 million for the quarter ended June 30, 2016. The increase from the prior period was primarily driven by expenses related to Ocaliva commercialization activities and additional personnel-related costs to support our commercial and international initiatives.

Research and development expenses increased to $44.2 million for the quarter ended June 30, 2017, up from $34.9 million for the quarter ended June 30, 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 June 30, 2017 was $7.3 million. The interest expense is related to the 3.25% convertible senior notes due 2023 issued in July 2016.

Six Months Ended June 30, 2017

Intercept reported a net loss of $176.5 million for the six months ended June 30, 2017, compared to a net loss of $204.0 million for the six months ended June 30, 2016. The net loss included $28.3 million and $14.5 million of non-cash stock-based compensation expenses for the six months ended June 30, 2017 and 2016, respectively, as well as a one-time net expense of $45.0 million for the settlement of the purported securities class action lawsuit in the six months ended June 30, 2016.

Cash Position

As of June 30, 2017, Intercept had cash, cash equivalents and investment securities available for sale of approximately $550.3 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, NASH and PSC 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 July 31 st at 8:30 a.m. ET

Intercept will hold its second quarter 2017 financial results conference call and webcast on Monday, July 31 st 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 six months ended June 30, 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 the utility of the results of the AESOP and CONTROL trials; 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 ex-U.S. launches of Ocaliva ® in PBC; the potential approval of OCA in PBC by regulatory bodies outside of jurisdictions in which Ocaliva is approved for use 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 initiation of the Phase 3 trial of OCA in NASH patients with cirrhosis; 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: the potential benefit and commercial potential of 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Product revenue, net	$ 30,441	$ 75	$ 51,044	$ 75
Licensing revenue	446	5,445	891	5,891
Total revenue	30,887	5,520	51,935	5,966
Operating expenses:				
Cost of sales	279	-	376	-
Selling, general and administrative	66,925	48,715	128,007	144,580
Research and development	44,192	34,900	88,024	66,880
Total operating expenses	111,396	83,615	216,407	211,460
Operating loss	(80,509)	(78,095)	(164,472)	(205,494)
Other income (expense):				
Interest expense	(7,279)	-	(14,486)	-
Other income, net	1,224	796	2,464	1,521
	(6,055)	796	(12,022)	1,521
Net loss	$ (86,564)	$ (77,299)	$ (176,494)	$ (203,973)
Net loss per common and potential common share:				
Basic and diluted	$ (3.46)	$ (3.14)	$ (7.07)	$ (8.31)
Weighted average common and potential common shares outstanding:				
Basic and diluted	25,029	24,612	24,980	24,553

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

	June 30, 2017	December 31, 2016
Cash, cash equivalents and investment securities	$ 550,305	$ 689,385
Total assets	$ 615,745	$ 739,253
Deferred revenue, total	$ 10,399	$ 10,147
Total liabilities	$ 446,041	$ 424,321
Stockholders' equity	$ 169,704	$ 314,932

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Total operating expense	$ 111,396	$ 83,615	$ 216,407	$ 211,460
Adjustments:				
Stock based compensation	14,286	4,253	28,347	14,497
Depreciation	1,072	860	1,874	1,544
Litigation settlement	-	-	-	45,000
Adjusted operating expense	$ 96,038	$ 78,502	$ 186,186	$ 150,419

Exhibit 99.2

Intercept Announces Positive Results from the Phase 2 AESOP Trial Evaluating OCA for the Treatment of Patients with Primary Sclerosing Cholangitis

- *OCA met the primary endpoint of alkaline phosphatase (ALP) reduction at 24 weeks*
- *AESOP represents a successful proof of concept for OCA in a second cholestatic liver disease*

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

NEW YORK, July 31, 2017 -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that the Phase 2 AESOP trial evaluating obeticholic acid (OCA) for the treatment of patients with primary sclerosing cholangitis (PSC) met its primary endpoint. Patients who initiated OCA 5 mg with the option to titrate to 10 mg achieved a statistically significant reduction in alkaline phosphatase (ALP) as compared to placebo ($p<0.05$).

AESOP is a 24-week, double-blind, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of OCA compared to placebo in 77 patients with PSC, followed by a two-year long term safety extension (LTSE) open-label phase which is currently ongoing. Patients were randomized to one of three treatment groups: placebo, OCA 1.5 – 3 mg, and OCA 5 – 10 mg (with dose titration occurring at the 12-week midpoint). Approximately half the patients were receiving ursodeoxycholic acid (UDCA) treatment at baseline and continued on a stable dose during the trial. The primary endpoint of the study was the change in ALP relative to placebo at week 24 for the OCA 5 – 10 mg group. Results for the intent-to-treat population are shown below.

(U/L)	Placebo (N = 25)	OCA 1.5-3 mg (N = 25)	OCA 5-10 mg (N = 26)
Mean Baseline ALP	563	423	429
Least Squares (LS) Mean Change from Baseline in ALP at Week 12	-53	-57	-135*
LS Mean Change from Baseline in ALP at Week 24	-27	-105	-110 * †
LS Mean Percent Change from Baseline at Week 24	+1%	-22%*	-22%*

* $p<0.05$

† Primary endpoint was ALP change for OCA 5-10 mg compared to placebo at week 24.

Pruritus is a common symptom of PSC and was the most common adverse event observed in the AESOP trial, occurring in 46%, 60% and 67% of patients in the placebo, OCA 1.5 – 3 mg and OCA 5 – 10 mg groups, respectively. Pruritus severity increased with OCA treatment in a dose-dependent manner. One (4%) patient in the OCA 1.5 – 3 mg group and three (12%) in the 5 – 10 mg group discontinued treatment due to pruritus compared to none with placebo.

Other treatment emergent adverse events were similar across all three arms and the proportion of patients completing the double-blind period was similar across treatment groups (84%, 76% and 81% for placebo, OCA 1.5-3 mg and OCA 5-10 mg, respectively). Of these patients, 59 of 61 (97%) chose to participate in the LTSE phase.

“Currently there are no therapies proven to be effective in treating patients with PSC, a chronic liver disease that results in significant morbidity and mortality,” said Kris V. Kowdley, MD, Director, Liver Care Network and Organ Care Research, Swedish Medical Center, Seattle, and one of the lead investigators of the trial. “The results of this Phase 2 study of OCA are encouraging because patients achieved improvement in ALP, a marker of chronic cholestasis. There is a pressing need for innovation in this disease and, given these results, additional studies are warranted to better define the role of OCA as a treatment for PSC.”

“These results provide proof of concept for OCA in a second cholestatic liver disease with a very high unmet need,” said David Shapiro, M.D., Chief Medical Officer of Intercept. “We look forward to sharing the complete results from AESOP with the hepatology community at an upcoming scientific congress. We believe these data warrant further investigation and look forward to speaking with PSC thought leaders and regulators to help inform our future development plans."

Conference Call on July 31 st at 8:30 a.m. ET

Intercept will discuss the AESOP results during its second quarter 2017 financial results conference call and webcast on July 31 st at 8:30 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 AESOP

AESOP is a Phase 2 randomized, double-blind, placebo-controlled, dose-finding evaluation of the efficacy and safety of 24 weeks of treatment with obeticholic acid (OCA) compared to placebo in 77 patients with PSC. The primary endpoint of the AESOP trial is the LS mean change in serum alkaline phosphatase (ALP) levels, as compared to placebo. Patients with well-controlled irritable bowel disease (IBD) at baseline were permitted to enroll in the AESOP trial and patients receiving ursodeoxycholic acid (UDCA) treatment at baseline (approximately 50% of patients) were permitted to continue on a stable dose.

About Primary Sclerosing Cholangitis

Primary sclerosing cholangitis (PSC) is a rare, life-threatening, chronic cholestatic liver disease characterized by progressive destruction of bile ducts that leads to the development of cirrhosis and end-stage liver disease or cancer in a majority of patients. [1-4] There are no approved therapies for PSC [5] , and estimated survival time from PSC diagnosis to death or liver transplant is 14.5 years. [6] Approximately 65% of PSC patients are male [4] , and 60%-80% of patients have concomitant inflammatory bowel disease (IBD), most often ulcerative colitis. [4,5,7] Although it is a rare disease, PSC is the seventh leading indication for liver transplant in adults in the United States. [8,9]

About Intercept

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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 the epidemiology and prevalence of PSC, the potential utility of the endpoints used in the AESOP trial, the potential of OCA to treat patients with PSC , and our 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: the potential benefit and commercial potential of 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; 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 its products and 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 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 third-party suppliers and manufacturers; 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; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, revenues and capital requirements and the accuracy thereof; Intercept's use of cash and short-term investments; 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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CONTROL Trial Shows Statin Therapy Reversed LDL Increases to Below Baseline Levels in NASH Patients Treated with OCA

- *Low dose atorvastatin rapidly reversed OCA associated LDL changes*

Conference call scheduled for 8:30 am ET

NEW YORK, July 31, 2017 -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced results from CONTROL, a placebo-controlled trial to prospectively characterize the lipid metabolic effects of obeticholic acid (OCA) and concomitant statin administration in patients with nonalcoholic steatohepatitis (NASH) with fibrosis or cirrhosis. The CONTROL trial met its primary objective by showing that newly initiated treatment with atorvastatin rapidly reversed OCA-associated increases in LDL to below baseline levels. Most of the effect was observed four weeks after initiation of the lowest available dose of atorvastatin and was sustained throughout the study period.

CONTROL is a 16-week double-blind, placebo-controlled, dose-ranging study of 84 NASH patients with fibrosis and compensated cirrhosis, followed by a two-year long term safety extension (LTSE) open label phase which is currently ongoing. Lipid changes were assessed every four weeks over the course of the double-blind phase. Details of the study design are as follows:

- Statin-naïve or washout patients were randomized to receive one of three doses of OCA (5 mg, 10 mg or 25 mg) or placebo.
- At week four, the lowest approved dose of atorvastatin (10 mg) was added in all patients.
- At week eight, patients were titrated to the next highest prescribed dose of atorvastatin (20 mg).
- At week 12, further titration of atorvastatin (up to 40 mg) was permitted at investigators' discretion.

The study was designed to measure treatment differences within each group relative to baseline. The intent-to-treat (ITT) analysis is shown below and includes all patients who received at least one dose of study medication.

At week four, mean LDL levels increased in each of the OCA treatment groups, while remaining relatively unchanged in the placebo group. The addition of 10 mg of atorvastatin rapidly reversed mean LDL to below baseline levels in all OCA treatment groups at the first assessed time point (week eight), and this effect was sustained through week 16. The observed mean LDL reductions in the OCA groups were approximately 40 – 45 mg/dL while placebo was 48 mg/dL.

(mg/dL)	Placebo (N=21)	OCA 5 mg (N=20)	OCA 10 mg (N=21)	OCA 25 mg (N=22)
Mean LDL at Baseline	118	135	122	126
Mean LDL at Week 4	113	153	141	158
Mean LDL at Week 8 (+atorvastatin 10 mg)	75	96	91	93
Mean LDL at Week 16 (+ atorvastatin 10 – 40 mg)	70	95	82	85
Mean LDL Change from Baseline at Week 16	-48	-40	-40	-45

The primary efficacy analysis was based on the efficacy evaluable (EE) population, defined as those patients who completed the double-blind phase and received all doses of OCA and atorvastatin (n=67). The overall results for the ITT population were similar to those in the EE population.

Lipid sub-fraction analysis showed that OCA-related increases in LDL were primarily driven by an increase in large buoyant LDL particles rather than small dense LDL particles. Changes in other lipid parameters were similar to those previously reported with OCA therapy in patients with NASH.

Mild to moderate pruritus was the most common adverse event in patients treated with OCA, occurring in 5%, 5%, 10% and 55% in placebo, 5 mg, 10 mg and 25 mg OCA groups, respectively. Two patients discontinued treatment in the 25 mg OCA treatment arm due to pruritus. Co-administration of atorvastatin and OCA was generally well tolerated and did not result in any unexpected safety observations.

The proportion of patients completing the double-blind period was similar across treatment groups (100%, 95%, 90% and 91% for placebo, OCA 5 mg, OCA 10 mg and OCA 25 mg, respectively). Of these patients, 77 of 79 (97%) chose to participate in the LTSE phase.

During the ongoing LTSE phase, there has been one patient death due to acute renal and liver failure. While Intercept determined it could not be ruled out that this was possibly related to treatment, the principal investigator and the independent Data Safety Monitoring Committee determined the death was unlikely related to OCA.

“The majority of NASH patients in CONTROL were statin eligible according to AHA treatment guidelines, and statins are recommended for patients with NASH in both AASLD and EASL treatment guidelines,” said David Shapiro, M.D., Chief Medical Officer of Intercept. “In CONTROL, we have shown that statin therapy can have an important role in managing LDL when co-administered with OCA in NASH patients with fibrosis and cirrhosis.”

Conference Call on July 31 st at 8:30 a.m. ET

Intercept will discuss the CONTROL results during its second quarter 2017 financial results conference call and webcast on July 31 st at 8:30 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 CONTROL

CONTROL is a randomized, double-blind, placebo-controlled trial to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. CONTROL enrolled 84 NASH patients who were naïve to statin therapy or underwent a statin washout, and includes a 16-week double-blind phase followed by an optional two-year long-term safety extension phase.

About 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. There are currently no medications approved for the treatment of NASH. The proportion of liver transplants attributable to NASH has increased rapidly in past years and by 2020 the disease is projected to become the leading indication for liver transplant.

About Intercept

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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 the effective management of LDL increases in NASH from OCA treatment with the use of statins, the potential utility of the results from CONTROL, the prevalence of NASH and NAFLD, the association of type 2 diabetes and fibrosis with increased risk in NASH patients, the potential of OCA to treat patients with NASH , and our 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: the potential benefit and commercial potential of 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; 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 its products and 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 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 third-party suppliers and manufacturers; 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; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, revenues and capital requirements and the accuracy thereof; Intercept's use of cash and short-term investments; 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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