UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

RAKESH CHAUHAN, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. INTERCEPT PHARMACEUTICALS, INC., MARK PRUZANSKI, and SANDIP S. KAPADIA, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff Rakesh Chauhan ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Intercept securities

between September 28, 2019 and October 7, 2020, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Intercept is a biopharmaceutical company that focuses on the development and commercialization of therapeutics to treat progressive non-viral liver diseases in the U.S.

3. Intercept's lead product candidate is Ocaliva (obeticholic acid ("OCA")), a farnesoid X receptor agonist used for the treatment of primary biliary cholangitis ("PBC"), a rare and chronic liver disease, in combination with ursodeoxycholic acid in adults. The Company is also developing OCA for various other indications, including nonalcoholic steatohepatitis ("NASH").

4. In 2016, the U.S. Food and Drug Administration ("FDA") granted accelerated approval of Ocaliva for treating PBC.

5. Then, in late 2017, both Intercept and the FDA issued warnings concerning the risk of overdosing patients with the drug, and multiple reports of severe liver injuries and deaths linked with its use.

6. Despite these concerns, Defendants continued to tout Ocaliva sales and purported benefits, and its potential indication for treating various other medical conditions. For example, just two years later, in September 2019, Intercept submitted a New Drug Application ("NDA") to the FDA for OCA to treat patients with liver fibrosis due to NASH.

7. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically,

Defendants made false and/or misleading statements and/or failed to disclose that: (i) Defendants downplayed the true scope and severity of safety concerns associated with Ocaliva's use in treating PBC; (ii) the foregoing increased the likelihood of an FDA investigation into Ocaliva's development, thereby jeopardizing Ocaliva's continued marketability and the sustainability of its sales; (iii) any purported benefits associated with OCA's efficacy in treating NASH were outweighed by the risks of its use; (iv) as a result, the FDA was unlikely to approve the Company's NDA for OCA in treating patients with liver fibrosis due to NASH; and (v) as a result of all the foregoing, the Company's public statements were materially false and misleading at all relevant times.

8. On May 22, 2020, Intercept reported that the FDA "has notified Intercept that its tentatively scheduled June 9, 2020 advisory committee meeting (AdCom) relating to the company's [NDA] for [OCA] for the treatment of liver fibrosis due to [NASH] has been postponed" to "accommodate the review of additional data requested by the FDA that the company intends to submit within the next week."

9. On this news, Intercept's stock price fell $11.18 per share, or 12.19%, to close at $80.51 per share on May 22, 2020.

10. On June 29, 2020, Intercept issued a press release announcing that the FDA had issued a Complete Response Letter ("CRL") rejecting the Company's NDA for Ocaliva for the treatment of liver fibrosis due to NASH. According to that press release, "[t]he CRL indicated that, based on the data the FDA has reviewed to date," the FDA "has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH." The press release further advised, among other things,

that the "[t]he FDA recommends that Intercept submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue."

11. On this news, Intercept's stock price fell $30.79 per share, or 39.73%, to close at $46.70 per share on June 29, 2020.

12. Then, on October 8, 2020, news outlets reported that Intercept was "facing an investigation from the [FDA] over the potential risk of liver injury in patients taking Ocaliva, [Intercept's] treatment for primary biliary cholangitis, a rare, chronic liver disease."

13. On this news, Intercept's stock price fell $3.30 per share, or 8.05%, to close at $37.69 per share on October 8, 2020.

14. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

15. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

17. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), as the alleged misstatements entered and the subsequent damages took place in this Judicial District. Pursuant to Intercept's most recent annual report on Form 10-K, the number of shares of the Company's common stock outstanding as of

December 31, 2019 was 32,853,066. Intercept's common stock trades on the Nasdaq Global Select Market ("NASDAQ"). Accordingly, there are presumably hundreds, if not thousands, of investors in Intercept's securities located within the U.S., some of whom undoubtedly reside in this Judicial District.

18. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

19. Plaintiff, as set forth in the attached Certification, acquired Intercept securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

20. Defendant Intercept is a Delaware corporation with principal executive offices located at 10 Hudson Yards, 37th Floor, New York, New York 10001. Intercept's common stock trades in an efficient market on the NASDAQ under the symbol "ICPT."

21. Defendant Mark Pruzanski, M.D. ("Pruzanski") is one of Intercept's co-founders, and has served as the Company's President, Chief Executive Officer, and a member of the Company's Board of Directors since Intercept's inception.

22. Defendant Sandip S. Kapadia ("Kapadia") has served as Intercept's Chief Financial Officer and Treasurer at all relevant times.

23. Defendants Pruzanski and Kapadia are sometimes referred to herein as the "Individual Defendants."

24. The Individual Defendants possessed the power and authority to control the contents of Intercept's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Intercept's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Intercept, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

25. Intercept is a biopharmaceutical company that focuses on the development and commercialization of therapeutics to treat progressive non-viral liver diseases in the U.S.

26. Intercept's lead product candidate is Ocaliva (OCA), a farnesoid X receptor agonist used for the treatment of PBC, a rare and chronic liver disease, in combination with ursodeoxycholic acid in adults. The Company is also developing OCA for various other indications, including NASH.

27. In May 2016, Intercept announced that the FDA had approved Ocaliva for the treatment of patients with PBC, granting the drug accelerated approval for that indication.

28. Then, in late 2017, both Intercept and the FDA issued warnings concerning the risk of overdosing patients with the drug, and multiple reports of severe liver injuries and deaths linked to its use. For example, in September 2017, Intercept issued a letter warning physicians against

overdosing patients with Ocaliva, advising them that the drug has been tied to liver injuries and death among patients suffering from PBC. The FDA also issued a safety announcement later in September 2017 entitled "FDA Drug Safety Communication: FDA warns about serious liver injury with Ocaliva for rare chronic liver disease," warning doctors after reports of multiple deaths linked to the drug.

29. Despite these concerns, Defendants continued to tout Ocaliva sales and OCA's purported benefits, and its potential indication for treating various other medical conditions. For example, just two years later, in September 2019, Intercept submitted an NDA to the FDA for OCA to treat patients with liver fibrosis due to NASH.

Materially False and Misleading Statements Issued During the Class Period

30. The Class Period begins on September 28, 2019. On September 27, 2019, during after-market hours, Intercept issued a press release touting that it had submitted an NDA to the FDA for OCA to treat patients with liver fibrosis due to NASH (the "September 2019 Press Release"). That press release further touted, in relevant part, that "[t]he submission is based on positive interim analysis results from the pivotal Phase 3 REGENERATE study in patients with liver fibrosis due to NASH"; that, "[i]n the study, OCA 25 mg achieved its primary endpoint by demonstrating robust improvement in liver fibrosis (by ≥1 stage) without worsening of NASH at 18 months (p=0.0002 vs placebo)"; that "OCA is the only investigational therapy to meet the primary endpoint of a Phase 3 study in patients with NASH and is the only such therapy that the FDA has designated a Breakthrough Therapy for NASH with fibrosis"; and that, "[a]s such, Intercept has requested a Priority Review for the NDA, which, if granted, would result in an anticipated six-month review period."

31. The September 2019 Press Release also quoted Defendant Pruzanski, who touted, in relevant part, that Defendants' "submission of the first NDA for the treatment of fibrosis due to NASH is a very important milestone for the field and the culmination of more than a decade of hard work," and that Defendants "look forward to continuing to work with the FDA through the NDA review period and believe that, if approved, OCA has the potential to become an essential treatment for people living with advanced fibrosis due to NASH."

32. On November 25, 2019, Intercept issued a press release touting that the FDA had accepted its NDA for OCA seeking accelerated approval for the treatment of liver fibrosis due to NASH, and had granted the NDA priority review (the "November 2019 Press Release"). That press release reiterated substantively the same statements as referenced in ¶ 30, *supra*, touting the NDA submission and the study results that supported it, while further representing, in relevant part, that "[t]he FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of March 26, 2020 for the NDA," and that, "[i]n the NDA filing acceptance notification letter, the FDA also indicated that it currently plans to hold an advisory committee meeting to discuss the application."

33. Additionally, the November 2019 Press Release quoted Defendant Pruzanski, who touted, in relevant part, that, "[i]f approved, OCA would be the first available therapy for patients with fibrosis due to NASH, a condition that is expected to become the leading cause of liver transplant in the U.S. as soon as 2020"; that "[i]t is exciting to achieve this critical regulatory milestone that brings [Defendants] one step closer to [their] goal of delivering the first approved therapeutic to those living with this devastating disease"; that, "[f]rom OCA's prior designation as a Breakthrough Therapy to the grant of priority review today, [Defendants'] work

with FDA continues to set an important precedent for the field"; and that Defendants "look forward to working with the [FDA] over the coming months as they review the first NDA in NASH."

34. On February 25, 2020, Intercept issued a press release announcing, among other things, its fourth quarter and full year 2019 financial results and certain business updates (the "February 2020 Press Release"). That press release quoted Defendant Pruzanski, who touted, in relevant part, that "2019 was a pivotal year for Intercept given the positive results in [Defedants'] Phase 3 REGENERATE study in liver fibrosis due to NASH and [their] subsequent filing for approval in both the U.S. and Europe"; that, "[a]t the same time, [Defendants'] commercial team's outstanding execution helped [them] deliver net sales of approximately $250 million for Ocaliva in 2019 and they continue to reach more PBC patients globally"; and that, "[a]s [Defendants] enter 2020, [they] are focused on successfully completing the U.S. regulatory process and ensuring full readiness to launch the first approved therapy for patients suffering from fibrosis due to NASH."

35. With respect to Intercept's sales of Ocaliva, the February 2020 Press Release touted, in relevant part, that "[f]ull year 2019 Ocaliva net sales were $249.6 million, which represented growth of 40% as compared to the prior year"; that "Ocaliva net sales in 2019 were comprised of U.S. net sales of $187.5 million and ex-U.S. net sales of $62.1 million, as compared to U.S. net sales of $140.8 million and ex-U.S. net sales of $37.0 million in 2018"; that Defendants "recognized $70.3 million of Ocaliva net sales in the fourth quarter of 2019, which represented growth of 33% as compared to the prior year quarter"; and that "Ocaliva net sales in the fourth quarter of 2019 were comprised of U.S. net sales of $53.5 million and ex-U.S. net sales of $16.8 million, as compared to U.S. net sales of $41.1 million and ex-U.S. net sales of $11.8 million in the prior year quarter"; all of which indicated to investors the sustainability of Intercept's revenues derived from its sales of the drug.

36. That same day, Defendants filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2019 (the "2019 10-K"). With respect to Intercept's sales of Ocaliva, the 2019 10-K touted, in relevant part, that "[f]or the years ended December 31, 2019 and 2018, product revenue, net was comprised of U.S. Ocaliva net sales of $187.5 million and $140.8 million, respectively, and ex-U.S. Ocaliva net sales of $62.1 million and $37.0 million, respectively"; and that "[f]or the years ended December 31, 2018 and 2017, product revenue, net was comprised of U.S. Ocaliva net sales of $140.8 million and $115.8 million, respectively, and ex-U.S. Ocaliva net sales of $37.0 million and $13.4 million, respectively"; further indicating to investors the sustainability of the Company's revenues derived from its sales of the drug.

37. The 2019 10-K also discussed the Ocaliva-related deaths in PBC patients reported by Intercept and the FDA in 2017, while simultaneously downplaying the continued risk of treatment with the drug, namely, by shifting the blame onto improper prescription practices by healthcare providers. In this regard, the 2019 10-K stated, in relevant part, that "[i]n the course of [Defendants'] post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment"; that "[i]n an analysis performed by [Defendants] and in consultation with the FDA, [Defendants] concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients"; that, "[a]s a result, in September 2017, [Defendants] issued a Dear Health Care Provider ('DHCP') letter"; that "the FDA also subsequently issued its own drug safety communication to reinforce recommended label dosing"; that "[b]oth communications remind healthcare providers of the importance of the recommended reduced dosing of Ocaliva in PBC patients with moderate or severe hepatic impairment, while reiterating

the importance of monitoring PBC patients for progression of their disease and the occurrence of liver-related adverse reactions"; and that, "[i]n addition to the DHCP letter, [Defendants] took actions to enhance education about appropriate use of Ocaliva," which included "reeducating physicians on the label, with a focus on ensuring appropriate dosing for patients with moderate or severe hepatic impairment; enhancing monitoring of patients for liver-related adverse reactions; and adjudicating reported cases of serious liver injury, including in patients with no or mild hepatic impairment."

38. The 2019 10-K further represented that, "[i]n February 2018, [Defendants] announced that the Ocaliva label in the United States had been updated by the FDA to include a boxed warning and a dosing table that reinforced the then-existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis"; that, "[i]n addition, the FDA issued an updated drug safety communication to accompany the revised label"; and that Defendants "remain focused on the safety of all of the patients using Ocaliva within and outside of [their] ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis."

39. Additionally, the 2019 10-K touted the regulatory hurdles Defendants had overcome, and milestones they had met, in seeking to commercialize OCA in the U.S. for treating patients with liver fibrosis due to NASH, stating, in relevant part, that "OCA has received breakthrough therapy designation from the FDA for the treatment of NASH patients with liver fibrosis"; that, "[i]n September 2019, [Defendants] submitted a NDA seeking accelerated approval of OCA for liver fibrosis due to NASH in the United States"; that "[t]he FDA subsequently accepted [Defendants'] NDA for filing and granted a priority review designation for OCA for liver

fibrosis due to NASH"; and that "[t]he FDA has set a PDUFA target action date of June 26, 2020 for the completion of its review of [the] NDA and has notified [Defendants] that it has tentatively scheduled an advisory committee meeting relating to [the] NDA for April 22, 2020."

40. With respect to OCA's purported benefits and safety profile for treating patients with liver fibrosis due to NASH, the 2019 10-K represented, *inter alia*, that, "[i]n February 2019, [Defendants] announced topline results from the planned 18-month interim analysis of [the] pivotal Phase 3 clinical trial of OCA in patients with liver fibrosis due to NASH, known as the REGENERATE trial"; that, "[i]n the primary efficacy analysis, once-daily OCA 25 mg met the primary endpoint agreed with the FDA of fibrosis improvement by at least one stage with no worsening of NASH at the planned 18-month interim analysis"; that "[a]dverse events were generally mild to moderate in severity and the most common were consistent with the known profile of OCA."

41. With specific respect to safety signals observed in the REGENERATE trial, the 2019 10-K represented, *inter alia*, that "[t]he 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"; that "[t]here were 3 deaths (2 in placebo: bone cancer and cardiac arrest, 1 in OCA 25 mg: glioblastoma) and none were considered related to treatment"; that "[t]he most common adverse event reported was dose-related pruritus (19% in placebo, 28% in OCA 10 mg and 51% in OCA 25 mg)"; that "[t]he 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)"; that "[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)"; and that, "[a]ccording to the clinical study protocol, investigator assessed severe pruritus mandated treatment discontinuation."

42. In this same vein, the 2019 10-K further represented that, "[c]onsistent with observations from previous NASH studies, OCA treatment was associated with an increase in low density lipoprotein ('LDL') cholesterol, with a peak increase of 22.6 mg/dL at four weeks and subsequently reversing and approaching baseline at month 18 (4.0 mg/dL increase from baseline)"; that "[s]tatin therapy was initiated in 10% of placebo patients and 24% of each OCA treatment arm"; that, "[a]mong OCA patients who initiated statins, LDL cholesterol increases reversed and fell to below baseline levels by month 6"; that "[t]riglycerides rapidly and continually decreased in the OCA treatment arms through month 18"; that "[t]here 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)"; that, "[i]n patients with type 2 diabetes, OCA treatment was associated with an early transient increase in fasting glucose and hemoglobin A1c with return to levels similar to placebo by month 6"; that "[n]o clinically meaningful changes were noted in non-diabetic patients"; that, "[w]ith 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"; and that, "[w]hile 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."

43. Additionally, the 2019 10-K contained generic, boilerplate representations concerning risks associated with the negative side effects of Intercept's OCA-based candidates and products, including Ocaliva, stating, *inter alia*, that "[u]nforeseen side effects from any of [Defendants'] product candidates, including OCA, could arise either during clinical development or, if approved, after the approved product has been marketed"; that "[s]erious adverse events,

including deaths, in patients taking OCA have occurred in clinical trials and in the post-marketing setting, and [Defendants] cannot assure you that additional serious adverse events in patients taking OCA in clinical trials or in the post-marketing setting will not occur"; and that "[t]he most common side effects observed in clinical trials of OCA for PBC were pruritus, fatigue, headaches, nausea, constipation and diarrhea." Plainly, this risk warning was a generic, catch-all provision that was not tailored to Intercept's actual known risks regarding the probability of the FDA rejecting the NDA for OCA for treating liver fibrosis due to NASH because the treatment's benefits failed to outweigh its risks, nor the foreseeability of an FDA investigation into liver disease associated with Ocaliva's use in treating PBC.

44. The 2019 10-K also contained generic, boilerplate representations regarding the risk that sales of Ocaliva may be adversely affected by safety and labeling changes required by the FDA, stating, in relevant part, that the "events [described in ¶¶ 37-38, *supra*, concerning the Ocaliva-related deaths and actions taken in 2017 and 2018], the revised label, any future label changes that may be required by the FDA or other relevant regulatory authorities and any safety concerns associated with Ocaliva, perceived or real, may materially and adversely affect [Defendants'] Ocaliva commercialization efforts and, consequently, [Intercept's] financial condition and results of operations." Plainly, this risk warning, too, was a generic, catch-all provision that was not tailored to Intercept's actual known risks regarding the foreseeability of an FDA investigation into liver disease associated with Ocaliva's use in treating PBC

45. Appended as an exhibit to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002, wherein the Individual Defendants certified that the 2019 10-K "fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act" and that

"[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

46. On May 11, 2020, Intercept issued a press release announcing its first quarter 2020 financial results and certain business updates (the "May 2020 Press Release"). That press release quoted Defendant Pruzanski, who touted, in relevant part, that "[i]n the first quarter [Defendants] saw better than anticipated Ocaliva net sales in [the] PBC business"; that these net sales "were supported by continued strong total prescription trends and modestly higher than expected inventory demand towards the end of the quarter as certain customers responded to the uncertainty of the early COVID-19 period"; that Defendants "have taken a number of important steps intended to [*inter alia*] . . . advance [their] NASH launch preparation activities, all while continuing to deliver solid results"; and that Defendants "remain very focused on the goal of bringing the first approved therapy to patients with advanced fibrosis due to NASH and expect to be well prepared for [the] upcoming FDA advisory committee meeting, which is tentatively scheduled for June 9, 2020."

47. Additionally, the May 2020 Press Release touted, in relevant part, that "Ocaliva net sales in the first quarter of 2020 were comprised of U.S. net sales of $50.8 million and ex-U.S. net sales of $21.9 million, as compared to U.S. net sales of $38.0 million and ex-U.S. net sales of $13.8 million in the prior year quarter," and that "[t]otal revenue in the first quarter of 2019 included approximately $0.4 million of licensing revenue," further indicating to investors the sustainability of the Company's revenues derived from its sales of Ocaliva.

48. The statements referenced in ¶¶ 30-47 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically,

Defendants made false and/or misleading statements and/or failed to disclose that: (i) Defendants downplayed the true scope and severity of safety concerns associated with Ocaliva's use in treating PBC; (ii) the foregoing increased the likelihood of an FDA investigation into Ocaliva's development, thereby jeopardizing Ocaliva's continued marketability and the sustainability of its sales; (iii) any purported benefits associated with OCA's efficacy in treating NASH were outweighed by the risks of its use; (iv) as a result, the FDA was unlikely to approve the Company's NDA for OCA in treating patients with liver fibrosis due to NASH; and (v) as a result of all the foregoing, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

49. On May 22, 2020, during pre-market hours, Intercept issued a press release providing a regulatory update concerning the Company's NDA for OCA for treating liver fibrosis due to NASH (the "May 2020 Press Release"). Specifically, that press release advised "that based on discussions earlier this week, the [FDA] has notified Intercept that its tentatively scheduled June 9, 2020 advisory committee meeting (AdCom) relating to the company's [NDA] for [OCA] for the treatment of liver fibrosis due to [NASH] has been postponed"; that "[t]he postponement will accommodate the review of additional data requested by the FDA that the company intends to submit within the next week"; that "[t]he FDA has indicated that it will reach out to Intercept in the near future with a new proposed AdCom date"; and that "Intercept now anticipates that the FDA's review of its NDA will extend beyond the Prescription Drug User Fee Act (PDUFA) target action date of June 26, 2020."

50. On this news, Intercept's stock price fell $11.18 per share, or 12.19%, to close at $80.51 per share on May 22, 2020. Despite this decline in the Company's stock price, Intercept's

securities continued to trade at artificially inflated prices throughout the Class Period as a result of Defendants' continued misrepresentations or omissions regarding the NDA for OCA for treating fibrosis due to NASH, as well as the true scope and severity of safety concerns with Ocaliva's use in treating PBC, which jeopardized Ocaliva's continued market acceptance and the sustainability of its sales.

51. For example, the May 2020 Press Release quoted Defendant Pruzanski, who assured investors that "[w]hile this delay was unanticipated, following [Defendants'] most recent dialogue with the FDA [Defendants] believe that the additional data being submitted will be important in facilitating a more informed discussion at the AdCom," and that Defendants "remain confident in [their] NDA submission and look forward to continuing to work with the FDA to bring the first treatment to patients with advanced fibrosis due to NASH."

52. Then, on June 29, 2020, during pre-market hours, Intercept issued a press release announcing that the FDA had issued a CRL rejecting the Company's NDA for Ocaliva for the treatment of fibrosis due to NASH (the "June 2020 Press Release"). According to that press release, "[t]he CRL indicated that, based on the data the FDA has reviewed to date," the FDA "has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH." The press release further advised, among other things, that the "[t]he FDA recommends that Intercept submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue."

53. Additionally, the June 2020 Press Release quoted Defendant Pruzanski, who admonished the FDA's purportedly "incomplete" review of the NDA submission, stating, in relevant part, that "[a]t no point during the review did the FDA communicate that OCA was not approvable on an accelerated basis"; that Defendants "strongly believe that the totality of data submitted to date both meet the requirements of the [FDA]'s own guidance and clearly support the positive benefit-risk profile of OCA"; that Defendants "are disappointed to see the determination the [FDA] has reached based on an apparently incomplete review, and without having provided medical experts and patients the opportunity to be heard at the anticipated Adcom on the merits of OCA, which is a designated Breakthrough Therapy"; that "[t]he FDA has progressively increased the complexity of the histologic endpoints, creating a very high bar that only OCA has so far met in a pivotal Phase 3 study"; that, "[o]n behalf of the hepatology community, [Defendants] are very concerned that the [FDA]'s apparently still evolving expectations will make it exceedingly challenging to bring innovative therapies to NASH patients with high unmet medical need"; and that Defendants "plan to meet as soon as possible with the FDA to review the CRL and discuss options for an efficient path forward to approval."

54. On this news, Intercept's stock price fell $30.79 per share, or 39.73%, to close at $46.70 per share on June 29, 2020. Despite this decline in the Company's stock price, Intercept's securities continued to trade at artificially inflated prices throughout the Class Period as a result of Defendants' continued misrepresentations or omissions regarding the true scope and severity of safety concerns with Ocaliva's use in treating PBC, which jeopardized Ocaliva's continued market acceptance and the sustainability of its sales

55. For example, on August 10, 2020, during pre-market hours, Intercept issued a press release announcing, among other things, its second quarter 2020 financial results and certain

business updates (the "August 2020 Press Release"). That press release quoted Defendant Pruzanski, who touted, in relevant part, that Defendants' "PBC business achieved its highest quarterly net sales to date in the second quarter"; that Defendants "plan to continue to invest in [their] growing PBC business"; and that Defendants "anticipate that [their] Ocaliva net sales, together with the announced reduction in [their] 2020 non-GAAP adjusted operating expense guidance, will help to ensure that [Defendants] are financially well positioned to support the path forward in NASH."

56. With respect to Intercept's sales of Ocaliva, the August 2020 Press Release touted, in relevant part, that Defendants "recognized $77.2 million of Ocaliva net sales in the second quarter of 2020, as compared to $65.9 million in the prior year quarter"; that "Ocaliva net sales in the second quarter of 2020 were comprised of U.S. net sales of $59.6 million and ex-U.S. net sales of $17.6 million, as compared to U.S. net sales of $50.7 million and ex-U.S. net sales of $15.2 million in the prior year quarter"; and that Defendants "are announcing 2020 Ocaliva net sales guidance of $300 million to $320 million, and lowering [the] previously announced 2020 non-GAAP adjusted operating expenses guidance by $100 million to a range of $460 million to $500 million from a range of $560 million to $600 million"; further indicating to investors the sustainability of the Company's revenues derived from its sales of the drug.

57. The statements referenced in ¶¶ 51-56 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Defendants downplayed the true scope and severity of safety concerns with Ocaliva's use in treating PBC; (ii) the foregoing increased the likelihood of an FDA investigation into Ocaliva's development,

thereby jeopardizing Ocaliva's continued marketability and the sustainability of its sales; and (iii) as a result of the foregoing, the Company's public statements were materially false and misleading at all relevant times.

The Truth Fully Emerges

58. On August 10, 2020, during after-market hours, Intercept filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2020 (the "2Q20 10-Q"). Rather than by press release (much less the August 2020 Press Release issued earlier that day touting sales of Ocaliva to the PBC community) or in a similarly conspicuous manner, Defendants disclosed in the 2Q20 10-Q, a 97-page document, in the middle of just two paragraphs, in plain text, unadorned by emphasis, in just two out of its over sixty risk disclosures, that the FDA had initiated an investigation into whether Ocaliva caused liver disease, rather than treating it, stating:

> ***The FDA has notified us that in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal regarding liver disorder for Ocaliva which the FDA classified as a potential risk.*** Pursuant to FDA guidance, this does not mean that the FDA has concluded that the drug has the listed risk or that the FDA has identified a causal relationship between Ocaliva and the potential risk. As part of our routine pharmacovigilance efforts, we have worked with the FDA to reconcile our internal safety database with the FDA Adverse Event Reporting System database and have been conducting additional signaling analysis and monitoring activities. Any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and approved products, including Ocaliva, and materially and adversely affect our business.

(Emphasis added.)

59. Foreseeably, given the lack of due regard and transparency with respect to this disclosure, following Defendants' filing of the 2Q20 10-Q, Intercept's stock price fell only $0.25 per share, or 0.47%, to close at $52.58 per share on August 11, 2020.

60. It was not until nearly two months later, on October 8, 2020, during intraday trading hours, that news outlets and the market truly absorbed the information that Intercept was "facing an investigation from the [FDA] over the potential risk of liver injury in patients taking Ocaliva, [Intercept's] treatment for primary biliary cholangitis, a rare, chronic liver disease." For example, *Seeking Alpha*, an investor news resource, reported that day that "Intercept . . . is down on 60% higher volume in reaction to a report that the FDA is investigating a potential safety signal related to Ocaliva (obeticholic acid), specifically, the risk of liver injury." The report at issue, titled "FDA investigating whether Intercept Pharma drug is tied to potential liver injury risk," published earlier that day by *STAT*, an outlet for in-depth biotech, pharma, policy, and life science coverage and analysis, stated, in relevant part, that the FDA "is evaluating a potential risk of liver injury in patients who take the Intercept Pharmaceuticals drug Ocaliva to treat a certain type of liver disease, and that "[t]he FDA's inquiry into Ocaliva began in May and could take one year to complete, Intercept spokesperson Christopher Frates told STAT."

61. On this news, Intercept's stock price fell $3.30 per share, or 8.05%, to close at $37.69 per share on October 8, 2020.

62. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

63. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Intercept securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein,

the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

64. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Intercept securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Intercept or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

65. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

66. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

67. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Intercept;

- whether the Individual Defendants caused Intercept to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Intercept securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

68. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

69. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Intercept securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Intercept securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

70. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

71. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

72. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

73. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

74. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Intercept securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Intercept

securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

75. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Intercept securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Intercept's finances and business prospects.

76. By virtue of their positions at Intercept, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

77. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Intercept, the Individual Defendants had knowledge of the details of Intercept's internal affairs.

78. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Intercept. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Intercept's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Intercept securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Intercept's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Intercept securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

79. During the Class Period, Intercept securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Intercept securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Intercept securities was substantially lower than the prices paid by Plaintiff and the other

members of the Class. The market price of Intercept securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

80. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

81. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

82. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

83. During the Class Period, the Individual Defendants participated in the operation and management of Intercept, and conducted and participated, directly and indirectly, in the conduct of Intercept's business affairs. Because of their senior positions, they knew the adverse non-public information about Intercept's misstatement of income and expenses and false financial statements.

84. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Intercept's financial condition and results of operations, and to correct promptly any public statements issued by Intercept which had become materially false or misleading.

85. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Intercept disseminated in the marketplace during the Class Period concerning Intercept's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Intercept to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Intercept within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Intercept securities.

86. Each of the Individual Defendants, therefore, acted as a controlling person of Intercept. By reason of their senior management positions and/or being directors of Intercept, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Intercept to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Intercept and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

87. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Intercept.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: November 5, 2020

Respectfully submitted,

POMERANTZ LLP

/s/ Jeremy A. Lieberman

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Attorneys for Plaintiff

CERTIFICATION PURSUANT
TO FEDERAL SECURITIES LAWS

1. I, Rakesh Chauhan, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed a Complaint against Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company") and authorize the filing of a comparable complaint on my behalf.

3. I did not purchase or acquire Intercept securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or otherwise acquired Intercept securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

5. To the best of my current knowledge, the attached sheet lists all of my transactions in Intercept securities during the Class Period as specified in the Complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not served or sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury that the foregoing is true and correct.

Executed 10/23/2020
(Date)

(Signature)

Rakesh Chauhan

(Type or Print Name)

Intercept Pharmaceuticals, Inc. (ICPT) **Chauhan, Rakesh**

List of Purchases and Sales

Transaction Type	Date	Number of Shares/Unit	Price Per Share/Unit
Purchase	6/29/2020	6	$46.3700
Purchase	6/29/2020	7	$47.4900
Purchase	6/29/2020	1	$47.8700
Purchase	6/29/2020	11	$48.0500
Purchase	6/29/2020	20	$47.9400
Purchase	6/30/2020	2	$46.1300
Purchase	6/30/2020	10	$45.8400
Purchase	7/15/2020	5	$44.0600
Purchase	9/9/2020	32	$44.6000
Purchase	9/23/2020	25	$39.6400