JUDGE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

14 CV 1123

[redacted] Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

INTERCEPT PHARMACEUTICALS, INC., MARK PRUZANSKI and DAVID SHAPIRO,

Defendants.

Civil Action No.

CLASS ACTION

COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

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 upon information and belief as to all other matters based on the investigation conducted by and through plaintiff's attorneys, which included, among other things, a review of Securities and Exchange Commission ("SEC") filings by Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company"), as well as media reports about the Company and conference call transcripts. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all persons who purchased Intercept publicly traded securities between January 9, 2014 and January 10, 2014, inclusive (the "Class Period"), and who were damaged thereby.

2. Intercept is a pharmaceutical company that has been developing and trying to bring to market new clinical drugs. The Company's primary drug compound, known as obeticholic acid ("OCA"), is in various phases of clinical development primarily for the purpose of treating chronic liver diseases. To date, none of the Company's drug products, including OCA, have received approval from the U.S. Food and Drug Administration ("FDA") for use in and promotion to humans.

3. On January 9, 2014 and January 10, 2014, Intercept announced that its Phase 2 trial of OCA for the treatment of non-alcoholic steatohepatitis ("NASH") had already met its efficacy endpoints with a high degree of statistical significance. As a result of the Company's announcements, the Company's common stock price skyrocketed from a January 8, 2014 close of $72.39 per share to a January 10, 2014 close of $445.83 per share.

4. On Friday, January 10, 2014, after the markets closed, the National Institutes of Health's ("NIH") National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK") issued a press release stating that while the efficacy primary end-point for OCA in the Phase 2 study had already been met, participants in the study who received the drug suffered disproportionate levels of lipid abnormalities.

5. As a result of the NIH's January 10, 2014 disclosure of OCA's safety risks, Intercept's stock price dropped over $81 per share – a decline of 18.2% – from $445.83 to $364.36 per share on Monday, January 13, 2014. The Company's stock continued to plummet on January 14, 2014, as investors continued to digest and react to this negative news. This decrease in Intercept's stock price was a result of the artificial inflation caused by defendants' misleading statements on January 9, 2014 and January 10, 2014 coming out of the stock price.

JURISDICTION AND VENUE

6. The claims herein are asserted under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act") and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Intercept's principal place of business is in New York, New York, and its securities trade on the NASDAQ, which is located in this district.

THE PARTIES

7. Plaintiff [redacted] a resident of [redacted] purchased Intercept common stock during the Class Period as set forth in the attached certification and was damaged thereby.

8. Defendant Intercept is headquartered in New York, New York. Intercept's common stock is traded on the NASDAQ, which is an efficient market.

9. Defendant Mark Pruzanski ("Pruzanksi") is and was the CEO and President of Intercept at all relevant times.

10. Defendant David Shapiro ("Shapiro") is and was the Chief Medical Officer ("CMO") and Executive Vice President of Development of Intercept at relevant times.

11. Defendants Pruzanski and Shapiro are referred to herein as the "Individual Defendants."

SCIENTER ALLEGATIONS

12. During the Class Period, the defendants had the motive and opportunity to commit the alleged fraud. Defendants also had actual knowledge of the misleading statements they made and/or acted in reckless disregard of the true information known to them at the time. In doing so, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchases of Intercept common stock during the Class Period.

PRE-CLASS PERIOD EVENTS AND STATEMENTS

13. Intercept was founded in 2002 around a bile acid chemistry drug discovery program. The Company's primary clinical focus for the past 10 years has been on developing treatments for chronic liver diseases with high unmet medical needs. The Company's chief drug compound is OCA, which is currently in various levels of clinical study for various disease indications.

14. One of the chronic liver diseases that defendants informed investors had a high unmet medical need was NASH. For instance, defendants informed investors that NASH was prevalent in the United States, with greater than 10% of the adult population, or over 6 million U.S. patients, estimated to suffer from advanced NASH. Currently, there are no drugs approved for the treatment of NASH. Accordingly, investors were led to believe that OCA, as a treatment for NASH, had the potential to be extremely profitable for Intercept.

15. One of the first clinical studies of OCA to get the attention of the investing public was the Phase 2 trial known as FLINT. FLINT's primary endpoint was liver biopsy-determined

improvement in non-alcoholic fatty liver disease ("NAFLD") by greater than or equal to 2%, with no worsening of liver fibrosis, versus patients taking placebo. Success in this Phase 2 trial was, therefore, critical as it would allow Intercept to begin Phase 3 studies to be submitted to the FDA for potential approval of OCA as a treatment for NASH.

CLASS PERIOD STATEMENTS

16. Before the opening of trading on January 9, 2014, defendants issued a press release announcing positive news that "the FLINT trial of obeticholic acid (OCA) for the treatment of non-alcoholic steatohepatitis (NASH) has been stopped early for efficacy based on a planned interim analysis showing that the primary endpoint of the trial has been met." Defendant Pruzanksi was quoted in the release as stating:

> "***The unexpected early stopping of FLINT due to OCA meeting the primary endpoint with such high significance is a major milestone.*** . . . NASH has grown to epidemic proportions worldwide, having become a leading cause of cirrhosis and liver failure. On its current trajectory, the disease is projected to become the leading indication for liver transplant."

17. As a direct result of defendants providing the Phase 2 efficacy results of OCA to investors, the Company's stock price jumped $203.48 per share. Not only did this represent a one-day price increase of 281.0%, but the volume of shares traded on January 9, 2014 increased over 900% to 6.8 million shares, compared to the stock's three-month average daily trading volume of 660,000 shares.

18. After the close of trading on January 9, 2014, defendants held an analyst and investor call to discuss the unexpected stopping of the FLINT study. Defendants Pruzanski and Shapiro participated in the conference call. During the call, defendant Pruzanksi announced additional positive news regarding the statistical significance of OCA's efficacy in the FLINT trial:

> Certainly, an interesting day for us here and for Intercept shareholders with the unexpected news this morning. ***I'm going to provide you with an update on the development of obeticholic acid*** . . . .

When we announced the call last week, we certainly planned to share exciting news on the progress of OCA for three different indications – our lead indication, primary biliary cirrhosis, or PBC, portal hypertension, and bile acid diarrhea, where as you know we have had a couple Phase II proof of concept studies ongoing. In addition, of course, today, we had the great privilege to announce unexpected great progress in the advancement of OCA for the treatment of nonalcoholic steatohepatitis, or NASH. Let me start then with the news and specifically the FLINT trial, and as many of you know on the call, NIDDK, which is a part of the NIH, and has been running and sponsors the FLINT trial informed us that the data safety monitoring board for the FLINT trial recommended stop of the trial early for efficacy. This was based on an interim analysis showing that OCA had met the primary histological endpoint. ***The decision to stop early was based on a predefined requirement that OCA show a much greater efficacy benefit with better than AP value of 0.0031 on an intention-to-treat basis. This is certainly a much higher bar to reach than would have been required for final analysis at the end of study.***

In addition, the interim efficacy analysis was prespecified to occur when approximately 50% of the patients of the 283 enrolled had completed both the baseline and end of treatment 72-week biopsies. ***As a result, the patients who did not complete the study and didn't therefore have a second biopsy were included in the ITT analysis as nonresponders. Nonetheless, the analysis still yielded a P-value of 0.0024. Therefore, coming in under the prespecified stopping guidance.*** Since I know it's on some of your minds, the P-value we were also informed per protocol was 0.0015 based on an analysis of only those patients who had completed the study and had a second biopsy.

19. Later in the January 9, 2014 conference call, defendants also informed investors why the early stopping of the FLINT trial was positive news for Intercept:

[Jim Birchenough - BMO Capital Markets]: And then, maybe just thinking about the opportunity here. Do you have a sense – I haven't looked at this recently – but what the number of patients on the liver transplant wait list is? And, what percentage of those have NASH? I'm just trying to get a sense of the identified patient population by looking at it that way.

[Defendant Pruzanski]: It's a good question. We would have to go back and get some updated information. I think if nothing else, this – almost a year earlier than anticipated result will spur us to expedite our market research here. I can tell you that currently based on the most recent stats I've seen, NASH, at least in the last couple of years has counted for close to about 15% of liver transplants. So, ranking third on the list behind Hep C and alcoholic liver disease, but that . . . is a tenfold increase over the last decade or so. I can't give you the exact numbers, Jim, right now, but I will be able to the next time we have a call like this. And, David just wants to adds something.

> **[Defendant Shapiro]**: And, just to emphasize Mark's point, I think that the point being is it is the fastest growing indication for liver transplant is where it is going to end up. We're in the middle of this. ***We are riding on the front end of this tsunami at the moment, and it is getting more and more every year.***

20. On January 10, 2014, as a direct result of defendants providing new, positive information concerning the statistical significance of OCA's efficacy and the marketing implications of the drug to investors, the Company's stock price increased to $445.83 per share, $169.96 per share higher than the closing price on January 9, 2014. Not only did this represent a one-day price increase of 61.6%, but the volume of shares traded on January 10, 2014 was over 800% higher than the stock's three-month average daily trading volume of 660,000 shares.

21. Defendants' statements set forth above in ¶¶16 and 18-19 were materially misleading when made because defendants failed to disclose the material adverse news that the FLINT study showed that participants taking OCA suffered disproportionate lipid abnormalities compared to those participants taking placebo and that the NIH had informed defendants of this fact before they made the positive statements concerning the drug on January 9, 2014 and January 10, 2014.

THE TRUTH BEGINS TO BE REVEALED

22. After the market closed on January 10, 2014, the NIH issued the following press release:

> **Interim Results of the FLINT Clinical Trial**
> **Statement from the NIH's National Institute of Diabetes and Digestive Kidney Diseases**
> January 10, 2014
>
> The NIH-funded FLINT clinical trial of obeticholic acid (OCA) for the liver disease nonalcoholic steatohepatitis (NASH) is a phase 2b study to test the effectiveness and further evaluate the safety of OCA. FLINT enrolled 283 patients. More than half completed 72 weeks of therapy with either OCA or placebo and had an end-of-treatment liver biopsy. At the end of therapy, patients are followed for another 24 weeks. The study protocol called for an interim analysis of histology and safety parameters after half of patients had completed treatment and had an end-of-treatment liver biopsy.

Based on the strength of these preliminary, interim results showing that OCA has a significant beneficial effect on liver damage due to NASH – and with the Data Safety and Monitoring Board's concurrence – NIDDK decided to stop treatment, move all patients into the 24-week follow up phase of the trial, and perform no additional liver biopsies – which carry their own risks. While treatment is being stopped early, the study is not over.

FLINT interim results also found disproportionate lipid abnormalities (increased total choloesterol with increased LDL and decreased HDL cholesterol) in patients on OCA compared to those on placebo. As lipid abnormalities are common in people with NASH, following all FLINT patients the full 24 weeks after stopping the drug will help determine whether lipid problems return to pre-OCA levels and weigh potential risks and benefits of the drug.

Our first priority following the decision to stop active treatment is to inform patients about interim results and give them additional instructions. For example, patients who are still taking study drugs are being notified that they should continue taking them until they return for a clinical visit on or before January 20.

To better understand the potential benefits and risks of OCA, the study will continue to collect information on patients until they have completed follow up visits. Investigators and patients will not know who received OCA or placebo until patients have their final visit 24 weeks after stopping the study drug.

NIDDK does not typically release interim results as they are preliminary. But as results have already been made public, we are providing limited additional information, giving a broader context for the findings. Additional information on the study will be available when the trial has been completed and all data have been thoroughly analyzed and presented to the broader scientific community, in 10 to 12 months.

23. On the evening of January 10, 2014, *The Wall Street Journal* also reported that defendant Pruzanski had confirmed that earlier in the week, prior to Intercept releasing the good news concerning the FLINT study, the NIH had also informed Intercept that patients taking OCA had, in fact, experienced adverse side effects and, in particular, lipid effects.

24. On January 12, 2014, Intercept issued a press release before the market opened revealing that the NIH's January 10, 2014 press release was correct and confirmed that patients taking OCA had suffered increased lipid abnormalities compared to placebo. As a result of investors learning the negative news about the FLINT trial, Intercept's stock price dropped $81.47 per share,

from $445.83 to $364.36, on Monday, January 13, 2014. This decrease in Intercept's stock price was a direct result of the artificial inflation caused by defendants' misleading statements coming out of the stock price.

25. On January 14, 2014, *MarketWatch* reported that the Company's common stock continued to plunge in trading that morning. While Intercept's common stock price had declined another 16%, *MarketWatch* added that "warnings from the [NIH] . . . said that those who used [OCA] . . . experienced 'disproportionate lipid abnormalities'" sending the Company's shares "into a free fall Monday, which continued" into Tuesday, January 14, 2014. This decrease in Intercept's stock price was a direct result of the artificial inflation caused by defendants' misleading statements coming out of the stock price.

LOSS CAUSATION/ECONOMIC LOSS

26. During the Class Period, defendants made false and misleading statements by means of concealment of critical clinical safety data and engaged in a scheme to deceive the market. Defendants' conduct artificially inflated Intercept's stock price and operated as a fraud or deceit on the Class (as defined below). Later, when defendants' prior misrepresentations were disclosed to market participants, Intercept's stock price plummeted, as the prior artificial inflation came out of the stock price over time. As a result of their purchases of Intercept securities during the Class Period, plaintiff and members of the Class suffered economic loss, *i.e.*, damages under the federal securities laws.

APPLICABILITY OF PRESUMPTION OF RELIANCE

27. Plaintiff and the Class are entitled to a presumption of reliance. During the Class Period, defendants made material misstatements and omissions that artificially inflated the prices of Intercept publicly traded securities. Plaintiff and other members of the Class purchased Intercept publicly traded securities between the time defendants misrepresented and failed to disclose material

facts regarding the safety of OCA and the time the true facts were disclosed, without knowledge of the misrepresented and omitted facts. At all relevant times, the market for Intercept securities was efficient and the prices of Intercept securities were impacted by defendants' misstatements and omissions.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

28. Plaintiff incorporates ¶¶1-27 by reference.

29. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

30. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or 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; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Intercept publicly traded securities during the Class Period.

31. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Intercept publicly traded securities. Plaintiff and the Class would not have purchased Intercept publicly traded securities at the prices they paid, or at

all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

32. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Intercept publicly traded securities during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act Against All Defendants

33. Plaintiff incorporates ¶¶1-32 by reference.

34. During the Class Period, defendants acted as controlling persons of Intercept within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about Intercept, the defendants had the power and ability to control the actions of Intercept and its employees. Intercept controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Intercept publicly traded securities during the Class Period (the "Class"). Excluded from the Class are defendants and their families, directors and officers of Intercept and their families and affiliates.

36. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Intercept had more than 19 million shares of stock outstanding, owned by hundreds or thousands of persons. More than 12.7 million shares of Intercept common stock were sold on January 9 and 10, 2014.

37. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:

(a) Whether the 1934 Act was violated by defendants;

(b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the prices o f Intercept securities were artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

38. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

39. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

40. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and plaintiff's counsel as Lead Counsel;

B. Awarding plaintiff and the members of the Class damages and interest;

C. Awarding plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

41. Plaintiff demands a trial by jury.

DATED: February 21, 2014