IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 18-cv-02381

UNITED STATES SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

CLOVIS ONCOLOGY, INC.,
PATRICK J. MAHAFFY, and
ERLE T. MAST

Defendants.

COMPLAINT

Plaintiff, the United States Securities and Exchange Commission (the "SEC" or "Commission"), for its Complaint against Clovis Oncology, Inc., Patrick J. Mahaffy, and Erle T. Mast (collectively, the "defendants") alleges as follows:

NATURE OF THE ACTION

1. From approximately July 8, 2015 through November 16, 2015 (the "relevant time period"), Clovis Oncology, Inc. ("Clovis" or the "company"), a biopharmaceutical company based in Boulder, Colorado and listed on NASDAQ, and its current Chief Executive Officer ("CEO"), Patrick Mahaffy ("Mahaffy"), negligently made untrue statements of material fact and/or omitted to state material facts necessary in order to make the statements they made not misleading to investors about its then flagship lung cancer drug, rociletinib ("Roci"). Clovis' former Chief Financial Officer ("CFO"), Erle Mast ("Mast"), aided and abetted such untrue statements and/or omissions. For investors, Clovis' value in 2015 was directly tied to the ability of Roci to compete in the market for lung cancer drugs. One important driver of the competition

was Roci's "efficacy" – how well the drug worked – and how that efficacy compared to a drug simultaneously under development by another biopharmaceutical company, referred to herein as "DRUG X."

2. On May 31, 2015, Clovis disclosed to investors at the American Society of Clinical Oncology ("ASCO") conference, that Roci's efficacy, referred to as Objective Response Rate ("ORR"), in ongoing clinical trials was 60% for its 500mg dose, meaning that in 60% of patients, Roci caused targeted tumors to shrink. That Roci's efficacy was 60% was material to investors, as investors believed that this efficacy rate was almost identical to DRUG X, which had a disclosed efficacy rate at the time of 63%. Investors therefore valued Clovis stock assuming that Roci would capture meaningful market share.

3. Shortly after the May 31, 2015 disclosure, the data provided to Mahaffy, Mast, and other Clovis senior executives began to show that Roci's efficacy rate was materially lower than 60%. In mid-June 2015, Clovis' updated Roci data provided to Mahaffy showed an ORR in the mid-40s. On July 7, 2015, Mahaffy and Mast learned that the Roci data that would be submitted in the initial submission to the U.S. Food and Drug Administration ("FDA") for Roci's approval showed an ORR of 42%.

4. While Clovis' non-public data, which was used to prepare its submission to the FDA, showed an ORR below 60%, Clovis continued citing to the May 2015 ASCO conference and its disclosure that Roci's ORR was 60%. On July 8, 2015, Clovis referenced the May 2015 ASCO conference and the 60% ORR for Roci in the solicitation materials for a $298 million offering of its securities (the "Offering"). After the Offering, Clovis continued to repeat the 60% ORR in public disclosures.

5. On November 9, 2015, the FDA informed Clovis that it disagreed with Clovis' calculation of the efficacy results for Roci, that an accurate calculation of Roci's efficacy put the ORR in the 20s, and that Clovis must provide new calculations to the FDA by November 16, 2015. On November 10, 2015, Clovis attended an investor conference and referenced the May 2015 ASCO conference and the 60% ORR figure, but without disclosing that the FDA had told Clovis it disagreed with Clovis' efficacy analysis.

6. On November 16, 2015, Clovis disclosed the true ORR, as calculated by the methodology required by the FDA, telling the market that Roci's ORR was 28%. The stock price collapsed as a result, dropping approximately 70% from $99.43 to $30.24 per share.

JURISDICTION AND VENUE

7. The Court has jurisdiction pursuant to Section 22(a) of the Securities Act of 1933 (the "Securities Act") [15 U.S.C. § 77v(a)] and Sections 21(d) and 27 of the Securities Exchange Act of 1934 (the "Exchange Act") [15 U.S.C. §§ 78u(d)-(e) and 78aa]. The Defendants, directly or indirectly, made use of the means or instruments of transportation or communication in interstate commerce, the means and instrumentalities of interstate commerce, or of the mails, in connection with the acts, practices, and courses of business set forth in this Complaint.

8. Venue lies in this judicial district pursuant to 15 U.S.C. §§ 77u(a) and 78aa and 18 U.S.C. § 1391(b)(2). Defendants Mahaffy and Mast reside in this district, Clovis' principal place of business is in this district, and violations occurred in this district.

DEFENDANTS

9. **CLOVIS ONCOLOGY, INC.**, a Delaware corporation, is a biopharmaceutical company with its principal place of business in Boulder, Colorado. Clovis' securities are registered under Section 12(b) of the Exchange Act and its common stock is listed on NASDAQ

(ticker symbol: CLVS). Clovis files periodic reports with the Commission pursuant to Section 13 of the Exchange Act and related rules thereunder. Throughout the relevant time period, Clovis issued stock to its employees in connection with their exercise of stock options pursuant to Clovis' stock incentive plan.

10. **PATRICK J. MAHAFFY** is a resident of this district. Since 2009, he has served as CEO and a director of Clovis. As CEO, Mahaffy reviewed and approved Clovis press releases and filings with the Commission.

11. **ERLE T. MAST** is a resident of this district. From 2009 to 2016, he served as CFO of Clovis. As CFO, Mast reviewed and approved Clovis press releases and reviewed, approved, and signed Clovis filings with the Commission. During the relevant time period, Mast sold Clovis securities, pursuant to a pre-established 10b5-1 plan, at inflated prices.

FACTS

Development of Roci

12. There are various types of lung cancer, one of which is referred to as non-small cell lung cancer ("NSCLC"). Some NSCLC patients can be treated with a class of drugs referred to as tyrosine kinase inhibitors ("TKIs"). However, many patients' disease will progress after treatment on TKIs because of an acquired resistance mutation called a "T790M" mutation. As a consequence of this mutation, patients become resistant to TKI therapy. Clovis developed Roci to treat NSCLC patients who become resistant to TKIs due to the emergence of the T790M mutation.

13. Before Roci could be sold in the U.S., Clovis needed to obtain approval from the FDA. In March 2012, Clovis began the Phase 1 portion of a Roci clinical trial referred to as "TIGER-X." The objective of the Phase 1 portion of TIGER-X was to evaluate Roci's safety

and determine the appropriate dose for further trials. The Phase 2 portion of TIGER-X, measuring, among other things, Roci's efficacy, began in February 2014. Clovis publicly disclosed that the primary endpoint of the TIGER-X Phase 2 clinical trial was ORR – "Objective Response Rate…per RECIST."

14. The Response Evaluation Criteria in Solid Tumours ("RECIST") guidelines are an industry-standard set of guidelines used in evaluating the response, measured by tumor shrinkage, to a cancer drug. Clovis' protocol for the TIGER-X trial required, per RECIST, that in order for tumor shrinkage to qualify as a response, among other criteria, the targeted tumor must shrink at least 30% and the tumor shrinkage must be sustained in a follow-up examination. This latter requirement is referred to as "confirmation."

15. The data from TIGER-X, and another ongoing Roci clinical trial called TIGER-2 (a Phase 2 study evaluating efficacy that began enrolling patients in June 2014), formed the basis of Clovis' New Drug Application ("NDA") submitted to the FDA. The TIGER-X and TIGER-2 data were also going to be used to support Roci's proposed labeling. A drug's "label" is the printed information that comes with the drug and includes efficacy data such as ORR.

16. Prior to 2015, there were no approved drugs to treat T790M-positive NSCLC patients. However, concurrently with Roci's development, another company was developing its own drug, referred to herein as DRUG X, to treat the same group of patients. The development of Roci and DRUG X was a race, with analysts and investors carefully comparing Roci's published efficacy data with DRUG X's published efficacy data to determine which drug might capture more market share once approved by the FDA.

Clovis Tells Investors That Roci's Efficacy is 60%

17. Clovis disclosed to investors in early 2015 that it expected to submit its NDA to the FDA for Roci in mid-2015. In advance of the NDA submission, Clovis told investors it would give a preview of its label at the ASCO conference in May 2015. The data presentation at ASCO was also a necessary step to raising capital from investors that Clovis needed.

18. At an investor meeting at the ASCO conference on May 31, 2015, Clovis disclosed findings from Phase 2 of TIGER-X, publicly announcing that Clovis' "recommended" or "go-forward" dose of Roci would be 500mg and that, at the 500mg dose, Roci's ORR was 60%. Mahaffy stated that the data "confirm [Roci's] compelling activity" and would "form the [NDA submission] in July [2015]." In its ASCO 2015 presentation, the company developing DRUG X disclosed that its current *confirmed* ORR was 63%.

19. The disclosed Roci ORR presented at ASCO 2015 and referenced throughout the relevant time period by Clovis was "unconfirmed," meaning that the initial tumor shrinkage was not necessarily sustained through a follow-up scan. Clovis' 60% ORR at ASCO included patients who had a single responsive scan, but then progressed (*e.g.*, their target tumors grew or they developed new tumors) without a confirmatory scan. In other words, Clovis' 60% ORR at ASCO included some patients who could never be confirmed responders; some patients who had a responsive scan, but had not yet progressed; and some patients who had not had the opportunity for a second responsive scan because they had not been on study long enough. Later analysis of the ASCO data set showed that the confirmed ORR for the ASCO data set at the time it was presented was 40%.

20. In the spring of 2015, Clovis statisticians provided Roci ORR data to Clovis senior clinical personnel showing a divergence between the confirmed and unconfirmed ORR.

Although Mahaffy, Mast and some other individuals at Clovis hoped that the FDA would allow Clovis to use Roci's unconfirmed ORR on Roci's label, certain senior Clovis employees believed that the FDA would require Clovis to follow RECIST and its own trial protocols in reporting a confirmed ORR on Roci's label.

Clovis Gets Initial NDA Data Showing Lower ORR, But Still Refers to the ASCO 2015 60% ORR In Connection With Raising $298 Million in the Offering

21. On June 19, 2015, Mahaffy and other members of Clovis senior management, not including Mast, received the "close to final" TIGER-X data which would be used for the NDA. The unconfirmed ORR was 45.1% for the 500mg dose, or 25% lower than the 60% ORR presented at the ASCO 2015 conference. Mahaffy at the time wrote to a Clovis executive that the data "[s]eem[ed] worrying."

22. After receiving the "close to final" TIGER-X data, Clovis prepared drafts of a Prospectus Supplement for filing with the SEC and a roadshow presentation for use in soliciting potential investors in connection with the Offering. Both the Prospectus Supplement and the roadshow presentation referenced that Clovis had presented TIGER-X data showing a 60% ORR at ASCO 2015, but without disclosing that the data was unconfirmed. And in the case of the Prospectus Supplement, Clovis stated that TIGER-X data, combined with data from the ongoing TIGER-2 trial (which had patients on the 625mg dose), would "form the basis" of the forthcoming NDA submission in late July 2015, without disclosing that Roci's NDA ORR for the 500mg dose was lower than 60%.

23. On July 7, 2015, the day before the Offering, Clovis management, including Mahaffy and Mast, received the "final" data to be included in Roci's initial NDA submission to the FDA. The data showed that Roci's unconfirmed ORR was 42% for the 500mg dose. The data also showed that Roci's confirmed ORR was only 31% for the 500mg dose, less than 50%

of DRUG X's confirmed ORR presented at ASCO. Later that same day, Mahaffy, Mast, and Clovis' most senior clinical executives conducted an internal conference call to discuss the data.

24. The defendants hoped, based on experience with prior Roci data sets, but did not know to any degree of certainty, that Roci's ORR would increase by the time of a planned 90-day efficacy update to the initial NDA submission. However, rather than disclose the current Roci ORR and Clovis' hope that it would increase, Mahaffy and Mast formally approved, in writing, the filing of the Prospectus Supplement with the SEC and the use of the roadshow presentation that both referenced the ASCO 2015 60% ORR. The Prospectus Supplement and the roadshow presentation omitted to disclose material facts necessary to make the reference to the ASCO 2015 data not misleading, including Roci's current unconfirmed and confirmed ORR. These documents gave investors the false impression that Roci's ORR continued to be 60%.

25. The following day, on July 8, 2015, Mahaffy led and Mast participated in multiple investor roadshow conference calls without disclosing Roci's current unconfirmed or confirmed ORR. During the conference calls Mahaffy described Roci and DRUG X as similarly efficacious.

26. Clovis raised approximately $298 million (net) in connection with the Offering. Not disclosing the current unconfirmed or confirmed ORR data inflated Clovis' stock price and enabled Clovis to receive substantial ill-gotten gains from the Offering.

Roci's ORR is Capped, But Clovis Continues to Reference the 60% Number from ASCO

27. On or about July 28, 2015, Clovis' lead statistician told Clovis' lead clinician that the confirmed ORR in the NDA would improve only slightly by the time of the planned 90-day efficacy update, if at all. The lead statistician also told the lead clinician, as well as Mahaffy, that the unconfirmed ORR might increase to 46% by the time of the planned 90-day efficacy

update. Mahaffy therefore should have known that Roci's unconfirmed ORR would not be more than 46% at the time of the 90-day efficacy update.

28. On August 6, 2015, Clovis issued a press release announcing its second-quarter 2015 earnings. Mahaffy and Mast reviewed and approved the issuance of the press release and the accompanying earnings call script. The press release was also furnished to the Commission on Form 8-K and signed by Mast.

29. The press release stated that Clovis had filed its initial NDA on July 30, 2015, and also summarized the data presented at the ASCO 2015 conference, again citing the 60% ORR figure (without disclosing it was unconfirmed) and again stating that the TIGER-X and TIGER-2 data formed the basis of Clovis' NDA for Roci. During the accompanying investor conference call on August 6, 2015, Mahaffy told investors that Clovis had "presented a full update of our data set at ASCO," giving the false impression that the ASCO 2015 data was consistent with the NDA data. Similarly, Mahaffy further stated on the August 6 investor call that, "[t]he primary dose we are seeking approval for is 500[mg], and that all comes from TIGER-X and the data you saw at ASCO." In describing the data submitted in the NDA, Mahaffy further claimed that the "data sets have continued to demonstrate compelling and consistent activity."

30. In approximately September 2015, another biopharmaceutical company ("Company Y") conducted due diligence, pursuant to a confidentiality agreement, as to Roci in connection with a potential acquisition of Clovis. When Company Y learned during the due diligence of the undisclosed ORR data concerning Roci – the same data that Clovis submitted to the FDA in its NDA – it withdrew from the potential acquisition of Clovis. The defendants knew or should have known that Company Y's view was that Roci would not be competitive with DRUG X.

31. The 90-day efficacy update for Roci, submitted to the FDA on October 22, 2015, showed confirmed ORR of 33% and unconfirmed ORR of 46% for the 500mg dose. The 90-day efficacy update data was shared and discussed with Mahaffy and Mast before it was submitted to the FDA.

32. On November 5, 2015, after submitting the 90-day efficacy update, Clovis issued a press release announcing its third-quarter 2015 earnings. Mahaffy and Mast reviewed and approved the issuance of the press release and the accompanying earnings call script. The press release was also furnished to the Commission on Form 8-K and signed by Mast.

33. In the press release and on the accompanying earnings conference call led by Mahaffy, Clovis highlighted medical presentations of Roci data that occurred during the third quarter and directed investors to review the presentations on Clovis' website. These medical presentations again highlighted the ASCO 2015 data and the 60% ORR at the 500mg dose, without disclosing that the data was unconfirmed, or disclosing the lower ORR data submitted in the initial NDA submission, or disclosing the lower ORR data submitted to the FDA in connection with the 90-day efficacy update.

Clovis' Disclosures Misled Investors

34. Clovis' references during the relevant time period to the ASCO presentation and its highlighting of the 60% ORR figure for the 500mg dose were misleading because the data submitted to the FDA showed response rates far below 60% for that dose, on either a confirmed or unconfirmed basis. Investors fairly understood that the ORR in the NDA submission, and the eventual Roci label, would be substantially similar to the 60% ASCO figure, when in fact the undisclosed data – which Clovis provided to the FDA – showed ORR ranging between 31% (confirmed) and 46% (unconfirmed).

35. Further, investors believed that the 60% ORR was "confirmed." Presenting an ORR comprised of only confirmed responses was customary, and therefore investors would have expected Clovis to disclose if it was deviating from customary practice and its own clinical trial protocols by presenting unconfirmed ORR. Indeed, even a Clovis employee involved with medical publications believed that the ASCO 60% ORR represented a confirmed response rate.

36. The continued use of the 60% ORR figure, without disclosing that it was unconfirmed, and without disclosing that the data submitted to the FDA showed responses rates far below 60%, on either a confirmed or unconfirmed basis, led investors to the false conclusion that Roci and DRUG X had similar efficacy and therefore that Roci would be competitive in the marketplace. As late as November 6, 2015, analysts continued to cite Roci's "60% response rate" in concluding that Roci's efficacy was "very similar" to DRUG X.

Clovis' Subsequent Disclosure of Roci's Confirmed ORR

37. On Friday, November 6, 2015, the FDA sent a memorandum to Clovis in advance of a planned conference call on November 9, 2015, referred to as the "Mid-Cycle Communication." In the memorandum and conference call on November 9, 2015, the FDA informed Clovis that its seeking approval for Roci on the basis of unconfirmed data that deviated from RECIST was unacceptable, and that the accurately calculated confirmed ORR may not be of sufficient magnitude to predict clinical benefit. Mahaffy and Mast both received the FDA's November 6, 2015 memorandum, and were informed following the November 9, 2015 conference call that the FDA would not change its position that Clovis must use confirmed ORR.

38. On November 10, 2015, Mast was scheduled to attend an investor conference that Mahaffy was originally scheduled to attend. Mahaffy and Mast spoke prior to the conference, and they decided together that Mast would still attend the conference. During the conference,

Mast spoke from a deck of slides that was displayed overhead for investors to see and also posted to Clovis' website. Even though Mahaffy and Mast knew or should have known that the FDA would require confirmed ORR, one of the slides included the ASCO 2015 60% ORR for the 500mg dose, but without disclosing that fact or the accurate ORR.

39. On November 16, 2015, Clovis disclosed that Roci's confirmed ORR for the NDA dataset was only 28%. When Clovis disclosed the true ORR, analysts reported that they were "shocked" and "blindsided." Analysts also concluded that Roci's ORR was now "meaningfully lower" than DRUG X and, accordingly, "reduced its competitiveness substantially." As a result, on November 16, 2015, Clovis' stock price closed down approximately 70%, or $69.19 per share (from a closing price of $99.43 per share on Friday, November 13, 2015 to a closing price of $30.24 per share on November 16). By May 2016, after receiving further feedback from the FDA, Clovis had ceased development of Roci and terminated enrollment in all Clovis-sponsored clinical studies of Roci.

FIRST CLAIM FOR RELIEF

Section 17(a)(2) of the Securities Act
[15 U.S.C. Sec. 77q(a)(2)]
(Clovis and Mahaffy)

40. Paragraphs 1 through 39 are hereby realleged and incorporated by reference.

41. Clovis and Mahaffy, directly or indirectly, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, negligently obtained money or property by means of an untrue statement of material fact or omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

42. By virtue of the foregoing, Clovis and Mahaffy, directly or indirectly, violated and, unless restrained and enjoined, will in the future violate Section 17(a)(2) of the Securities Act.

SECOND CLAIM FOR RELIEF

Aiding and Abetting Clovis' Violations of Section 17(a)(2) of the Securities Act [15 U.S.C. Sec. 77q(a)(2)] (Mast)

43. Paragraphs 1 through 39 are hereby realleged and incorporated by reference.

44. Clovis, directly or indirectly, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, negligently obtained money or property by means of an untrue statement of material fact or omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

45. By engaging in the conduct described above, Mast aided and abetted the misstatements and omissions by Clovis, in that he, acting with the requisite state of mind, provided substantial assistance to Clovis in committing these violations.

46. By reason of the foregoing, Mast has aided and abetted and, unless restrained and enjoined, will in the future aid and abet, Clovis' violations of Section 17(a)(2) of the Securities Act.

THIRD CLAIM FOR RELIEF

Violations of Section 13(a) of the Exchange Act and Rules 12b-20 and 13a-11 [15 U.S.C. § 78m(a) and 17 C.F.R. §§ 240.12b-20 and 204.13a11] (Clovis)

47. Paragraphs 1 through 39 are hereby realleged and incorporated by reference.

48. Clovis, which is an issuer of securities registered pursuant to Section 12 of the Exchange Act, filed materially false and misleading reports with the SEC that made untrue statements of material fact 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, in violation of Section 13(a) of the Exchange Act and Rules 12b-20 and 13a-11 thereunder.

49. By reason of the foregoing, Clovis violated and unless restrained and enjoined will in the future violate Section 13(a) of the Exchange Act and Rules 12b-20 and 13a-11 thereunder.

FOURTH CLAIM FOR RELIEF

Aiding and Abetting Clovis' Violations of Section 13(a) of the Exchange Act and Rules 12b-20 and 13a-11 [15 U.S.C. § 78m(a) and 17 C.F.R. §§ 240.12b-20 and 204.13a-11] (Mahaffy and Mast)

50. Paragraphs 1 through 39 are hereby realleged and incorporated by reference.

51. Clovis, which is an issuer of securities registered pursuant to Section 12 of the Exchange Act, filed materially false and misleading reports with the SEC that made untrue statements of material fact 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, in violation of Section 13(a) of the Exchange Act and Rules 12b-20 and 13a-11 thereunder.

52. By engaging in the conduct described above, Mahaffy and Mast each aided and abetted the reporting violations of Clovis, in that they, acting with the requisite state of mind, provided substantial assistance to Clovis in committing reporting violations.

53. By reason of the foregoing, Mahaffy and Mast each aided and abetted, and unless restrained and enjoined will in the future aid and abet, Clovis' violations of Section 13(a) of the Exchange Act and the rules thereunder.

PRAYER FOR RELIEF

WHEREFORE, the Commission requests that this Court:

A. Enter a permanent injunction restraining the defendants and each of their agents, servants, employees and attorneys and those persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in the conduct described above, or in conduct of similar purport and effect;

B. Require that each of the defendants disgorge any and all ill-gotten gains, together with pre-judgment interest, derived from the improper conduct set forth in this Complaint;

C. Require that each of the defendants pay appropriate civil monetary penalties pursuant to Section 20(d) of the Securities Act [15 U.S.C. §77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)];

D. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

E. Award such other and further relief as the Court deems just and proper.

Respectfully submitted this 18th day of September, 2018.

s/ Nicholas Heinke
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