IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:15-cv-2546

SONNY P. MEDINA, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

CLOVIS ONCOLOGY, INC. and PATRICK J. MAHAFFY,

Defendants.

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS AND JURY TRIAL DEMAND

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Plaintiffs M.Arkin (1999) LTD and Arkin Communications LTD (collectively "Lead Plaintiff") and named plaintiff the City of St. Petersburg Employees' Retirement System bring this securities class action on behalf of themselves and all other persons and entities who purchased or otherwise acquired (1) any of the publicly-traded securities of Clovis Oncology, Inc. ("Clovis" or the "Company") from May 31, 2014 through April 7, 2016 (the "Class Period"), or (2) the common stock of Clovis pursuant or traceable to the secondary offering conducted on or about July 14, 2015 (the "July 2015 Offering"), and were damaged thereby (collectively, the "Class").[1]

I. PRELIMINARY STATEMENT

1. This case is about a pharmaceutical company, Clovis, that repeatedly misled investors regarding the commercial prospects, safety profile, and efficacy of its single most important product – a proprietary cancer drug called rociletinib. During the Class Period, Clovis and its senior executives – Chief Executive Officer Patrick Mahaffy, Chief Financial Officer Erle Mast, Chief Medical Officer Andrew Allen, and Chief Regulatory Officer Gillian Ivers-Read (the "Executive Defendants") – told investors that the Company was developing a revolutionary new cancer medication that was designed to treat lung cancer patients who were resistant to front-line therapies.

2. Analysts estimated that there was a $3 billion untapped global market for this type of drug. During the Class Period rociletinib was the most prominent drug in Clovis' pipeline and, as such, it was absolutely critical to the Company's success that the

[1] Plaintiffs file this Amended Complaint pursuant to Fed. R. Civ. P. 15 and this Court's Order dated February 9, 2017. As set forth in this Court's Order, the amendments set forth herein are "directed solely" to Plaintiffs' Section 12(a) claim.

market perceive the rociletinib drug trials to be proceeding well. The Company was reporting significant losses every quarter and had been forced to conduct two massive offerings of securities during the Class Period. These offerings collectively raised nearly $600 million from investors and allowed Clovis to access the capital necessary to fund the research, development, and marketing costs of rociletinib and other products.

3. As Defendants knew, rociletinib was facing stiff competition from a similar experimental drug called Tagrisso, which was being developed by pharmaceutical giant Astra-Zeneca to treat the same class of patients targeted by rociletinib. Defendants were acutely aware that if the market perceived Tagrisso as being significantly safer and more efficacious than rociletinib, then investors would place far less value on Clovis and the Company's stock price would plummet. As Defendant Mahaffy himself stated in response to analyst questions about Tagrisso, "we are in a race. They [Astra-Zeneca] are a very able competitor with an active drug."

4. In order to receive approval from the U.S. Food and Drug Administration ("FDA"), Clovis enrolled rociletinib in a series of clinical tests, including an important multi-year safety and efficacy trial called "TIGER-X." The TIGER-X trial generated the entirety of the rociletinib data Defendants reported during the Class Period and formed the principal basis of the rociletinib New Drug Application ("NDA") that was ultimately filed with the FDA. Throughout the Class Period, Defendants repeatedly told investors that rociletinib was performing extremely well in the TIGER-X trial by, among other things, exhibiting an "impressive" and "highly compelling" safety and efficacy profile. Defendants claimed that rociletinib would "compete very effectively" against Tagrisso,

which was undergoing similar testing and reporting similarly positive results to the marketplace.

5. One of the key metrics that doctors, regulators, and investors were focused on for both rociletinib and Tagrisso was the purported "objective response rate" or "ORR" that the drugs exhibited in their respective trials. ORR describes the percentage of patients who experience clinically meaningful tumor shrinkage when treated with the drug. ORR was the "primary endpoint" – the central measure of success – in the TIGER-X trial. The rules for calculating ORR are unambiguous. They are set forth in the definitive cancer trial standards, referred to as the Response Evaluation Criteria in Solid Tumors ("RECIST"), which expressly provide that each observation of tumor shrinkage (called a "response") must be "confirmed" by subsequent observation in order to be included in the calculation of ORR. Doctors and researchers view response confirmation as essential to ensuring that reported results are reliable, reproducible, and do not overstate an experimental drug's efficacy.

6. Knowing that it would instill market confidence in its reported results, Clovis explicitly incorporated RECIST into the clinical trial protocol for the TIGER-X trial. Clovis also repeatedly stated during the Class Period that it was adhering to RECIST standards. Moreover, FDA guidance made clear that the agency would make regulatory determinations based only on "confirmed ORRs," which analysts noted was "an unambiguous fact from the FDA" during the Class Period.

7. At medical and investor conferences, in press releases, and in filings with the Securities and Exchange Commission ("SEC") throughout the Class Period, Defendants touted purportedly "impressive" ORRs for rociletinib of around 60%, which

was the same rate or better than Astra-Zeneca was reporting for Tagrisso. As Defendants knew, investors believed from the RECIST standard incorporated into the TIGER-X protocol, long-established FDA guidance, industry practice, and the context in which Defendants' statements were made, that the reported ORRs included only confirmed responses.

8. For instance, in an April 30, 2015 *New England Journal of Medicine* article coauthored by Defendant Allen, Clovis reported a 59% ORR based on data that had been in Defendants' possession since June 18, 2014. In that article, Defendants explicitly stated that "tumor response was assessed according to Response Evaluation Criteria in Solid Tumors (RECIST)." And as late as November 5, 2015, Clovis was continuing to tell investors that rociletinib was exhibiting ORRs of around 60% in the TIGER-X trial. On multiple occasions during the Class Period, Defendants made explicit comparisons between the ORR being reported by rociletinib and the similar ORRs being reported by Astra-Zeneca for Tagrisso.

9. Throughout this time, Defendants were also telling investors that rociletinib had a strong safety profile, was "well tolerated," and that the "primary side effect that comes with rociletinib" was "easily managed" hyperglycemia (high blood sugar).

10. Defendants characterized these results as "great data" that was "extremely encouraging" and demonstrated that rociletinib would "compete very effectively" against Tagrisso. Repeatedly throughout the Class Period, Defendants told investors that Clovis' data showed "***clear evidence of meaningful activity for rociletinib,***" and that Clovis was "extremely enthusiastic about moving the rociletinib program forward."[2]

[2] Throughout the Complaint, emphasis added unless otherwise noted.

11. Defendants also assured investors that they were closely monitoring this data because they knew it was important to investors. The CEO of Clovis, Mahaffy himself, stated during an investor conference call that "the data are open to us … we have access to all that," and he assured investors and analysts that "we will continue to provide updates. ***We know that's important to investors***."

12. These and other statements detailed below caused the price of Clovis' stock to triple from approximately $38 per share near the start of the Class Period to a high of $114 per share in September 2015.

13. Unbeknownst to investors, however, these statements were false. On November 16, 2015, Clovis announced that – contrary to Defendants' prior public statements – the ORR for rociletinib the Company had reported throughout the Class Period was "based primarily on ***unconfirmed responses***." On that same day, Defendants disclosed for the first time that rociletinib's true ORR, based on confirmed responses, was just 30% – or ***half*** the rate they previously reported (and half the rate reported for Tagrisso, which, consistent with standard practice, had been reporting confirmed ORRs all along). In other words, it was now clear that throughout the Class Period, Defendants had knowingly reported scientifically illegitimate results that had falsely inflated the apparent efficacy of rociletinib and grossly overstated the drug's commercial and competitive viability.

14. Investors and market commentators were shocked by these disclosures. One analyst stated that Clovis "blindsided the Street this morning," specifically saying that "management credibility obviously takes a significant hit." Another analyst said that "any rational investor knows that this fails the simple 'smell test.' ***They knew, and delayed***

informing their investors." Longtime cancer drug development expert Dr. Kapil Dhingra has since publicly stated that rociletinib's "efficacy data have, ***consistently and repeatedly, over many years, been misrepresented.***" As detailed below, another leading biotech columnist compared Defendants' conduct to the notorious ImClone securities fraud: "like Imclone, Clovis kept the bad news about its lung cancer drug hidden from investors until FDA action compelled the company to make the information public."

15. In response to these disclosures, Clovis' stock price plummeted, declining from $99.43 per share to $30.24 per share, a drop of nearly ***70% in a single day***. The only reason that Clovis' share price did not fall even further was because Defendants continued to assure investors that rociletinib had a highly favorable safety profile that might allow it to garner some market share as a second-line therapy for patients who could not tolerate Tagrisso.

16. But even this was not true. On April 8, 2016, the FDA publicly released additional rociletinib data in connection with a meeting of the agency's Oncological Drug Advisory Committee ("ODAC"), a panel of outside experts charged with making recommendations to the FDA. As described below, these data revealed that – far from being "well-tolerated" – rociletinib significantly increased the risk of "serious or life threatening" adverse cardiovascular events, specifically a dangerous type of arrhythmia called QT prolongation.

17. Indeed, rociletinib's propensity to increase cardiovascular risk was so significant that the FDA concluded that if the drug ever was approved for commercial use it would be required to display a "Boxed Warning" – the strongest warning label a drug

can carry. Moreover, Clovis' safety data showed that rociletinib was so toxic, adverse side effects had forced more than half of all patients to interrupt, modify, or discontinue therapy.

18. In light of the April 8, 2016 disclosures, analysts concluded that rociletinib was "***dead***" and "***a commercial zero***." In response, Clovis' stock fell a further 17%, from $20.43 per share to $15.77 per share.

19. It is now clear that Defendants knowingly made false and misleading statements and omissions designed to artificially inflate Clovis' stock price for their own benefit. For instance, based on the falsely positive reports of rociletinib's performance in the TIGER-X trial, Clovis conducted a massive secondary offering of common stock in July 2015. In that July 2015 Offering the Company sold approximately 4.1 million shares of stock at artificially inflated prices, raising nearly $300 million from investors.

20. Notably, less than a month before the July 2015 Offering, Defendant Allen, the Company's co-founder and Chief Medical Officer, resigned from Clovis under highly suspicious circumstances. Allen had closely overseen the TIGER-X trials and had himself reported supposedly positive results to the market on several occasions. Allen's abrupt departure from the Company he co-founded occurred shortly after Clovis held a private meeting with the FDA and less than two weeks before the Company was set to file its rociletinib NDA. Allen had shepherded rociletinib through development and his resignation came just months before the drug's supposed market launch, which the Company had led investors to believe would cause Clovis' stock price to explode.

21. Defendant Allen forfeited significant stock options by resigning when he did, and he also sold approximately 44% of his Clovis stock prior to his departure,

generating proceeds of more than $5 million. This was more than three and a half times the number of shares he had sold in the entire two-year period preceding the Class Period.

22. The Company has still not recovered from the fraud alleged herein. While Clovis' stock traded as high as $114.65 during the Class Period, it trades at approximately $12.50 per share as of the filing of this Complaint. Moreover, experts and commentators continue to raise "serious questions about the truthfulness and timing involved in the way Clovis Oncology corrected pivotal data on its cancer drug rociletinib." As Dr. Dhingra stated in an April 2016 article published in the prominent medical journal *Annals of Oncology*:

> I feel that [Clovis' rociletinib] efficacy data have, consistently and repeatedly, over many years, been misrepresented. ***This is not simply a case of gray zones, this is black and white untrue presentation of the data***. And it is not just a minor misrepresentation . . . the true efficacy is about half of what they represented.

23. On April 12, 2016, the FDA's ODAC voted 12 to 1 to delay FDA action on rociletinib's NDA until Clovis could provide concrete evidence that its overall risk/benefit profile merited FDA approval.

24. On May 5, 2012, Clovis issued a press release telling investors that the Company had withdrawn its NDA for rociletinib and "terminated enrollment in all ongoing sponsored studies of rociletinib." As Clovis made clear from the press release, it was anticipating receiving a Complete Response Letter from the FDA on or before June 28, 2016 and "the FDA issues a Complete Response Letter to indicate that their review of an application is complete and that the application is not ready for approval."

25. In other words, when the FDA looked at the true efficacy and safety data from the TIGER trials (as opposed to the false and misleading presentation of the data Defendants made to investors), it was clear that rociletinib had no commercial value. As

discussed in more detail below, investors are now entitled to recover against the individuals and entities responsible for their losses.

II. THE CLAIMS ASSERTED IN THE COMPLAINT

26. In this Complaint, Plaintiffs assert two separate sets of claims. Counts One and Two, found in Part One of the Complaint, assert fraud claims pursuant to Section 10(b) and Section 20(a) the Securities Exchange Act of 1934 (the "Exchange Act"). These claims are asserted against Clovis and the Executive Defendants and allege that these Defendants intentionally or recklessly made material false and misleading statements and omissions during the Class Period.

27. Counts Three, Four, and Five, found in Part Two of the Complaint, assert strict liability and negligence claims pursuant to the Securities Act of 1933 (the "Securities Act"). These non-fraud claims are asserted against those defendants (identified below in Section II.C) who are statutorily liable for the untrue statements in the prospectus and registration statement for the July 2015 Offering.

28. Plaintiffs specifically disclaim any allegations of fraud in those non-fraud claims, which are pleaded separately in this Complaint from Plaintiffs' Exchange Act claims, except that any challenged statements of opinion or belief made in connection with the July 2015 Offering are alleged to have been materially misstated statements of opinion or belief when made and at the time of the July 2015 Offering.

III. JURISDICTION AND VENUE

29. The claims asserted herein arise pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5), and under Sections 11, 12(a)(2), and 15 of the Securities Act (15 U.S.C. §§ 77k, 771, 77o).

30. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337, Section 27 of the Exchange Act (15 U.S.C. § 78aa), and Section 22 of the Securities Act (15 U.S.C. § 77v).

31. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), Section 27 of the Exchange Act, 15 U.S.C. § 78aa(c) and Section 22 of the Securities Act 15 U.S.C. § 77v(a). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading statements, occurred in substantial part in this District. Additionally, Clovis' principal place of business is located in this District.

32. 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 a national securities exchange.

IV. THE PARTIES

A. Plaintiffs

33. On February 18, 2016, the Court appointed M.Arkin (1999) LTD and Arkin Communications LTD (collectively, the "Lead Plaintiff") as Lead Plaintiff. Lead Plaintiff purchased Clovis common stock and call options, and wrote Clovis put options, during the Class Period, and suffered damages as a result of the violations of federal securities laws alleged herein.

34. Named Plaintiff the City of St. Petersburg Employees' Retirement System ("St. Petersburg" or "Named Plaintiff") is a public retirement system that provides defined benefit pension payments to the retired public employees of St. Petersburg, Florida. As set forth in the certification attached as Exhibit A to this Complaint and St. Petersburgh's

trading records attached as Exhibit B, St. Petersburg purchased Clovis common stock during the Class Period, including Clovis shares in, and traceable to, the Company's July 2015 Offering, and suffered damages as a result of the violations of federal securities laws alleged herein. As detailed in Exhibits A and B, St. Petersburgh entered a purchase order for 956 shares of Clovis common stock directly from lead underwriter JPM (defined below) on July 9, 2015 (the date the prospectus for the July 2015 Offering was filed), which settled on July 14, 2015 (the exact date of the July 2015 Offering). St. Petersburgh purchased these shares for $78.00 per share – the ***exact*** offering price for the July 2015 Offering. St. Petersburgh paid no commission on its purchases, which would have been impossible if the purchases had been made in the aftermarket.

35. The Lead Plaintiff and Named Plaintiff are collectively referred to herein as "Plaintiffs."

B. Exchange Act Defendants

36. The Complaint asserts fraud and control person claims under Section 10(b) and Section 20(a) of the Exchange Act against the following defendants.

1. Clovis

37. Defendant Clovis is a biopharmaceutical company headquartered in Boulder, Colorado. The Company was founded in 2009 and has been publicly traded since November 2011. Clovis' business focuses on acquiring, developing, and commercializing oncology products worldwide. During the Class Period, the Company marketed no drug products, but had three drugs in development: rociletinib, rucaparib, and lucitanib. Clovis stock trades on the Nasdaq under the symbol CLVS.

2. The Executive Defendants

38. Defendant Patrick Mahaffy is a co-founder of Clovis and has served as its CEO and Chairman of its board of directors since the Company's inception in 2009.

39. Defendant Erle T. Mast is a co-founder of Clovis and served as its Executive Vice President and Chief Financial Officer ("CFO") from the Company's inception in 2009 until his resignation on March 31, 2016.

40. Defendant Andrew Allen is a co-founder of Clovis and served as the Company's Chief Medical Officer ("CMO") and Executive Vice President for Clinical and Pre-clinical Development and Pharmacovigilance from the Company's inception in 2009 until his resignation on June 22, 2015.

41. Defendant Gillian Ivers-Read is a co-founder of Clovis and has served as its Chief Regulatory Officer ("CRO") and Executive Vice President for Technical Operations since the Company's inception in 2009.

42. Defendants Mahaffy, Mast, Allen and Ivers-Read are collectively referred to herein as the "Executive Defendants."

C. Securities Act Defendants

43. The Complaint asserts strict liability, negligence, and control person claims under Sections 11, 12(a)(2) and 15 of the Securities Act against Clovis and the Executive Defendants, as well as the additional following Defendants.

1. The Underwriter Defendants

44. Defendant J.P. Morgan Securities LLC ("JPM") was lead underwriter of Clovis' July 2015 Offering.

45. Defendant Credit Suisse Securities (USA) LLC ("Credit Suisse") was an underwriter of Clovis' July 2015 Offering.

46. Defendant Stifel, Nicolaus & Company, Incorporated ("Stifel") was an underwriter of Clovis' July 2015 Offering.

47. Defendant Mizuho Securities USA Inc. ("Mizuho") was an underwriter of Clovis' July 2015 Offering.

48. Defendants JPM, Credit Suisse, Stifel, and Mizuho are collectively referred to herein as the "Underwriter Defendants."

2. The Venture Capital Defendants

49. Defendants NEA Partners, 13 L.P., NEA 13 GP, LTD, Scott D. Sandell and Forest Baskett (the "NEA Defendants") along with Clovis Director M. James Barrett, are a part of New Enterprise Associates, a venture capital firm that beneficially owned 6.7% of Clovis' shares at the time the Company conducted its July 2015 Offering. At the time of that offering, an affiliated partnership, New Enterprise Associates 13, L.P. held the Clovis shares beneficially owned by New Enterprise Associates. NEA Partners, 13 L.P. was the sole general partner of New Enterprise Associates 13, L.P.; NEA 13 GP, LTD was the sole general partner of NEA Partners, 13 L.P. Sandell and Baskett, along with Barrett, are members of NEA 13 GP, LTD. At the time of the July 2015 Offering, the NEA Defendants and Barrett held all dispositive and voting power with respect to all Clovis shares held by New Enterprise Associates 13, L.P. By virtue of their significant stake in Clovis, their voting power qua shareholder, and their representation, through Barrett, on Clovis' board of directors, the NEA Defendants had the power to control, and did control, Clovis in its conduct of the July 2015 Offering.

50. Defendant Aberdare Ventures IV, L.P. ("Aberdare") is a venture capital firm that beneficially owned 2.5% of Clovis' shares at the time the company conducted its July 2015 Offering. Clovis Director Paul Klingenstein founded Aberdare, and at the time

of Clovis' July 2015 Offering, was (and still is) its managing director, as well as managing director of Aberdare GP IV, LLC, the sole general partner of Aberdare (a position he likewise still holds). At the time of the July 2015 Offering, Aberdare and Klingenstein held all dispositive and voting power with respect to all Clovis shares held by Aberdare. By virtue of its significant stake in Clovis, its voting power qua shareholder, its representation, through Klingenstein, on Clovis' board of directors, and as a party to a 2009 investor rights agreement with Clovis, entitling Aberdare to, among other things, registration right and access to Company information, Aberdare had the power to control, and did control, Clovis in its conduct of the July 2015 Offering.

51. NEA Defendants and Aberdare are collectively referred to herein as the "Venture Capital Defendants."

V. FACTUAL BACKGROUND

A. It Was Critical For Clovis That Rociletinib Appear To Be Performing Well In Its Clinical Trials

52. During the Class Period, Clovis had no revenue generating products on the market and was heavily dependent on capital raised from investors in order to keep the Company afloat and fund the research and development costs for its three pipeline drugs, rociletinib, rucaparib and lucitanib.

53. By far the most important of these drugs during the Class Period, and the one that received the most attention from investors and analysts was rociletinib, or "CO-1686" – a drug presented to investors as a breakthrough therapy in the treatment of lung cancer. As J.P. Morgan securities analysts noted in a report issued prior to the start of the Class Period:

> We have an Overweight rating on CLVS shares. Our thesis is based on the potential for CO-1686 [rociletinib] and rucaparib, the company's lead

> assets. Focus is now on 1686 and we believe it's noteworthy that this is where management's greatest excitement has been all along.

54. Rociletinib generated such intense investor excitement because Defendants presented it as a drug that was poised to dominate the untapped $3 billion marketplace for lung cancer therapies aimed at the many patients who develop resistance to front-line treatments.

55. The front-line lung cancer treatment is a class of drugs called "tyrosine kinase inhibitors" ("TKIs"), which are designed to inhibit proteins responsible for "turning on" cellular functions and stopping mutated cells from indiscriminately and pathologically proliferating. For example, mutations in a cell's "epidermal growth factor receptor" ("EGFR") (a protein responsible for cellular growth, proliferation, and survival) have been associated with a number of cancers, including lung cancer. These mutations cause cellular functions to essentially become "stuck in the on position," leading to unregulated cell growth and, eventually, the development of cancers.

56. Unfortunately, patients treated with TKIs overwhelmingly develop a resistance to treatment within one year. In 60% of those cases, resistance to treatment is caused by a secondary mutation in the EGFR protein called the "T790M" mutation, which changes the structure of the protein such that TKIs can no longer form a molecular bond with it and inhibit its activity. According to Clovis, rociletinib binds with EGFR activating mutations, even where the T790M resistance mutation is present. In other words, rociletinib was supposed to provide an effective treatment for patients who exhibited resistance to TKI's due to the T790M mutation.

57. Investors and analysts agreed that the commercial potential for a lung cancer drug that targets T790M-positive mutant EGFR is enormous. As analysts explained,

"[t]here are currently no targeted therapies approved for the treatment of tumours with the T790M resistance mutation so this represents a large commercial opportunity and indicates the importance of these drugs to their proprietors." Indeed, analysts and commentators estimated at the start of the Class Period that the market for such drugs was "worth at least $3 billion in annual sales."

58. Throughout the Class Period, analysts focused on the commercial possibilities of rociletinib, stating that it "may prove to be a ***class-leading*** drug" (Piper Jaffray), saying it was "the core of our investment thesis [for Clovis]" (J.P. Morgan) and it was the "Street's predominant focus" (Leerink).

59. The prospect that Clovis might be the first drug company to break into this valuable new market generated additional excitement amongst investors. Drug companies that are the first to bring a new therapy to market gain what is known as a "first-mover advantage," *i.e.*, a preexisting presence in the marketplace allowing the "first-mover" to preempt potential competition and gain significantly more market-share. Accordingly, analysts were excited by the prospect that "CO-1686 [rociletinib] can be the first approved drug for treating EGFRm-T790M+ NSCLC [non-small cell lung cancer]."

60. By the start of the Class Period, rociletinib was Clovis' most important asset and was subjected to intense scrutiny by Clovis' executives, investors, and the market at large. Indeed, Clovis began almost every investor call and press release with a discussion of rociletinib's latest clinical trial results, and Clovis executives routinely fielded questions from analysts about those results.

61. In addition to rociletinib, Clovis was also developing two other drugs: rucaparib, a treatment for ovarian cancer, and lucitanib, a treatment for breast

cancer. Although Clovis had three cancer drugs in development, it did not have a single drug on the market and the Company generated no sales revenue. In order to fund its significant operating expenses during the Class Period – over $475 million – Clovis heavily relied on its ability to raise capital from investors. As Defendants stated in periodic reports filed with the SEC throughout the Class Period:

> We continue to incur significant research and development and other expenses related to our ongoing operations . . . . Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, ***we expect to finance future cash needs through a combination of public or private equity offerings***, collaborations, strategic alliances, and other similar licensing arrangements.

In fact, the Company's capital needs exploded during the Class Period, as Clovis ramped up its development programs. Clovis' operating expenses grew from $84 million in 2013 to $172 million in 2014; these expenses ballooned again to $230 million in just the first 9 months of 2015 alone.

62. In order to fund its operations, and as discussed in more detail below, Clovis conducted two offerings during the Class Period: raising $287.5 million in a September 9, 2014 private placement of senior notes, and $298 million in the July 2015 Offering.

B. Astra-Zeneca's Tagrisso Emerges As A Competitor To Rociletinib

63. Prior to the start of the Class Period, rociletinib was the primary developmental drug targeting the untapped $3 billion marketplace for TKIs that target T790M-positive mutant EGFR. In late 2013, however, Astra-Zeneca's Tagrisso, or "AZD9291," began to emerge as a potential rival to rociletinib. As a Credit Suisse analyst explained in a report issued on September 9, 2013, until that point, "AZD9291 ha[d] been off the radar screen of investors." That month, however, Astra-Zeneca published a "proof-

of-concept" article in a major medical journal showing that the AZD9291 molecule, like rociletinib, could irreversibly bind with T790M-mutated EGFR.

64. Investor concerns about the commercial threat posed by Tagrisso came into sharp focus on September 29, 2013, when Astra-Zeneca reported a small set of "promising" efficacy data: two confirmed partial responses in six patients evaluated at Tagrisso's lowest dose. Analysts observed that while "many investors may have believed that CO-1686 was the lead T790M-targeting candidate in the space, [t]his recent data from AZ is likely to change that perception . . . ." Throughout the remainder of the Class Period analysts repeatedly emphasized that Clovis' rociletinib was in a "close first-to-market race" with its principal competitor, Astra-Zeneca's Tagrisso.

65. Defendants were highly aware of the threat posed by Tagrisso. For example, in response to a Credit Suisse analyst's question about the "emerging" profile of Tagrisso on an October 31, 2013 earnings call, Mahaffy acknowledged, "We are in a race. They are a very able competitor with an active drug." Defendants also understood that investors were keenly focused on the forthcoming "phase II" rociletinib efficacy results. Indeed, on the October 31, 2013 earnings call, Mahaffy told investors, "we understand the great desire for information regarding the progress of 1686," as he fielded questions from analysts on that call and others asking Clovis management when it "expect[ed] to see Phase 2 data for 1686."

C. Clovis Sets Up Its Clinical Trial Protocols For Rociletinib, With A Focus On Objective Response Rate (ORR)

66. The FDA typically classifies clinical trials of new drugs into four phases: small phase I trials are conducted to evaluate the drug's safety in humans; larger phase II trials are conducted to evaluate efficacy; still larger phase III trials are conducted to

compare the experimental drug to competing therapies in terms of both efficacy and safety; finally, large phase IV trials are conducted after the drug has been marketed to continue to evaluate safety and investigate efficacy for new indications. *See, e.g.*, Friedman, et al., *Fundamentals of Clinical Trials*, at 3-8 (4th ed. 2010).

67. The data Defendants reported throughout the Class Period came principally from the "phase II" extension of the TIGER-X trial. It was this phase II data, along with a small set of additional efficacy data from another phase II trial called TIGER-2, which ultimately formed the basis of the rociletinib NDA Clovis submitted to the FDA in July of 2015.

68. The single most critical metric that Defendants, regulators, medical professionals, and investors focused on during these phase II trials was rociletinib's objective response rate (defined above as ORR). Oncologists and researchers view ORR as a particularly meaningful measure of a cancer drug's efficacy. As leading oncology experts explained in 2009, "objective response carries with it a body of evidence greater than for any other biomarker supporting its utility as a measure of promising treatment effect in phase II screening trials."

69. The primary challenge facing Clovis during the Class Period was to show that the ORR reported by rociletinib in the phase II trials compared favorably to the ORR reported by Tagrisso. As analysts explained in September 2013, "We believe larger Phase II datasets for both compounds [rociletinib and Tagrisso] possibly available in 2Q:14 could begin to better characterize their emerging and longer-term potential." "To remain competitive," analysts concluded, "CO-1686 [rociletinib] will likely need to show a response rate that is relatively close to that of AZD9291."

70. In short, as Defendants knew, in order for rociletinib to become a commercial success it would have to show an ORR that compared favorably to Tagrisso's.

D. Defendants Knew That When They Reported Objective Response Rates (ORR), Investors Believed They Were Reporting "Confirmed" Responses

71. During the Class Period, Defendants knew or were reckless in failing to know that investors expected and understood that the ORR Defendants reported for rociletinib throughout the Class Period included only confirmed "responses" (observations of tumor shrinkage).

72. Defendants knew this because, among other things, (1) Clovis expressly incorporated RECIST guidelines into rociletinib's clinical trial protocols, and RECIST requires the use of only confirmed responses in the calculation of ORR; (2) Defendants made repeated public statements during the Class Period that they were adhering to RECIST; (3) long standing industry practice and FDA guidance required the use of confirmed responses; and (4) members of the medical community believed – and stated publicly – during the Class Period that Clovis was reporting confirmed responses.

1. Defendants Incorporated RECIST Into The TIGER-X Protocol, And RECIST Requires The Use Of "Confirmed" Responses In The Calculation Of ORR

73. Before a trial begins, clinical drug trial standards require a drug company to specify how the clinical trial will be conducted, how the trial data will be analyzed, and how success will be defined and measured. This prespecified plan is memorialized in a "clinical trial protocol." *See, e.g.*, Friedman, et al., *Fundamentals of Clinical Trials*, at 3-8 (4th ed. 2010). "The study protocol can be viewed as a written agreement between the investigator [the drug company], the participant, and the scientific community." Results

generated as a consequence of protocol deviations are inadequate to support empirical conclusions about the experimental therapy. *See, e.g.*, *id.*

74. Clovis developed, approved, and agreed to abide by protocols for both the TIGER-X and TIGER-2 studies. Those protocols were publicly disclosed and state that the primary objective of both phase II trials was "To evaluate tumor response . . . to CO-1686 in patients with T790M" – *i.e.,* the efficacy, or effectiveness, of the drug. The primary endpoint – the criteria defining success in terms of that primary objective – for the rociletinib trials was "ORR and duration of response per RECIST Version 1.1." The protocols, pursuant to RECIST standards, defined a "response" as an event where a patient's tumors shrink by 30% or more from the "baseline" measurement taken when the patient starts the trial. The protocols define ORR as the percentage of patients in the trial who experience a response. In other words, rociletinib's efficacy would be judged by the percentage of patients who had their tumors shrink by 30% or more.

75. "RECIST" – the "Response Evaluation Criteria in Solid Tumours" – is a set of standard and uniform criteria for evaluating the most important clinical efficacy measures in oncology trials. "RECIST, since its initial publication in 2000, and subsequent update in 2008 [Version 1.1], has become ***the most widely used system for assessing response in cancer clinical trials, and is the preferred and accepted system for use in new drug applications to regulatory agencies***." Manola et al., *Assessment of treatment outcome*, *in* UICC Manual of Clinical Oncology 40, 44 (Brian O'Sullivan et al. eds., 9th ed. 2015).

76. Clovis made absolutely clear in the TIGER-X and TIGER-2 protocols that it would adhere to RECIST guidelines in analyzing and reporting the ORRs observed in

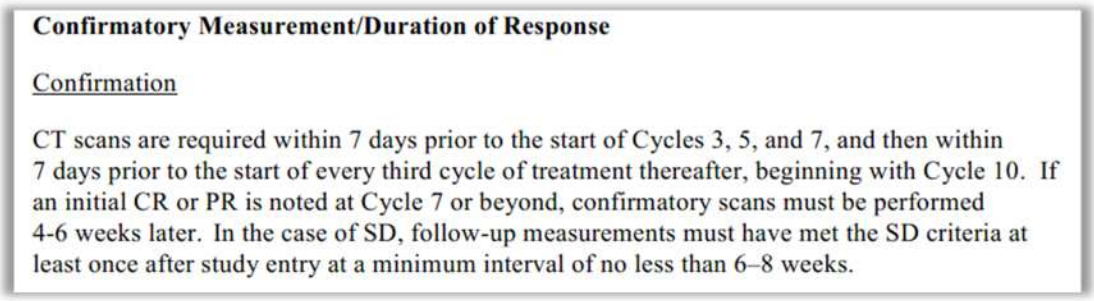
these trials. For instance, the protocols themselves define the studies' primary endpoint itself as ORR "per RECIST Version 1.1," and state unambiguously that "[t]he efficacy endpoints will be evaluated using RECIST Version 1.1," and that "[t]umor response will be interpreted using RECIST Version 1.1."

77. Clovis' purported adherence to RECIST standards gave investors confidence in the Company's reported results. Moreover, making use of a widely-implemented set of criteria gives scientists, doctors, and investors comfort that a drug maker's comparisons between its drug and competing therapies, for instance, actually compare apples to apples.

78. RECIST unequivocally requires each instance of tumor shrinkage (a response) to be "confirmed." This means that any initial observation of a 30% or greater reduction in a tumor's size be observed again in a subsequent scan, before it can be included in the calculation of ORR. The published standards state:

> In non-randomised trials where response is the primary endpoint, ***confirmation*** of PR ["partial response," *i.e.*, shrinkage between 30% and 99%] and CR ["complete response," *i.e.*, eradication of the tumor] ***is required*** to ensure responses identified are not the result of measurement error.
>
> * * *
>
> [In such trials,] Complete or partial responses may be claimed ***only if*** the criteria for each are met at a subsequent time point as specified in the protocol (generally 4 weeks later).

79. Clovis' TIGER-X and TIGER-2 protocols not only imported the RECIST standards into their definition of ORR, they took the additional step of separately spelling out the requirement that each response be confirmed, and setting out a schedule for performing confirmatory tumor scans, as shown in Figure 1 below (excerpted from Appendix A of the TIGER-X clinical protocol).



Confirmatory Measurement/Duration of Response

Confirmation

CT scans are required within 7 days prior to the start of Cycles 3, 5, and 7, and then within 7 days prior to the start of every third cycle of treatment thereafter, beginning with Cycle 10. If an initial CR or PR is noted at Cycle 7 or beyond, confirmatory scans must be performed 4-6 weeks later. In the case of SD, follow-up measurements must have met the SD criteria at least once after study entry at a minimum interval of no less than 6–8 weeks.

Figure 1.[3]

80. The rociletinib protocols constructed by Clovis thus required that efficacy scans would be conducted within 7 days of the end of each even numbered "Cycle" up to Cycle 7. The protocols provide that each Cycle is 21 days long. Additionally, the protocols provide that for an initial response up to Cycle 7, the next efficacy scan acts as the "confirmation" scan. Consequently, an initial response will be confirmed in 42±7 days. For Cycles 7 and beyond, confirmation takes place even more quickly: within 4-6 weeks. Therefore, any initial response Clovis observed would have to be confirmed or disconfirmed no more than 35 to 49 days later, in the longest possible scenario.

81. In sum, the clinical trial protocols for the TIGER trials (1) expressly incorporated RECIST's requirement that only confirmed responses could be included in the calculation of ORR, and (2) required that confirmatory scans be performed within 35-49 days.

2. Defendants Repeatedly Stated That They Were Adhering To RECIST Throughout The Class Period

82. Defendants own statements to investors reinforced the market's belief that Clovis was reporting confirmed ORRs. Throughout the Class Period, Defendants

[3] Available at http://www.nejm.org/doi/suppl/10.1056/NEJMoa1413654/suppl_file/nejmoa1413654_protocol.pdf

repeatedly claimed that Clovis was adhering to the RECIST criteria, including specifically claiming that the Company was reporting ORRs as defined by RECIST Version 1.1.

83. For instance, during a major medical conference held on November 21, 2014 (the EORTC-NCI-AACRS Symposium on Molecular Targets and Cancer Therapeutics), Clovis highlighted to doctors and analysts that it was presenting ORRs "per RECIST 1.1," as an excerpt from the Company's presentation at the conference included at Figure 2 below makes clear.

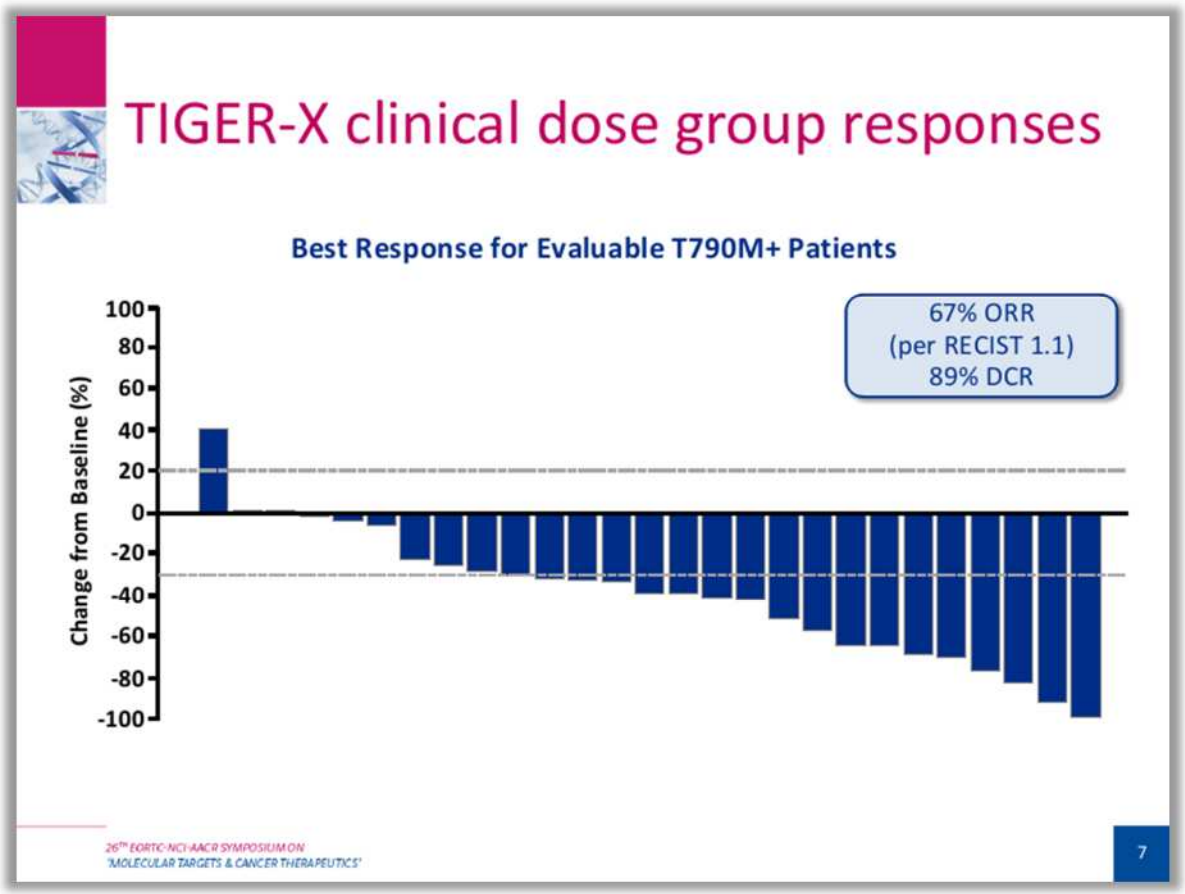


Figure 2.

84. During the Class Period, Clovis made this claim at virtually ***every*** major medical conference at which it presented ORR data from its key TIGER-X trial, including the:

- May 31, 2014 American Society of Clinical Oncology ("ASCO") medical conference;
- November 21, 2014 EORTC-NCI-AACRS Symposium on Molecular Targets and Cancer Therapeutics ("ENA conference");
- March 4, 2015 13th International Congress on Targeted Anticancer Therapies ("TAT") medical conference;
- May 31, 2015 ASCO medical conference; and
- September 27, 2015 and September 28 2015 European Cancer Congress ("ECC") medical conference.

85. Likewise, when Clovis scientists, including Defendant Allen, disclosed rociletinib efficacy data from its TIGER-X trial in an April 2015 article published in the *New England Journal of Medicine*, one of the most prominent and widely-read medical journals in the world, they reassured the public that "[t]umor response was assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1." *See* Sequist et al., *Rociletinib in EGFR-Mutated Non-Small-Cell Lung Cancer*, 372 New Eng. J. Med. 1700, 1704 (2015).

86. Defendants made similar representations on conference calls with investors. For example, on Clovis' May 31, 2014 ASCO conference call, Defendant Allen expressly stated, "the primary outcome for Phase II is Objective Response Rate with duration of response using RECIST 1.1)."

3. **Long-**Standing Industry Practice And FDA Guidance Required Using Confirmed Responses **In The Calculation Of ORR**

87. Even if Defendants had not specifically represented that they were adhering to RECIST standards, "for decades" it has been standard practice in the medical community and at the FDA to require response confirmation, as experts in the field have explained.

88. Members of the medical and scientific communities view response confirmation as critical to guaranteeing the reliability, soundness, and reproducibility of claimed efficacy results. "The main goal of confirmation of objective response in clinical trials is to avoid overestimating the response rate observed." Indeed, a 2009 study published in the *European Journal of Cancer* found that "removing the requirement for response confirmation led to a significant increase in the numbers of patients classified as responders, resulting in a relative increase of approximately 19% in response rate. "As discussed above, confirmation of responses serves "to ensure responses identified are not the result of measurement error." In addition, and of particular importance here, scholars note that because confirmation is the "industry standard," mandating confirmation of responses in a particular trial is a predicate to making valid and useful comparisons across different trials and drugs. *See* Eisenhauer, et al., *New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1)*, 45 European J. Cancer, 228, at 236 (2009) (confirmation "will also permit appropriate interpretation of results in the context of historical data where response has traditionally required confirmation in such trials."). As one market commentator has explained, "an **un**confirmed response rate," by contrast, "is not considered a meaningful (let alone approvable) endpoint." *See* Hammer, *Biotech portfolio update – Clovis, Array, ImmunoGen*, November 22, 2015.

89. The requirement for response confirmation has been codified not only in RECIST but also in international standards promulgated by the Union for International Cancer Control, which mandate that:

> [C]onfirmation of PR and CR is *required* to ensure responses identified are not the result of measurement error" in "[n]on-randomized trials where response is the primary end-point."

90. Defendants and investors were also aware during the Class Period that the FDA would make its decision on rociletinib's NDA based only on confirmed responses. As analysts later observed, "the regulatory standard is to consider only ***confirmed response rates*** and this was an ***unambiguous fact*** from the FDA" during the Class Period. For instance, in an April 24, 2015 presentation, FDA officials noted that in determining whether to grant expedited status to an oncology drug the agency's "[a]nalysis approach" has, and would continue, to "[u]se[] confirmed ORRs in the analysis."

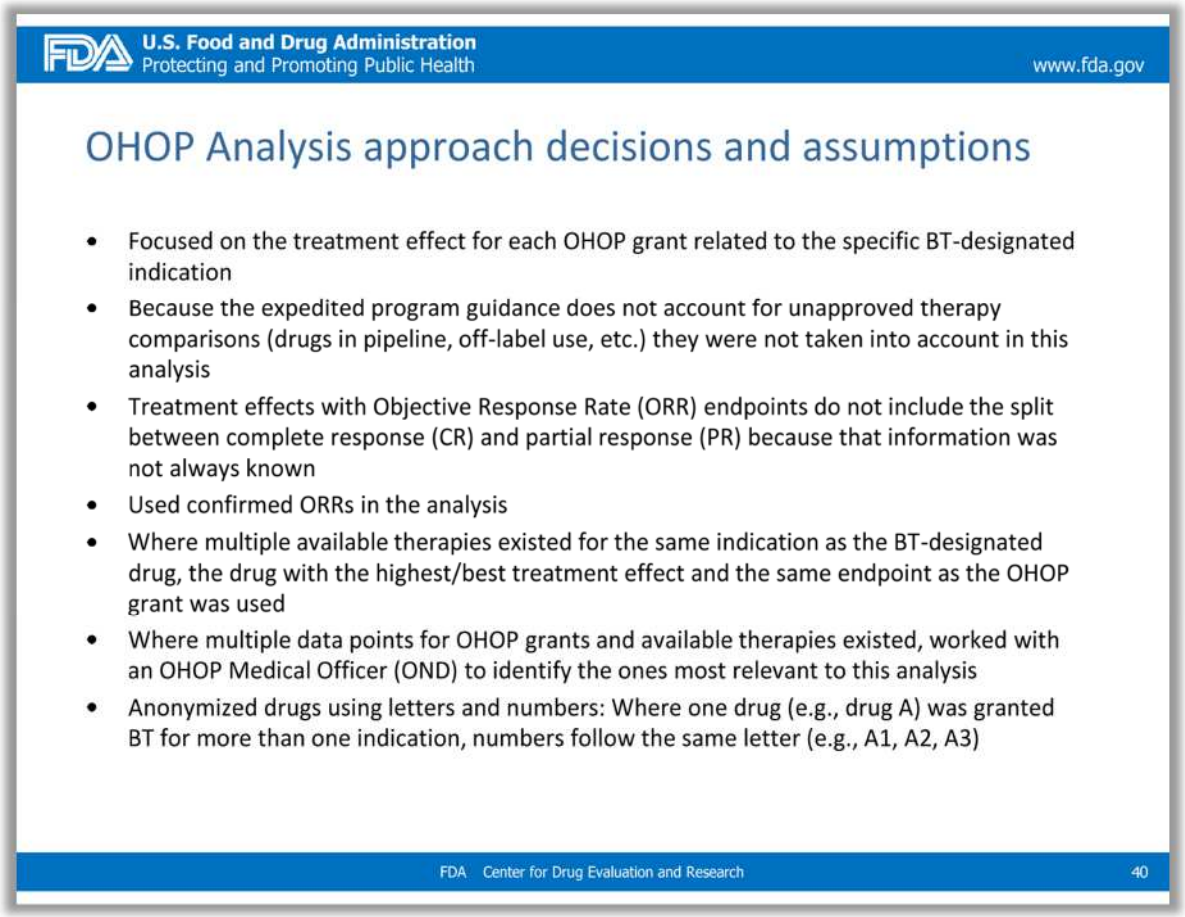


Figure 3. Excerpt from April 24, 2015 FDA presentation, *Breakthrough Therapy Designation: Exploring the Qualifying Criteria*.

4. The Medical Community Believed That Clovis Was Reporting Confirmed Responses

91. Not surprisingly given Clovis' public representations and the standard practice in the industry, members of the medical community, like investors, understood that Clovis was reporting confirmed ORRs at medical conferences conducted during the Class Period. For instance, as mentioned above, Clovis misleadingly reported at the November 21, 2014 ENA conference that it observed a 67% ORR in T790M positive patients and a 36% ORR in T790M negative patients, "per RECIST 1.1," in the Company's rociletinib data. A press release issued by the ENA conference's own sponsors incorrectly

reported that those ORRs were confirmed: "18 [T790M-positive rociletinib patients] had a ***confirmed*** response, giving an overall response of 67%," and that "four [T790M-negative rociletinib patients] had a ***confirmed*** response (overall response rate of 36%)."

92. At least three other medical journals and research publications also incorrectly reported that the ORRs Clovis reported at the ENA conference were based on confirmed responses:

- A November 19, 2014 article in *Cancer Discovery*, ranked by Thompson Reuters as the number 5 oncology journal in the world by impact factor, reported "Among the 27 rociletinib-treated patients who received optimal doses of the drug and for whom the team had CT scan results, 18 had a confirmed response to the drug";

- Both a December 17, 2014 article in *Oncology Nurse Advisor* and a December 26, 2014 article in *Science Daily* reported that "18 [T790M-positive rociletinib patients] had a confirmed response to the treatment, giving an overall response of 67%."

E. Clovis' Stock Price Soars As Defendants Assure Investors That Rociletinib's ORR Compares Favorably With Tagrisso

93. On multiple occasions during the Class Period, in press releases, SEC filings, at medical conferences, and in articles published in major medical journals, Defendants told investors that rociletinib was performing well in the TIGER trials and demonstrating strong safety and efficacy. Knowing that it was critically important to investors, Defendants often made direct comparisons between rociletinib's and Tagrisso's ORR results.

94. On May 31, 2014, the first day of the Class Period, Clovis presented at the 2014 ASCO medical conference, and reported the first eagerly anticipated rociletinib efficacy results from its phase II TIGER-X dataset. This disclosure came just a few weeks after Astra-Zeneca had published efficacy data for Tagrisso. Astra-Zeneca had reported a confirmed ORR for Tagrisso of at least 56%.

95. At the ASCO medical conference, Clovis reported a similar ORR to Tagrisso's, stating that rociletinib had exhibited a "58 percent objective response rate (ORR)" in patients with the T790M mutation across all rociletinib doses. Clovis expressly stated that ORR was evaluated "per RECIST v1.1." In a press release issued on a Form 8-K and filed with the SEC that same day, Mahaffy told investors that the Company was "extremely pleased with the consistency of the efficacy demonstrated to date, the growing evidence of a lengthy duration of benefit and that [rociletinib] is so well-tolerated with a manageable side effect profile."

96. Defendants repeated these statements on a May 31, 2014 conference call with investors, with Defendant Allen emphasizing that "the primary outcome for Phase II is Objective Response Rate with duration of response ***using RECIST 1.1***."

97. Analysts reacted favorably to these statements because they indicated that rociletinib had strong prospects for approval and was in a strong position to compete with Tagrisso on the commercial market. For instance, on June 3, 2014, Piper Jaffray analysts reported, "Data for '1686 [rociletinib] continues to look good, with a 58% response rate." Based on this, analysts concluded, "[d]espite a potential competitor [Astra-Zeneca] putting the 'pedal to the metal,' we still see significant market share for '1686 [rociletinib] and reiterate our Overweight rating and $87 price target on Clovis."

98. On August 7, 2014, Clovis issued a press release filed with the SEC on a Form 8-K, which stated that "Highlights from the data presented for evaluable, centrally-confirmed T790M positive patients treated at a therapeutic dose of rociletinib included a 58 percent objective response rate." Defendants held a conference call with investors on

that same day. On that call, Mahaffy again cited the purported 58 percent ORR and called it one of the "***highlights of the data presented at ASCO***."

99. Mahaffy also stated that "we remain extremely encouraged by the impressive durability of benefit we are seeing," that Clovis had seen "***clear evidence of meaningful activity***," and that Clovis was "***extremely enthusiastic*** about moving the rociletinib program forward rapidly." Mahaffy also assured investors that "the data are open to us . . . we have access to all that," and he assured "we will continue to provide updates. ***We know that's important to investors***."

100. Analysts once again responded favorably to Defendants' statements. For instance, in an August 8, 2014 report, analysts at Leerink rated Clovis "Outperform," and noted that "rociletinib is emerging as one of the most interesting new agents for cancer due to its demonstrated activity." Piper Jaffray analysts stated in an August 8, 2014 report that "[w]e continue to view rociletinib as ***best-in-class***."

101. In response, Clovis' stock price rose steeply. By the end of August, Clovis' common stock was trading above $49 per share, an increase of 30% from the $38 per share it was trading at just two months earlier in June 2014.

102. Defendants acted quickly to take advantage of the situation. On September 2, 2014, the Company filed with the SEC a Form 8-K announcing that they intended to conduct a $287 million offering of convertible senior notes through a private placement. That sale was consummated a week later, on September 9, 2014 raising significant additional capital for the Company.

103. Also on September 9, 2014, Clovis participated in the annual Morgan Stanley Healthcare Conference. At that conference, Mahaffy cited the favorable rociletinib

efficacy data the Company had presented at ASCO as helping to create positive market conditions for the offering and allowing the Company to secure financing on favorable terms: "And the timing [of the offering] for us was good. And I must say, our ASCO experience influenced it." He further highlighted the importance of the offering to Clovis, explaining it would allow the Company to stay afloat until "May or June. You know we're going to get pretty far."

104. Moreover, as they did throughout the Class Period, Defendants expressly compared rociletinib's results with Tagrisso's, and claimed that the two drugs had similar efficacy profiles. At the September 9, 2014 conference, a securities analyst asked Mahaffy, "I think you and your main competitor [Astra-Zeneca] showed similar response rates. Maybe you could just sort of talk to us about what you think are the key differences between the drugs and where you may or may not have a competitive advantage?" Mahaffy replied, "I think what you see is a similar response rate [between rociletinib and Tagrisso]."

105. In the wake of the successful notes offering, Defendants continued to face stiff competition from Tagrisso. On September 28, 2014, at the annual European Society for Medical Oncology ("ESMO") medical conference, Astra-Zeneca reported a highly favorable confirmed ORR of 61% in T790M-positive patients. *See* Figure 4.

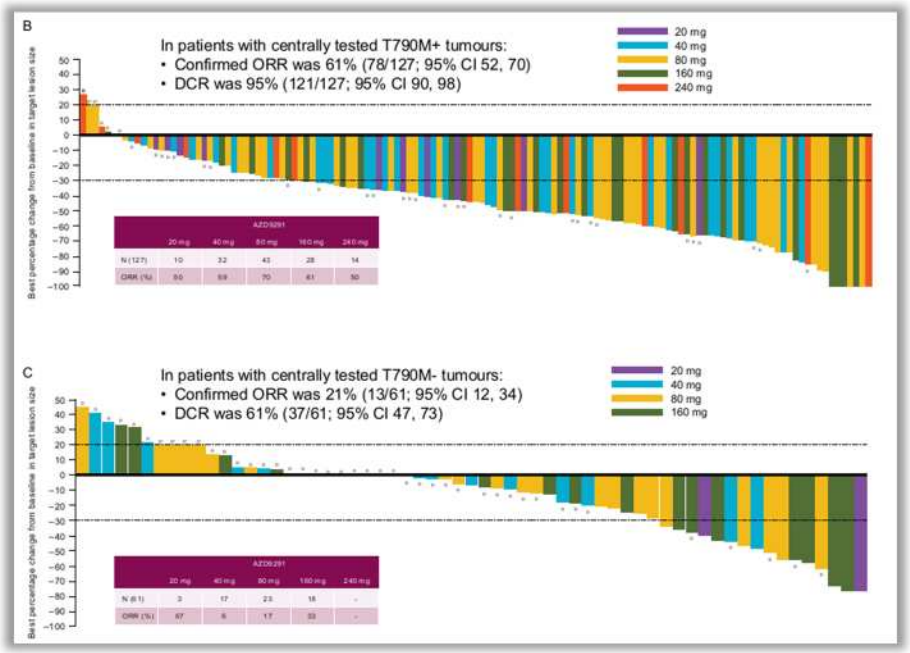


Figure 4.

106. Investors and analysts compared the results reported by Astra-Zeneca with the results Clovis had reported at the 2014 ASCO conference and concluded that rociletinib and Tagrisso continued to have similar efficacy profiles and were, therefore, in competitive equipoise. For instance, a UBS analyst reported that the Tagrisso data Astra-Zeneca disclosed was "in the same ballpark as Clovis' CO-1686 (58% at ASCO)," while Credit Suisse analysts stated that their "thesis on [Clovis] remains unchanged" after Astra-Zeneca's presentation.

107. On November 18, 2014, Clovis issued a press release in advance of the Company's presentation at the 2014 ENA conference, which is jointly hosted by the European Organisation for the Research and Treatment of Cancer ("EORTC"), the National Cancer Institute ("NCI"), and American Association for Cancer Research ("AACRS"). That press release, which was attached to a Form 8-K and filed with the SEC,

reported efficacy results for the key rociletinib doses for which Clovis planned to seek approval: 500mg and 625mg. Defendants' press release reported impressive ORR results:

> **Evidence of Activity**
>
> The objective response rate (ORR) in 27 evaluable T790M-positive patients receiving either 625 or 500mg BID was 67%. The ORR was comparable in the 625mg BID and the 500mg BID dose groups.

108. In the press release, Mahaffy characterized these results as "demonstrat[ing] the very encouraging activity and tolerability observed with rociletinib at our go-forward dose of 625mg BID, and our step-down dose of 500mg BID."

109. In a further effort to distinguish rociletinib from Tagrisso, Defendants for the first time claimed rociletinib had exhibited "surprising" efficacy in TKI-resistant patients who ***did not*** have the T790M-mutation. This was important because, apart from chemotherapy, there were virtually no treatment options available or in development for the 40% of TKI-resistant lung cancer patients who were T790M-negative. Accordingly, a drug that demonstrated meaningful efficacy in that population would, as Mahaffy told investors, meet a "significant unmet medical need."

110. Astra-Zeneca, meanwhile, had reported at the September 2014 ESMO conference that Tagrisso showed a confirmed ORR of 21% in TKI-resistant patients without the T790M mutation. Tagrisso was principally designed to treat patients with the T790M mutation, so its inferior efficacy in patients without that mutation was unsurprising. However, rociletinib's apparently promising results in this patient group helped to persuade investors that Clovis' drug had a potential commercial edge in its battle with Tagrisso.

111. On November 21, 2014, Clovis presented the ORR results described above at the 2014 ENA medical conference. Notably, Clovis' presentation claimed the Company had observed "durable RECIST responses, particularly in T790M+ patients," despite the

fact that the ORRs reported were unconfirmed and, therefore, (1) failed to meet RECIST's definition of "ORR"; and (2) could provide no evidence of response durability.

112. On a call with investors that same day, Mahaffy touted the "strong response rates" Clovis had reported in its press release and at the ENA conference. Defendants also highlighted the "encouraging data we've observed in T790M-negative patients," and responded to an analyst question about the commercial implications of these findings by touting the Company's "interactions with clinicians . . . . where the response to the data that you now saw for the first time today is[, ']That's really exciting because I want to use [rociletinib] in everybody.[']"

113. Analysts once again reacted positively, and once again drew favorable comparisons between rociletinib and Tagrisso. For example, a J.P. Morgan analyst reported on November 19, 2014, that Defendants had presented an "impressive ORR of 67%" in T790M-positive patients taking 500mg or 625mg of rociletinib, that this ORR "is competitive" with Tagrisso, and that "these results reinforce our ultimate confidence in roci's approvability."

114. Analysts also reacted enthusiastically to Defendants' statements concerning rociletinib's efficacy in T790M-negative patients. Leerink analysts, for example, also issued a November 19, 2014 report in which they observed, "Importantly in T790M- patients, there was a 36% ORR (4/11) . . . which appears to compare favorably to the 21% ORR (13/61)" reported for Tagrisso.

115. In response, Clovis' stock price continued to rise. By mid-December Clovis' common stock was trading at approximately $58 per share, an increase of more than 50% from the $38 per share it was trading at in early June 2014.

F. As Tagrisso Accelerates Its NDA, Defendants Continue To Release Positive Results For Rociletinib

116. By January 2015, Clovis had fully enrolled the patient population that would form the basis of its NDA during the fourth quarter of 2014, and the phase II TIGER-X expansion study was, as Mahaffy told investors, already "wind[ing] down."

117. Meanwhile, Astra-Zeneca had announced in November 2014 that it was accelerating its timeline for bringing Tagrisso to market and intended to file its NDA in the second quarter of 2015, leapfrogging Clovis. The fact that Clovis appeared to be losing the first-to-market race put additional pressure on the Company to continue reporting positive efficacy results and attempt to differentiate rociletinib by peddling its purported "surprising" results in T790M-negative patients.

118. On January 12, 2015, Clovis presented at the J.P. Morgan Healthcare Conference, where Mahaffy continued to tout the purported rociletinib efficacy results that Clovis had presented at the ENA conference, and highlighted what he characterized as new evidence of "striking activity" in patients without the T790M mutation:

> What continues to be fascinating about about [sic] this drug, is that ***we have striking activity in the T790M negative patients***. This is an update from the data that we presented at the [ENA] meeting. So, these are data that include about 20 patients who are treated at either 625 mg or 500 mg dose. And what you see in T7 -- in central negative T790M negative patients is ***a 42% overall response rate, and at the 625 mg dose, our response rate is 50%***.
>
> * * *
>
> And in fact most notable, our response rate in patients who immediately failed the TKI is 50% . . . . So, ***these are really compelling data for what is a significant unmet medical need***.

119. Throughout the remainder of the first and second quarters of 2015, Defendants continued to tout rociletinib's purported efficacy results and positive ORRs. For instance, Defendant Mast participated in the February 12, 2015 Leerink Global

Healthcare Conference on Clovis' behalf, where he stated that Clovis had observed a 67% ORR in T790M-positive patients. In response to an analyst question about how rociletinib's efficacy compared to Tagrisso's in the critical T790M-positive population, Mast stated that the data reported to date showed the two drugs' "response rates are clustered together," and that "from an efficacy perspective, we may have a lot of similarities."

120. Mast also reiterated the purported "50% response rate" observed in the T790M-negative patients taking 625mg of rociletinib, and again explicitly compared rociletinib's efficacy results in T790M negative patients with Tagrisso's, claiming that "[i]f these data continue to play out in [a] larger patient population, that will be a ***very significant distinguishment from the competing drugs***."

121. Defendants made similar statements on multiple occasions throughout the first part of 2015. For instance, in a conference call with investors on February 25, 2015, Mahaffy stated that "we believe these data demonstrate the safety and effectiveness of rociletinib in a real-world patient population." Mahaffy claimed that rociletinib had a "unique profile" compared with other developmental drugs, *i.e.,* Tagrisso, and "has been demonstrated to be highly active and well tolerated." Many additional positive statements that Defendants made during this time period are set forth below.

122. Rociletinib's safety profile had also become increasingly important to investors as they searched for ways to differentiate the drug from Tagrisso, which appeared to be in a dead heat with rociletinib when it came to the most important efficacy measures. Accordingly, Clovis had enthusiastically trumpeted rociletinib's supposedly strong safety profile, claiming that its most salient side effect was manageable hyperglycemia. This

compared favorably with Tagrisso's principal side effects, rash and diarrhea, which many prescribers viewed as significantly more detrimental to patients' quality of life.

123. For instance, at the February 12, 2015 Leerink investor conference, Mast told the market that the "primary side effect that comes with rociletinib that is easily managed is hyperglycemia" and that rociletinib had a "very manageable side effect profile." Likewise, on a May 6, 2015 earnings conference call, Mahaffy told investors that Clovis' data "demonstrate" rociletinib's "safety," and that "[o]verall, rociletinib is ***well tolerated with treatment related adverse events generally infrequent and mild, with the only grade 3 adverse event of note, hyperglycemia***, which when observed and requiring treatment is typically managed with a commonly prescribed single oral agent."

124. In a February 25, 2015 report, a J.P Morgan analyst highlighted the "***impressive response rates***" Clovis reported in its "updated data for roci in T790M-[negative] EGFRm patients." Likewise, in a February 26, 2015 report, Piper Jaffray analysts "reiterate[d their] Overweight rating and $100 price target," explaining, "In our view, T790M-negative (as well as -positive) NSCLC patients have become a focus and we believe this is warranted given the increasing body of encouraging data in that setting, and potential for that to enable a new paradigm for treatment. We expect Clovis to file for approval for ≥2nd-line use irrespective of T790M status."

125. These analysts also relied on the rociletinib ORR data Defendants presented to favorably compare the drug's commercial viability to Tagrisso's: "Further, based on data we've seen so far, we're not convinced AZ [*i.e.,* Tagrisso] will have a strong case in T790M negative patients with a 17% response rate." These analysts further concluded that rociletinib's "safety and efficacy as monotherapy has been established," highlighted the

"absence of cutaneous toxicity in contrast to other EGFR inhibitors [including Tagrisso]," and noted that the only notable adverse side effect, hyperglycemia, was "managed with oral hyperglycemic agent."

126. In response, Clovis' stock price continued to rise. By February 26, 2015, Clovis' common stock was trading at approximately $78 per share, an increase of more than 100% from the $38 per share it was trading at in June 2014.

G. Defendants Publish An Article In The Prestigious *New England Journal Of Medicine* Touting Rociletinib's Purportedly Strong ORR

127. On April 30, 2015, Defendants published data from the TIGER-X trial in the *New England Journal of Medicine* ("*NEJM*"), one of the most widely read medical journals in circulation. Defendant Allen was listed as a coauthor of the *NEJM* article and several other Clovis employees drafted and edited the manuscript, and approved the final published article.

128. The article purported to report efficacy data from the TIGER-X dataset that had been available to Defendants since June 18, 2014. In the article, Defendants again presented misleading ORR results, including a purported 59% ORR across all rociletinib doses in T790M-positive patients, while reassuring readers that "[t]umor response was assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1."

129. Clovis' *NEJM* article was timed to coincide with the publication of an Astra-Zeneca article in the same issue of the *NEJM* reporting the confirmed Tagrisso ORR data Astra-Zeneca had reported at the September 2014 ESMO conference (61% ORR across all doses). Thus, once again, although Clovis was presenting its efficacy data back-to-back with Astra-Zeneca's – this time in the same widely-read and prestigious

publication – it failed to disclose that unlike Astra-Zeneca, Clovis had included unconfirmed responses in its ORR results.

130. By May 14, 2015, in response to these favorable disclosures Clovis' common stock was trading at approximately $100 per share, an increase of more than 160% from the $38 per share it was trading at near the start of the Class Period.

H. Clovis Presents Critical Data At The May 31, 2015 ASCO Medical Conference

131. The May 31, 2015 ASCO medical conference was extremely important for Clovis and its investors. Defendants' presentation at ASCO would not only reflect the largest rociletinib dataset published during the Class Period, but was supposed to preview the data that would ultimately be submitted to the FDA in the rociletinib NDA. Moreover, Clovis' 2015 ASCO presentation came just ahead of a much-needed $300 million public financing, and the Company's access to investor capital was contingent upon its ability to continue to demonstrate competitive rociletinib results and sustain investor confidence in a positive regulatory outcome. As such, investors eagerly anticipated Defendants' 2015 ASCO presentation. For instance, in a May 6, 2015 report, J.P. Morgan analysts characterized Clovis' ASCO presentation as a "[k]ey upcoming event." In a report issued the next day, Leerink analysts alerted investors to "[s]ignificant data updates on rociletinib and rucaparib to be presented at ASCO." Likewise, biotech columnist Adam Feuerstein counted Clovis' rociletinib presentation as among the anticipated highlights of ASCO, noting that "[t]he competition between Clovis Oncology and Astra-Zeneca over their respective drugs to treat T790-mutated lung cancer is fierce."

132. At the May 31, 2015 ASCO conference, Clovis claimed that it had observed an "ORR of 60% . . . in centrally confirmed tissue T790M+ patients" at the "recommended

dose" of 500mg twice daily,[4] characterizing this result as "demonstrat[ing the drug's] compelling activity." Clovis also claimed the Company had observed a 54% ORR in T790M-positive patients taking the step-up 625mg dose. In addition, Clovis claimed the Company had observed an "ORR [of] 37%" associated with rociletinib in "[c]entral T790M [n]egative [p]atients" across all doses, and an ORR of 50% in T790M-negative patients taking the 625mg dose.

133. On a conference call with investors that same day, Allen underscored the consistency of the rociletinib ORR results reported by Clovis, stating that Clovis had "very consistently shown an objective response rate of around 60%" in T790M-positive patients, and an ORR "greater than 35%" in T790M-negative patients. Allen also emphasized the supposed durability of the responses Clovis reported, stating, "We have seen these ***consistent responses with durable patient benefit in now a large, very advanced Western patient population*** using our commercial drug formulation."

134. Likewise, a May 31, 2015 press release, quoted Mahaffy as stating: "***responses and durability of this magnitude*** in a very advanced U.S. patient population, of whom nearly half have a history of CNS metastases, is ***extremely encouraging*** . . . . These maturing data confirm rociletinib's ***compelling activity*** in patients with the most advanced stage of mutant EGFR [non-small cell lung cancer]."

[4] In advance of the 2015 ASCO conference, Clovis switched its recommended dose of rociletinib from 625mg to 500mg. Allen explained in a May 31, 2015 call with investors that Clovis chose 500mg as the recommended dose over 625mg because "efficacy is similar" between the two doses, but "toxicity is less" at the 500mg dose.

I. Clovis Holds A Private "Pre-NDA" Meeting With The FDA And Immediately Afterwards Defendant Allen Unexpectedly Resigns From The Company

135. In anticipation of Clovis' upcoming rociletinib NDA filing, the Company privately met with the FDA on June 9, 2015 to discuss the content, format, and timelines of the submission. Documents publicly released by the FDA on April 8, 2016 demonstrate that at that June 9, 2015 meeting, Clovis privately reported an ORR of 50% (without informing the FDA that the ORR was unconfirmed) in the TIGER-X study's 500mg dose group. Notably, as discussed in more detail below, Defendants continued to publicly tout the 60% ORR they had reported at the May 31, 2015 ASCO conference throughout the remainder of the Class Period.

136. On June 22, 2015, less than two weeks after the pre-NDA meeting with the FDA and less than two weeks before Clovis was set to file the rociletinib NDA, Allen resigned from the Company without warning. Allen had co-founded Clovis in 2009, and he had devoted years to shepherding rociletinib through development. By June 22, 2015, the Company was supposedly mere months away from rociletinib's approval.

137. By resigning his position when he did, Allen forfeited at least 25% of his lucrative performance pay. This was even more surprising given that, as discussed below, his pay would only have become more lucrative after approval as a function of the ensuing surge in Clovis' stock price.

J. Clovis Files Its NDA And Defendants Leverage The Company's Soaring Stock Price To Raise $300 Million From Investors

138. On June 24, 2015, Clovis filed its rolling NDA submission for rociletinib, seeking approval for use with patients who have EGFR non-small cell lung cancer, are

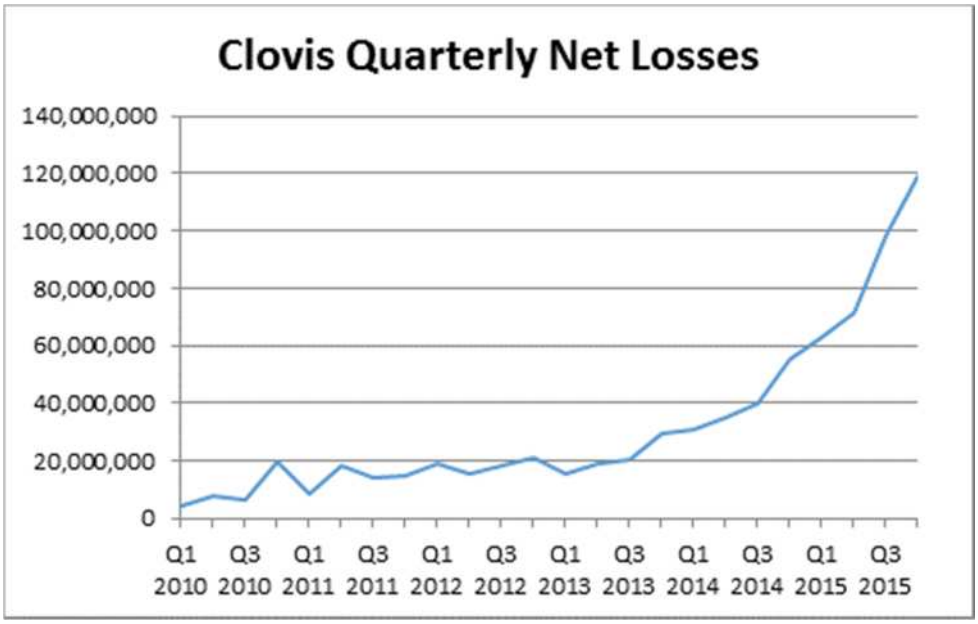
T790M-positive, and have been previously treated with an EGFR-targeted therapy. Clovis based its NDA on efficacy data primarily from the phase II TIGER-X study.

139. Shortly after filing the NDA, Defendants took advantage of the purportedly strong results being exhibited by rociletinib and the excitement surrounding the filing of the NDA to raise nearly $300 million from public investors through a secondary offering of common stock. On or about July 14, 2015, Clovis conducted the July 2015 Offering, offering 4.1 million shares of Clovis stock at $78 per share.

140. The July 2015 Offering raised more than $316 million from public investors, with net total proceeds to Clovis (after underwriting commissions) of approximately $298 million.

141. The 2015 Offering was conducted pursuant to a shelf registration statement filed with the SEC on a Form S-3 and dated June 11, 2013. Clovis disclosed that it intended to use the proceeds of the offering for, among other things, "expenses associated with the potential launches of rociletinib and rucaparib."

142. Clovis desperately needed these funds. Without a single drug on the market, Clovis' operating costs had increased significantly and the Company needed an infusion of investor capital to stay afloat. Indeed, Clovis had a $55 million net loss in the fourth quarter of 2014, up from $29 million in the same quarter the prior year. Clovis' losses continued to balloon over the next two quarters to $63 million and $72 million, as shown in the chart below.



143. With the price of Clovis' common stock trading at extremely high levels due to the positive disclosures regarding its drug trials, Defendants knew that the July 2015 Offering provided a prime opportunity to raise capital on favorable terms.

144. The prospectus supplement for the July 2015 Offering repeated many of the positive statements Defendants had previously made regarding rociletinib, including that data from the TIGER-X trial purportedly showed a "60 percent ORR" at the "recommended dose of 500mg" and "across all doses, a 53 percent ORR [was] observed." The prospectus supplement also claimed that the "clinical benefit" observed in these data was "durable."

145. The prospectus supplement further stated that Clovis' data "continue to demonstrate rociletinib is well-tolerated," that "the only common grade 3 [side effect] was hyperglycemia," and that "hyperglycemia was readily managed with commonly prescribed oral agents."

146. The rolling NDA submission was finalized on August 3, 2015. On August 6, 2015, during a conference call, Defendant Mahaffy told investors that, "Importantly,

with the $298 million equity offering we completed in July, we're well-capitalized to pursue our development and commercial objectives."

K. As Clovis Engages In Private Discussions With The FDA, Defendants Continue To Report Overwhelmingly Positive News To Investors

147. Clovis' rolling NDA submission allowed "completed portions of [the] NDA to be submitted and reviewed by the FDA on an ongoing basis." That process made possible close dialogue between Clovis and the FDA throughout the submission period and after.

148. While these discussions were ongoing, Defendants kept up the steady stream of positive disclosures to the market. For instance, on September 8, 2015, Clovis made a presentation at the World Conference on Lung Cancer ("WCLC"). At that conference, Clovis reiterated its claim that rociletinib's "ORR in centrally confirmed tissue T790M-positive pts (n=48) enrolled at the 500mg BID dosing level was 60%," and presented new efficacy results in T790M-negative patients, including an ORR of 45% in the subgroup of patients whose T790M-negative status was confirmed by plasma testing.

149. On September 17, 2015, at the Morgan Stanley Healthcare Conference, Mahaffy repeated these results and specifically told investors that they were "in contrast with our competitor who does not show this type of activity in the [T790M] negative [patients]." Mahaffy also claimed that "a very big positive is that [rociletinib] is the first and only mutant EGFR-directed therapy that doesn't cause rash and only a limited amount of diarrhea. ***So in terms of typical side effects . . . we don't have them****."*

150. In response, Clovis' stock price continued to rise. By September 18, 2015, Clovis' common stock was trading at approximately $114 per share, an increase of 200% from the $38 per share it was trading at in June 2014.

151. On September 27 and 28, 2015, Clovis reported at another medical conference, the 2015 ECC. At that conference, Defendants also stated that "[r]ociletinib is generally well tolerated[,] 2.5% of patients discontinued study due to treatment-related adverse events (4% overall)."

L. Defendants Privately Submit Data To The FDA That Directly Contradicts Their Prior Statements

152. In October 2015, pursuant to an FDA request Defendants privately submitted rociletinib data to the FDA that showed ***a confirmed ORR of just 28%*** in T790M-positive patients taking the recommended 500mg dose. Astonishingly, this was ***less than half*** the 60% ORR Defendants had been touting since the May 2015 ASCO conference.

153. Defendants' update also privately disclosed to the FDA that their data showed ***a confirmed ORR of just 34%*** in T790M-positive patients taking 625mg of rociletinib, ***nearly 40% less*** than the 54% ORR Defendants had touted since ASCO 2015.

154. Despite privately reporting, in response to an FDA request, the shocking fact that rociletinib's confirmed ORRs were far less than the inflated and illegitimate unconfirmed results Defendants had publicly touted – and far less than those reported for Tagrisso – Defendants continued to make misleading disclosures to investors.

155. On November 5, 2015, Clovis issued a press release announcing the Company's third quarter 2015 results, and held a conference call with investors, attended by Mahaffy and Mast, to discuss those results. In the press release and on the earnings conference call, Clovis and Mahaffy directed investors to the Company's presentations at the WCLC and ECC in September 2015, which, again, claimed that Clovis had observed, among other things, a 60% ORR in T790M-positive patients at the recommended 500mg

dose – ***more than double the 28% confirmed ORR Clovis had already been privately forced to disclose to the FDA.***

156. During that same November 5, 2015 earnings call, a Stifel Nicolaus securities analyst raised a number of questions about Clovis' rociletinib NDA, and specifically asked Defendants, "Have we seen everything that the FDA is going to see or is TIGER-2, does that have a lot of 500 milligram patients?" In other words, the analyst specifically asked whether any unreported data would impact the efficacy and safety results the Company had publicly reported. Mahaffy failed to disclose that the Company had already submitted to the FDA data significantly undermining the picture of rociletinib's efficacy Defendants had publicly painted. Instead, Mahaffy responded, "I'm going to stick to what we said before. We have never disclosed the agreed number of patients at that dose with FDA. It is actively under review. We certainly believe it is a sufficient number based on dialogue with FDA to allow for a review at that dose in our label."

157. On November 9, 2015 Clovis executives attended a meeting with the FDA, at which, as Mahaffy subsequently revealed, the agency "emphasized that its efficacy analysis would focus solely on confirmed responses." In truth, this was a fact that Defendants had long known.

158. The ***very next day***, on November 10, 2015, Mast attended the Credit Suisse Healthcare Conference on Clovis' behalf and promoted rociletinib's efficacy on the basis of the inflated unconfirmed ORRs Defendants had presented at the 2015 ASCO conference. Indeed, Mast told investors that the "majority of patients received some sort of clinical benefit from taking rociletinib," when, in fact, Clovis had already disclosed to the FDA,

but not to investors, that far fewer than half of the patients taking rociletinib actually had confirmed, clinically meaningful responses.

159. Additionally, at that same November 10, 2015 conference, Mast continued to tout rociletinib's safety profile, claiming, among other things, that the drug was "well tolerated" and that the "only grade 3 or 4 adverse event that has been identified in more than 10% of patients is hyperglycemia." Yet, Clovis had already reported data to the FDA showing that rociletinib increased cardiovascular risk – including a 12% incidence of grade 3 or higher QT prolongation – and that more than half of rociletinib patients underwent dose modification or discontinuation as a result of negative drug side effects.

VI. THE TRUTH IS REVEALED

160. The truth about rociletinib was revealed in two disclosures: (1) a November 16, 2015 announcement that the ORRs Clovis had been disclosing throughout the Class Period were based on ***unconfirmed*** responses, which caused Clovis' stock price to decline by 70%; and (2) an April 8, 2012 announcement that rociletinib had been causing severe side effects and was not nearly as safe as previously reported, which caused Clovis' stock price to decline a further 17%.

1. November 16, 2015: Clovis' Stock Price Plummets By 70% When Defendants Are Forced To Admit They Inflated Rociletinib's Efficacy Results

161. On November 16, 2015, Defendants' fraud was partially revealed when, to investors' astonishment, Clovis revealed that the ORRs Defendants presented throughout the Class Period were "based primarily on unconfirmed responses." Defendants also disclosed that rociletinib's true ORR was just 28% among T790M-positive patients taking the recommended 500mg dose and a mere 34% among T790M-positive patients taking the

625mg dose, about half the rates previously reported and significantly lower than the confirmed ORR Astra-Zeneca reported for Tagrisso.

162. Moreover, Defendants admitted that they knew rociletinib's confirmed ORR was 30% ***prior to*** the Company's November 5, 2015 third quarter earnings call and the November 10, 2015 Credit Suisse investor conference (indeed, as discussed below, Defendants indisputably knew this information throughout the Class Period), but nevertheless presented the much higher unconfirmed ORR at both events:

> **(Stifel Nicolaus analyst) Q:** This is certainly not what we were expecting. Can you -- these rates you are giving us now, these were submitted in the 90-day update, so these rates you had since October, is that right?
>
> **(Clovis CEO Mahaffy) A:** These were submitted in the 90-day update that was submitted at the end of October.

163. Investors and market commentators were shocked by Defendants' disclosures. On November 17, 2015, J.P. Morgan published a report titled *Clovis Oncology CLVS Dealt Huge (and Surprising) Setback*. The J.P. Morgan report stated that the Company's announcement "blindsided the Street this morning," specifically noting that "management credibility obviously takes a significant hit" because "the company continued to talk enthusiastically about potential for near-term approval/launch despite having this data in hand."

164. Analysts from Alpha Biopharma similarly reported that "[Clovis'] announcement revealing that Rociletinib's true efficacy was about half of what was previously reported to investors the week prior despite having this data in-house since October," explaining that "[t]he response rates were clearly different and this dramatically changes the market opportunity for Rociletinib." The Alpha Biopharma analysts, like the

J.P. Morgan analysts, viewed these disclosures as seriously impugning Defendants' honesty and forthrightness during the Class Period:

> During its ASCO 2015 investor presentation in June [Clovis] presented data on unconfirmed response rates without noting this anywhere on the presentation itself. Similarly in September it reported the same ORR's at the World Conference on Lung Cancer . . . .

These analysts also explained that based on available FDA guidance, Defendants knew from the outset of the Class Period that the agency would assess rociletinib's efficacy on the basis of confirmed ORRs.

> ***[T]he regulatory standard is to consider only confirmed response rates and this was an unambiguous fact from the FDA***. So how can an "experienced" management team expect special treatment or exemptions from regulatory standards? ***Any rational investor knows that this fails the simple "smell test." They knew, and delayed informing their investors.***

165. These analysts also explained that "the wide divergence between unconfirmed and confirmed objective responses by RECIST criteria suggests that" contrary to Defendants' statements touting the "durability" of the responses they observed, in reality, "durability of responses appears to be the fundamental weakness with Rociletinib." Finally, these analysts stated that because Clovis had acknowledged it included unconfirmed responses in all efficacy results reported throughout the Class Period, results reported in the T790M-negative subgroup were worthless: "In light of recent events, trusting any data beyond confirmed ORRs is risky; these [T790M-negative] numbers are likely to fall too."

166. Another well-known biotech blogger and venture capitalist, Ohad Hammer, echoed analysts' anger that Clovis could tout ORR results without disclosing that those results included unconfirmed responses, and while withholding significantly less favorable confirmed ORRs. Hammer explained that "at the end of the day an ***unconfirmed response***

rate is not considered a meaningful (let alone approvable) endpoint. This is why companies and investigators often distinguish between confirmed and unconfirmed responses." Hammer concluded,

> ***As an investor, I find the behavior of Clovis' management disturbing*** because I fail to see how the issue of response confirmation could be overlooked. Not only is distinguishing between confirmed and unconfirmed responses a common practice, Clovis knew AstraZeneca used confirmed response rate and did not bother to do so as well, thereby leading investors to assume the drugs are comparable in terms of response rate.

167. Biotech columnist Adam Feuerstein was similarly outraged, comparing Defendants' conduct to the infamous ImClone fraud. Feuerstein reported that "investors were led to believe" that Clovis' "lung cancer drug was better than AstraZeneca's." Yet, "[l]ike ImClone, Clovis kept the bad news about its lung cancer drug hidden from investors until FDA action compelled the company to make the information public."

168. Multiple other experts and commentators also raised "serious questions about the truthfulness and timing involved in the way Clovis Oncology corrected pivotal data on its cancer drug rociletinib." As noted above, longtime cancer drug development expert Dr. Kapil Dhingra authored an analysis in the *Annals of Oncology*, in which he emphasized just how unusual it was for Clovis to report unconfirmed ORRs, noting that response confirmation had been standard industry practice "[f]or decades" and that "[t]he authors of RECIST 1.1 (the response criteria used for the rociletinib trials) could not have been more explicit" in imposing the requirement for confirmation.

169. Dr. Dhingra concluded that Clovis' failure to even warn investors and doctors it was including unconfirmed responses in its publicly reported efficacy data "raises concerns," and that the data disclosed to date indicated a "lack of full disclosure of

the [rociletinib] data [on Clovis' part], consistently and repeatedly." As Dr. Dhingra stated in an interview with FierceBiotech concerning his *Annals of Oncology* article:

> I feel that [Clovis' rociletinib] ***efficacy data have, consistently and repeatedly, over many years, been misrepresented*** . . . This is not simply a case of gray zones, ***this is black and white untrue presentation of the data***. And ***it is not just a minor misrepresentation*** . . . ***the true efficacy is about half of what they represented***."

170. Following Defendants' disclosures, Clovis' stock collapsed by 70% on November 16, 2015, falling from $99.43 per share to $30.24 per share, on heavy trading volume of over 30 million shares (compared to 824,233 shares average volume over the prior three months), and wiping out approximately $2.7 billion in shareholder value.

171. The following stock price chart reflects the sharp decline:

172. Clovis' stock price did not decline even more only because investors continued to believe that rociletinib had a favorable safety profile that would allow it to gain at least some market share for patients who could not tolerate Tagrisso.

2. April 8, 2016: Clovis' Stock Price Declines By A Further 17% When Investors Learn That Defendants Had Also Inflated Rociletinib's Safety Profile

173. In the months following the November 2015 disclosure, Defendants continued to tell the market that despite rociletinib's inferior efficacy relative to Tagrisso, its favorable safety profile might still allow it to garner some market share as a second-line therapy for patients who could not tolerate Astra-Zeneca's drug.

174. For instance, at the January 13, 2016 annual J.P. Morgan Healthcare conference, Mahaffy told investors that rociletinib would "compete just fine" and "may have some advantages" because of its safety profile, and that that the "greater differentiator between rociletinib and Tagrisso" was a choice between easily-managed hyperglycemia (with rociletinib) and rash (with Tagrisso).

175. As a result of these and other similar statements, investors continued to attribute some revenue potential to rociletinib based on the drug's purported safety profile. For instance, in their November 27, 2015 report, Alpha Biopharma analysts stated, "[w]ith Rociletinib's seemingly inferior efficacy profile relative to AZN's Tagrisso, the last remaining differentiator for Rociletinib remains its safety profile."

176. On April 8, 2016, Defendants' fraud was fully revealed when both the FDA and Clovis released rociletinib safety data in anticipation of an April 12, 2016 meeting of the FDA's ODAC, which was specifically convened to discuss the rociletinib NDA. As discussed below, the newly-released safety data showed that – contrary to Defendants' prior statements – rociletinib significantly increased the risk of "serious or life threatening" adverse cardiovascular events (specifically, QT prolongation) more than any other competing therapy and far more than Tagrisso. Defendants had known this information since ***at least*** January 2015, but concealed it from investors.

177. In a report to the ODAC, the FDA insisted that if rociletinib was ever approved for use, it would have to carry on its label "a Boxed Warning for the risk of QTc prolongation." The FDA also recommended that prescribing physicians implement an extensive "risk mitigation" plan, which included cumbersome patient monitoring requirements, in order to safeguard patients using rociletinib.

178. Finally, the safety data showed that an alarming rate of rociletinib patients interrupted treatment (56%), reduced their dosage (51%), or discontinued therapy altogether (12%) because of rociletinib's harmful side-effects – far in excess of the rates reported for Tagrisso or previously reported for rociletinib.

	Rociletinib (500mg) (available to Clovis since mid-April 2015)	**Rociletinib (625mg) (available to Clovis since mid-January 2015)**	**Rociletinib (all doses) (available to Clovis since mid-April 2015)**
QT Prolongation	33%	37%	36%
Grade 3 or Higher QT Prolongation	8%	13%	12%
QT Prolongation > 500 ms	12%	12%	13%
Increase in QT Interval > 30 ms	76%	72%	76%
Increase in QT Interval > 60 ms	26%	33%	34%
Mean Change in QT Interval (ms)	36	39	41

179. The April 8, 2016 disclosures revealed for the first time that rociletinib was not only less efficacious than Tagrisso, it was less safe as well. Analysts and market commentators reacted by revising their prior valuations to reflect zero revenue attributable to rociletinib. In an April 8, 2016 report, Stifel Nicolaus analysts stated that rociletinib is "***dead***."

180. Likewise, an April 8, 2016 article in the *TheStreet* stated that:

> The insurmountable challenge facing Clovis is roci is significantly less effective than its direct competitor, the lung cancer drug Tagrisso from AstraZeneca, which is already approved. ***Roci is also tied to more serious side effects, including potentially lethal heart arrhythmia, than Tagrisso***.

181. Other market commentators noted, "If safety weren't an issue, that lower response rate might not have been a deal breaker for rociletinib on its own. Unfortunately, roughly half of rociletinib patients suffer from severe adverse events and many of those patients pass away because of them." *Bloomberg* likewise reported, "FDA staff's concerns with [rociletinib] include the risk of fast and irregular heartbeats, a condition known as QTc prolongation. If eventually approved, FDA staff recommended a boxed notification, the agency's strongest warning, concerning the heart risk." Indeed, for months, analysts had expressed the view that rociletinib might be used in patients who experienced or were at risk for QT prolongation, which was a side effect of Tagrisso. As Credit Suisse analysts stated in a January 20, 2016 report, "[c]urrently, we see need for a second T790M inhibitor for patients who are unable to tolerate Tagrissos' side effect profile (risk of ILD, ***QTc prolongation***, cardiomyopathies, etc.)." Analysts and investors were unaware that the risk of QT prolongation was far worse with rociletinib.

182. Following Defendants' April 8, 2016 disclosures, Clovis' stock fell by an additional 17%, from $20.43 per share to $15.77 per share, on heavy trading volume of over 8 million shares.

3. April 12, 2016: The FDA Votes 12-1 To Delay Rociletinib's NDA

183. On April 12, 2016, the FDA's ODAC met at the FDA's request to discuss the rociletinib NDA. The ODAC voted 12 to 1 to delay FDA action on the NDA until

Clovis could provide concrete evidence that rociletinib's overall risk/benefit profile merited FDA approval. The ODAC concluded that the available efficacy data (which Clovis had misleading inflated throughout the Class Period) and safety data (which Clovis had fraudulently failed to disclose during the Class Period) failed to show that rociletinib possessed any clinically meaningful advantage over available therapies, especially Tagrisso.

184. In particular, the panel echoed the concerns the FDA had expressed about rociletinib's safety, especially with respect to the risk of QT prolongation and the alarming rate of dose interruptions, modifications, and discontinuations, noting that while there was no definite benefit associated with rociletinib, the drug carried a "definite risk." Indeed, the FDA's cancer czar Richard Pazdur stated, "We don't know what is going on with this drug as regards QT." Ultimately, panel members concluded that Clovis' data failed to identify any patient group that would benefit from rociletinib therapy. Panel members agreed that given a choice between Tagrisso and rociletinib, Clovis' clinical data (which Defendants misrepresented to investors throughout the Class Period) indicated that practitioners should choose Tagrisso.

4. May 5, 2016: Clovis Announces That It Is Withdrawing Its NDA For Rociletinib

185. On May 5, 2016, Clovis issued a press release stating that the Company had withdrawn its NDA for rociletinib and "terminated enrollment in all ongoing sponsored studies of rociletinib." The press release further stated that:

> In a recent meeting with the FDA, Clovis was notified that it could anticipate receiving a Complete Response Letter (CRL) for the rociletinib NDA on or before the PDUFA date of June 28, 2016. The FDA issues a CRL to indicate that their review of an application is complete and that the application is not ready for approval. In

> anticipation of receiving the CRL, Clovis has terminated enrollment in all ongoing sponsored clinical studies of rociletinib.

186. In other words, when the FDA looked at the true efficacy and safety data from the TIGER trials (as opposed to the false and misleading presentation of the data Defendants made to investors), it was clear that rociletinib had no commercial value. As a further consequence of the failure of rociletinib, Clovis announced that the Company is reducing its staff, eliminating contractor positions and delaying or eliminating planned new positions. "This will result in the ***reduction of our staff and contractor positions by 35*** percent by the end of 2016, compared to year-end 2015."

187. While Clovis' stock traded as high as $114.65 just a few weeks before Defendants' fraud began to be disclosed on November 16, 2015, the Company stock now trades at approximately $12.50 as of the filing of this Complaint.

VII. CLOVIS AND THE EXECUTIVE DEFENDANTS KNEW THEIR STATEMENTS WERE MATERIALLY FALSE AND MISLEADING

188. Throughout the Class Period, Clovis and the Executive Defendants knew or recklessly disregarded that their statements concerning rociletinib's efficacy and safety were materially false and misleading.

189. Among other things, these Defendants knew or should have known that (1) the unconfirmed ORR results they presented to the market inflated the apparent efficacy of rociletinib and exaggerated the drug's commercial and competitive viability relative to Tagrisso; (2) those unconfirmed ORR results failed to reflect the confirmed ORR endpoint that was prespecified in Clovis' clinical trial protocols, which would be used by the medical and regulatory communities to evaluate rociletinib's efficacy; (3) the confirmed ORR associated with rociletinib in Clovis' trial data was significantly lower than – indeed, at times ***half*** – both the illegitimate unconfirmed rate Defendants reported and the confirmed

rate Astra-Zeneca reported for Tagrisso; and (4) rociletinib was not only less efficacious than Tagrisso, it was less safe as well.

A. Defendants Were Unblinded To The Rociletinib Efficacy And Safety Data

190. Rociletinib's efficacy and safety data were available to Defendants on a continuous basis throughout the Class Period. In certain types of drug trials, drug company personnel may be "blinded" to the results of the study until all of the relevant data is collected and the trial database is "locked," in order to avoid biasing their interpretation of the data.

191. This was not the case for rociletinib. The TIGER-X and TIGER-2 trials were "open label" studies, *i.e.,* trial data was unblinded throughout the life of the study and fully available to Clovis and its executives. As a result, the data from these trials was continuously reviewed and analyzed by Defendants, and trial results were continuously updated.

192. Investors and analysts were aware that Clovis and its senior executives had unfettered access to data being generated in the TIGER studies and were constantly monitoring and evaluating that data. This fact provided comfort to the market in assessing the data reported by Clovis and the Executive Defendants at multiple points during the Class Period because investors knew that these executives had personal knowledge of the data.

193. As Mahaffy himself explained to investors on the Company's August 7, 2014 conference call, "The data are open to us . . . . [W]e have access to all that info . . . . [A]s the data mature we will continue to provide updates. ***We know that's important to investors."***

B. Rociletinib Was The Company's Most Important Drug

194. Rociletinib was by far the most important product for Clovis during the Class Period. It was the farthest along of only three drugs Clovis had in development and, throughout the Class Period, Defendants knew that investors were keenly focused on the drug's clinical trial results. Analysts characterized rociletinib as one of Clovis' "lead assets" and "the core of our investment thesis," noted the "Street's predominant focus on [rociletinib,]" and that "investor focus is likely to remain fixated on rociletinib." As noted, analysts also repeatedly rated Clovis stock positively when the Company published favorable clinical trial results. In particular, analysts noted that their "[f]ocus [during the Class Period was] on how [rociletinib] compares to [Tagrisso] on both efficacy (objective response rate – ORR and duration of response – DoR) as well as safety/tolerability in EGFRm-T790M+NSCLC."

195. The Executive Defendants began almost every investor call and press release during the Class Period with a discussion of rociletinib's efficacy data, and they routinely fielded questions from analysts about those data, particularly the ORR results. For example, at the September 9, 2014 Morgan Stanley Healthcare conference, an analyst prefaced a question to Clovis management as follows, "So I thought we'd start with 1686 [rociletinib], ***since I'm sure that's where people are focused***." As Mahaffy duly acknowledged, "***That's where most people start***."

196. Indeed, the Executive Defendants gave detailed, data-laden responses to analyst questions on multiple occasions, evincing their familiarity with the rociletinib data and their focus on this all-important drug. On Clovis' August 7, 2014 earnings call, for example, Mahaffy responded to an analyst question about dose escalation, stating, "one thing if I can chip in, too. One thing to remind you is we have basically equivalent efficacy

across all of these efficacious doses, including 900mgs of the free base, 500 mgs BID, 625 and 750."

197. As another example, on the Company's May 6, 2015 conference call, Mahaffy and Allen answered an analyst's question about what the data showed for a particular endpoint that had not been presented. Neither Allen nor Mahaffy demurred or told the analyst that they would have to review the rociletinib database (or ask others for that information) since those data had not been presented; both assured the analyst, without hesitation, that the data were consistent between both the presented and unpresented endpoint. Mahaffy stated, for example, "One quick thing, Corey [J.P. Morgan Analyst], from a regulatory and hygiene standpoint, we've seen a great amount of consistency between the investigator assessment and from the independent assessment and the local assessment, which is a really positive thing."

C. Analysis Undertaken By The Former Chair Of Statistics Of Columbia University Demonstrates That The ORR Results Defendants Presented Throughout The Class Period Were Significantly Inflated

198. Statistical analysis by a preeminent mathematician, based on the confirmed results Clovis disclosed after the Class Period, demonstrates that Defendants knew throughout the Class Period that the confirmed ORRs associated with rociletinib were significantly lower than the illegitimate unconfirmed rate Defendants were publicly reporting.

199. Lead Counsel contacted Dean David Madigan, the Dean of the Faculty and Executive Vice President of Arts and Sciences at Columbia University in New York City and asked him to analyze the probability that during the Class Period the (concealed) confirmed ORR for rociletinib approximated the (disclosed) unconfirmed ORR Defendants

reported. Dean Madigan is a Professor and former Chair of Statistics at Columbia, and one of the most widely-cited mathematicians in the world.

200. While the exact number of confirmed responses Defendants observed at any given time can only be ascertained through discovery, Dean Madigan used the data disclosed by Clovis after the Class Period to perform a probabilistic analysis designed to assess the largest confirmed ORR Defendants could have observed with any statistical plausibility at a given time point. In an effort to be conservative, the Complaint generously assumes that a confirmed ORR is "plausible" if there is more than a 10% chance it could have been observed at a given time point during the Class Period.

201. As discussed below, Dean Madigan's analyses showed that to a high degree of statistical probability (*i.e.,* a virtual statistical certainty) the unconfirmed ORRs reported were materially higher than the confirmed ORRs actually reflected in Defendants data.

202. In the wake of Defendants' disclosures about rociletinib's true efficacy, commentators and experts have echoed the gravamen of this analysis. These articles have noted that given the large difference between the unconfirmed ORR Clovis reported during the Class Period and the confirmed ORR it reported after the Class Period, it would be "quite extraordinary" if the undisclosed confirmed response rate throughout the Class Period was consistent with what was publicly reported.[5]

203. Dean Madigan's analysis quantifies this observation as follows for various statements made during the Class Period:

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[5] K. Dhingra, *Rociletinib: has the TIGER lost a few of its stripes*, *Ann. of Onc.* (Advance Access), at 2 *available at https://annonc.oxfordjournals.org/content/early/2016/04/02/annonc.mdw140.full*; *see also Did Clovis play a deceptive game with rociletinib data in the leadup to its PhIII stunner*, FierceBiotech, April 3, 2016.

204. **May 31, 2014 ASCO Conference**. At the May 31, 2014 ASCO conference, Defendants reported a 58% ORR "per RECIST v1.1" in patients with the T790M mutation across all rociletinib doses. In truth, there is less than a 10% probability that the unreported confirmed ORR exceeded even 46%. Accordingly, the illegitimate and unconfirmed 58% ORR Defendants reported likely overstated rociletinib's true ORR by ***at least 26%,*** while the confirmed 56% ORR Astra-Zeneca had reported for Tagrisso just before that conference was likely ***at least 22%*** higher than rociletinib's unreported confirmed ORR.

205. **November 18, 2014 Press Release**. In a November 18, 2014 press release issued just before the 2014 ENA medical conference, Defendants reported a 67% ORR for T790M positive patients taking either 500mg or 625mg of rociletinib. In truth, there is less than a 5% chance that the unreported confirmed ORR in those key dose groups exceeded 48%. Accordingly, the illegitimate and unconfirmed 67% ORR Defendants reported likely overstated rociletinib's true ORR by ***at least 40%***, while the 61% confirmed ORR Astra-Zeneca had most recently reported for Tagrisso at the September 2014 ESMO conference was likely ***at least 27%*** higher than rociletinib's unreported confirmed ORR.

206. **May 31, 2015 ASCO Conference**. At the May 31, 2015 ASCO meeting, Clovis claimed it had observed a 60% ORR in T790M positive patients taking the recommended 500mg dose and a 54% ORR in patients taking the stepped-up 625mg dose. In truth, there is less than a 5% chance that rociletinib's confirmed ORR in T790M-positive patients taking either the recommended 500mg or stepped-up 625mg dose exceeded 36%. Accordingly, the illegitimate unconfirmed ORRs Defendants reported likely overstated rociletinib's true ORR by ***at least 56%***, while the 54% confirmed ORR Astra-Zeneca had

reported for Tagrisso just a few weeks earlier was likely ***at least 50%*** higher than rociletinib's unreported confirmed ORR.

207. **November 2015 Statements**. In Clovis' November 5, 2015 third quarter earnings press release and at the November 10, 2015 Credit Suisse Healthcare Conference, Defendants repeated the ORR results presented at the May 2015 ASCO meeting. These statements were indisputably false and misleading because the Company had ***already*** (in October 2015) submitted data to the FDA showing confirmed ORRs of ***28% and 34%*** in T790M-positive patients taking the recommended 500mg dose and the 625mg dose, respectively. Accordingly, the illegitimate unconfirmed 60% and 54% ORRs Defendants reported undeniably overstated rociletinib's true ORRs in the key 500mg and 625mg dose groups by ***more than 100%*** and ***59%***, respectively. Moreover, the 66% ORR Astra-Zeneca had most recently reported for Tagrisso was ***136%*** higher than rociletinib's unreported confirmed ORR in the recommended 500mg dose.

208. Statistical analysis likewise shows that the ORR results Defendants reported in T790M-negative patients were also significantly inflated. For instance, data disclosed after Defendants' fraud was revealed shows that as of November 16, 2015, only 7 T790M-negative patients taking 625mg of rociletinib had confirmed responses. Yet, at the January 2015 J.P. Morgan investor conference one year earlier, Defendants claimed that 8 such patients were "responsive," and at the May 2015 ASCO conference, claimed that 9 such patients were "responsive." Accordingly, Defendants disclosures make clear they improperly included unconfirmed responses in the ORR results presented in T790M-negative patients during the Class Period. Moreover, there is no more than a 3% chance Clovis had observed even 7 confirmed responses among T790M-negative patients in the

625mg dose group as of January 2015, and no more than a 9% chance Clovis had observed that many responses as of May 2015.

209. The magnitude by which Defendants misstated rociletinib's efficacy results further supports a strong inference of fraud. As noted, industry observers stated after the Class Period that Defendants' reporting of unconfirmed ORR results is "not simply a case of gray zones, ***this is black and white untrue presentation of the data***. And ***it is not just a minor misrepresentation . . . the true efficacy is about half of what they represented***."

D. Defendants Knowingly Included Unconfirmed Responses In The Calculation of ORR

210. Pursuant to the relevant TIGER study protocols, an initial observation that a patient's tumor had shrunk by at least 30% was "confirmed" only when a subsequent follow-up scan, occurring no more than 7 weeks after the initial scan, showed the tumor's size remained 30% smaller than it was at study entry.

211. Pursuant to the TIGER-X protocol, confirmation of an initial observed response would take no more than 49 days. This is because, as shown above, the protocol provides for efficacy scans within 7 days of the end of each even numbered "Cycle" up to Cycle 7.

212. The protocol further provides that each Cycle is 21 days long. The protocol also provides that for an initial response up to Cycle 7, the next efficacy scan acts as the "confirmation" scan. Accordingly, an initial response in all cases will be confirmed in 42±7 days. For Cycles 7 and beyond, confirmation takes place even more quickly: within 4-6 weeks. Therefore, any initial response Clovis observed would have to be confirmed or disconfirmed no more than 49 days later.

213. On multiple occasions during the Class Period, Defendants presented unconfirmed ORR results comprised of initial responses observed at least 7 weeks prior. At the time those presentations were made, Clovis' data already showed that the vast majority of those initial responses were actually adjudicated not responsive when assessed in follow-up efficacy scans. In other words, Defendants knew not only that their reported ORR results were artificially inflated by the presence of numerous unconfirmed responses, but that those unconfirmed responses themselves had failed to "hold up" when reassessed in subsequent scans.

214. Defendants presented unconfirmed responses that had already been adjudicated non-responsive on at least the following occasions:

- In statements made on August 7, 2014 and September 9, 2014, Defendants repeated the ORR data presented at the May 31, 2014 ASCO conference, more than 9 and 11 weeks after the May ASCO conference;
- All of the responses reported in Clovis' November 18, 2014 press release and at the November 21, 2014 ENA conference occurred on or before September 25, 2014, and, therefore, they would have been conclusively confirmed or disconfirmed no later than November 13, 2014;
- All of the responses reported in Clovis' *NEJM* paper, published April 30, 2015, were observed on or before June 18, 2014, and, therefore, they would have been conclusively confirmed or disconfirmed no later than August 6, 2014;
- Defendants repeated the ORR reported at the May 31, 2015 ASCO conference in August, September, and November of 2015. The responses comprising those results occurred on or before April 27, 2015, and, therefore, would have been conclusively confirmed or disconfirmed no later than June 15, 2015.

215. In short, Defendants intentionally reported ORRs that they knew were fictitious throughout the Class Period.

E. Defendants' Reporting Of Unconfirmed ORR Contravened Clovis' Own Study Protocols, Controlling Clinical Trial Standards, And FDA Guidance

216. As noted above, Defendants knew or should have known that including unconfirmed responses in publicly-reported ORRs was materially false and misleading because it deviated diametrically from the Company's own prespecified protocols, from standard industry practice, from FDA guidance, from Clovis' own public statements, and from the manner in which its closest competitor reported efficacy data. As alleged above, Defendants were well aware that the medical and regulatory communities would assess rociletinib's efficacy on the basis of its confirmed ORR results, and that such results were, therefore, material to investors.

F. Clovis Continued To Present Falsely Positive Efficacy And Safety Data Even After Privately Reporting Less Favorable Data To Regulators

217. On June 9, 2015, Defendants met with the FDA to discuss Clovis' upcoming NDA filing, which was submitted a few weeks later. Documents released on April 8, 2016 by the FDA demonstrate that at that June 9, 2015 meeting, Clovis privately reported an unconfirmed ORR of 50% (without informing the FDA that the ORR was unconfirmed) in the TIGER-X study's 500mg dose group.

218. Nonetheless, Defendants continued to publicly tout the unconfirmed 60% ORR they had reported at the 2015 ASCO conference. Thus, even putting aside the fact that it was wholly improper and materially misleading for Clovis to include unconfirmed responses in rociletinib's reported ORR, Clovis' deliberate reporting of stale data (even its misleadingly inflated unconfirmed ORR data) strongly indicates that the Company and its management acted in bad faith when reporting rociletinib's efficacy results.

219. Defendants also played the same misleading game with the rociletinib safety data. Defendants continued to claim on November 10, 2015, for instance, that rociletinib was "well tolerated" and that "[t]he only grade 3 or 4 adverse event that has been identified in more than 10% of patients is hyperglycemia," when data they had already submitted to the FDA no later than September 2015 showed that 12% of rociletinib patients experienced grade three or higher QT prolongation.

G. Clovis Routinely Compared Rociletinib ORR Results With The Confirmed ORR Data Astra-Zeneca Presented For Tagrisso

220. The fact that Clovis often presented unconfirmed ORR results for rociletinib back-to-back with the obviously confirmed ORRs Astra-Zeneca presented for Tagrisso, and repeatedly made misleading comparisons between the efficacy results of the two drugs supports an inference of scienter. For example, although Clovis presented rociletinib ORR data alongside Tagrisso data at the March 2015 TAT conference, and presented major efficacy updates at the 2014 ENA and 2015 ASCO conferences just weeks after Astra-Zeneca presented such updates for Tagrisso, none of Clovis' presentations at those conferences, or contemporaneous statements touting those presentations in press releases and investor calls, disclosed that Clovis, unlike Astra-Zeneca, was including unconfirmed responses in its ORR results.

221. As another example, in September 2014, Mahaffy, in response to an analyst question, claimed Clovis' data showed rociletinib had "a similar response rate" to Tagrisso's, despite the fact that Astra-Zeneca's presentation made clear the company was reporting ***confirmed*** ORRs while Mahaffy (and the other Executive Defendants) knew that Clovis was not.

222. As analysts and market commentators observed, Defendants' conduct was, at a minimum, "disturbing" because "[n]ot only is distinguishing between confirmed and unconfirmed responses a common practice, Clovis knew AstraZeneca used confirmed response rate and did not bother to do so as well, thereby leading investors to assume the drugs are comparable in terms of response rate."

H. Defendants Knew From Rociletinib's Clinical Trial Data That Its Safety Profile Was Much Worse Than They Were Disclosing

223. During the Class Period, and no later than January 2015, a troubling cardiovascular safety signal had emerged in the Company's rociletinib safety data. Clovis' data showed that rociletinib patients taking the recommended 625mg dose experienced a greater risk of "QT prolongation" than patients taking any other competing therapy and far more than patients taking Tagrisso. QT prolongation is a delayed heart repolarization that increases the risk of serious and fatal cardiac arrhythmias and sudden cardiac death; the larger the size of the delay in repolarization experienced by the patient, the greater the risk of arrhythmia and death.

224. As the FDA explained in an April 12, 2016 presentation concerning the rociletinib NDA, there are three criteria relevant to assessing the risk of QTc prolongation associated with a drug. First, pursuant to international medical guidelines adopted by the FDA prior to the start of the Class Period, "Drugs that prolong the mean QT/QTc interval by > 20 ms [milliseconds] have a substantially increased likelihood of being proarrhythmic"; a total QT interval exceeding 500 ms is considered "a threshold of particular concern." Second, guidance from the FDA's Interdisciplinary Review Team for QT Studies flags drugs that increase the mean QT interval by more than 30 ms as

significantly increasing cardiovascular risk. Third, the National Cancer Institute characterizes Grade 3 and 4 QT prolongation as "severe" or "life threatening."

225. As the FDA stated publicly after the Class Period, ***by each and every one of these criteria,*** rociletinib's safety data showed by January 2015 that the drug carried far more cardiovascular risk than competing drugs, particularly Tagrisso.

226. First, no later than January 15, 2015, Clovis' data showed that 12% of patients taking the recommended 625mg of rociletinib experienced QT prolongation greater than 500 ms, as compared with only 0.2% of Tagrisso patients who reached this "threshold of particular concern." By the end of April 2015, Clovis' data showed that 13% of rociletinib patients, and 12% of patients taking the 500mg dose for which Clovis was seeking FDA approval experienced this adverse event. Indeed, the rate of rociletinib patients experiencing this "particular[ly] concern[ing]" adverse event was ***more than triple*** the rate experienced by patients taking vandetanib, the oncology drug with the next highest rate of QT prolongation greater than 500 ms.

227. Indeed, the TIGER-X protocol characterized a QT interval greater than 450 ms in men or 470 ms in women as "significant[ly] abnormal." At least 22% of rociletinib patients taking 625mg experienced "significant[ly] abnormal" QT prolongation as defined by Clovis' own protocol.

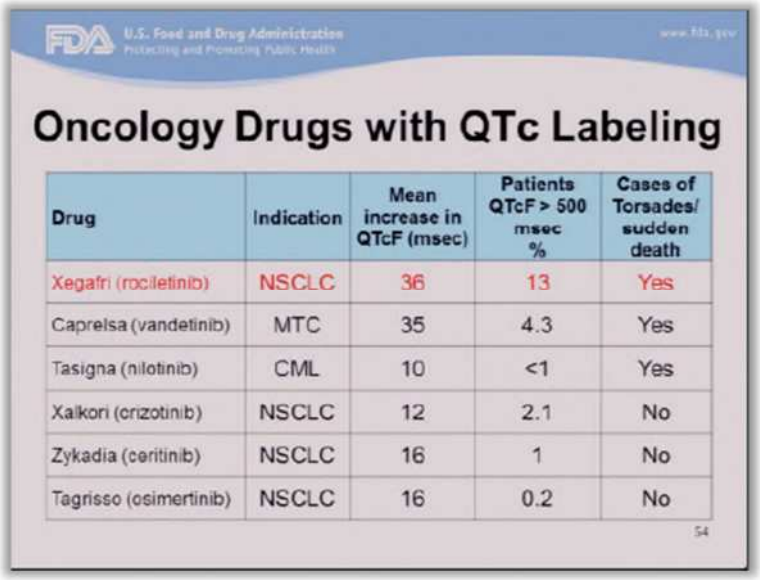
228. Second, no later than January 15, 2015, Clovis' data showed that 72% of patients in the recommended 625mg dose group had QT intervals increase more than 30 ms while taking rociletinib, while 33% of patients in that dose group experienced QT interval increases greater than 60 ms. By the end of April 2015, Clovis' data showed that 76% of rociletinib patients, and 76% in the 500mg dose group had their QT intervals

increase by more than 30 ms; and 34% of all rociletinib patients, and 26% of patients in the 500mg group, experienced QT prolongation greater than 60 ms, while only 2.7% of Tagrisso patients taking the recommended dose experienced an increase of that magnitude. Indeed, rociletinib patients experienced a mean QT interval change of 41 ms (36 ms in patients taking 500mg and 39 ms in patients taking 625mg) – the highest mean change of any of rociletinib's peer drugs and more than double Tagrisso's mean change of 16 ms.

229. Third, no later than January 15, 2015, Clovis' data showed that 13% of rociletinib patients in the 625mg dose group experienced grade 3 or higher prolongation (compared with 1% of Tagrisso patients at the recommended 80mg dose). By the end of April 2015, Clovis data showed that 12% of rociletinib patients, and 8% of patients in the 500mg group experienced grade 3 or higher QT prolongation, significantly higher than the rates Astra-Zeneca had reported in all Tagrisso patients (0.4%), and in its recommended dose (1%).

230. Finally, no later than January 15, 2015, Clovis' data showed that in the 625mg group there were three cases of serious ventricular tachyarrhythmia, one case of Torsades de pointes (a troubling type of arrhythmia), and one sudden death (which is considered a cardiovascular adverse event), as well as a sudden death in the 750mg dose group.

231. Analysis by the FDA released after the Class Period makes clear that rociletinib poses far greater cardiovascular risk than its oncology peers, as the slide below demonstrates.



U.S. Food and Drug Administration

Oncology Drugs with QTc Labeling

Drug	Indication	Mean increase in QTcF (msec)	Patients QTcF > 500 msec %	Cases of Torsades/ sudden death
Xegafri (rociletinib)	NSCLC	36	13	Yes
Caprelsa (vandetinib)	MTC	35	4.3	Yes
Tasigna (nilotinib)	CML	10	<1	Yes
Xalkori (crizotinib)	NSCLC	12	2.1	No
Zykadia (ceritinib)	NSCLC	16	1	No
Tagrisso (osimertinib)	NSCLC	16	0.2	No

54

Figure 5. Excerpt from FDA presentation at April 12, 2016 ODAC meeting.

232. Ultimately, this troubling safety signal, evident in Clovis' data no later than mid-January of 2015, led the FDA to conclude, and Clovis to finally acknowledge after the Class Period, that rociletinib's propensity to increase cardiovascular risk was so significant that if the drug were ever approved, it would be required to carry a "Boxed Warning" – the most severe warning that a drug's label can carry – and prescribing physicians would be required to implement an extensive "risk mitigation" plan in order to safeguard patients. By comparison, Tagrisso was approved without such labeling and prescribing restrictions.

233. In addition to rociletinib's alarming cardiovascular safety signal, Clovis safety data showed that shocking numbers of rociletinib patients were experiencing negative side effects that forced them to interrupt therapy, reduce their dosage, or discontinue from the trial altogether. Indeed, 65% of rociletinib patients (including 63% and 60% of patients in the 625mg and 500mg dose groups, respectively) experienced adverse events leading to dose interruption or reduction, compared with 20% of Tagrisso

patients. Moreover, 12% of rociletinib patients (with the same incidence in the 625mg and 500mg groups) discontinued because they experienced adverse side effects, while 21% of such patients discontinued overall (including patients who discontinued because their tumors continued to grow despite rociletinib therapy). AstraZeneca reported that less than 3% of Tagrisso patients discontinued due to an adverse event.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

234. As alleged herein, at all relevant times Clovis and the Executive Defendants acted with scienter in making materially false and misleading statements and omissions during the Class Period. Additional allegations supporting the scienter of Clovis and the Executive Defendants are set forth below.

A. Insiders Sold Clovis Stock During The Class Period

235. Defendant Ivers-Read sold more than $600,000 in personally held shares of Clovis stock during the Class Period. Ivers-Read was co-founder of the Company, and was the Company's principal liaison with the FDA. She made no sales of Clovis stock during the Control Period (the two-year period immediately preceding the Class Period). But on August 18, 2015, after the NDA was fully submitted, she suddenly set up a Rule 10b5-1 plan to facilitate the sale of her stock for the first time ever.

236. In the course of a single month, over September and October 2015, Ivers-Read sold 6,000 Clovis shares, valued at $613,410. She made no open market purchases of Clovis stock during the Class Period. Ivers-Read's proceeds from her sales exceeded her 2015 base salary of $412,000.

Transaction Date	Shares Sold	Sales Proceeds	Percentage of Shares	Control Period Shares Sold	Control Period Proceeds	Open Market Purchases During Class Period
9/18/2015	3,000	$337,680				
10/5/2015	3,000	$275,730				
Total	**6,000**	**$613,410**	**3%**	0	0	0

237. Defendant Allen sold nearly half of his Clovis stock in the months before his sudden departure in June 2015, notwithstanding the fact that Clovis stock was ostensibly headed for a sharp uptick owing to rociletinib's imminent FDA approval. Specifically, in January 2015, Allen sold 44% of his Clovis stock: 80,000 shares with proceeds of $5,269,895.80. Allen's sales generated proceeds in excess of ***eleven times*** his base salary of $463,500.

238. In those January 2015 transactions alone, Allen sold more than three and a half times the number of shares he sold during the Control Period. Despite the fact that Allen was a Clovis co-founder and had been with the Company since its inception, his Rule 10b5-1 trading plan was not set up until June 10, 2014, shortly after the start of the Class Period.

Transaction Date	Shares Sold	Sales Proceeds	Percentage of Shares	Control Period Shares Sold	Control Period Proceeds	Open Market Purchases During Class Period
1/15/2015	300	$19,500				
1/16/2015	30,524	$1,992,225.17				

1/16/2015	49,176	$3,258,170.63				
Total	**79,990**	**$5,269,895.80**	**44%**	22,594	$1,548,683	0

B. CMO Allen Unexpectedly Resigned From Clovis Shortly Before Rociletinib Was Supposed To Be Approved

239. On June 22, 2015, less than two weeks after Clovis' "Pre-NDA meeting" with the FDA and less than two weeks before Clovis filed the rociletinib NDA, Allen suddenly resigned from the Company. Allen had co-found Clovis in 2009 and had devoted years to shepherding rociletinib through development. By June 22, 2015, the Company was supposedly mere months away from rociletinib's approval. From both a pecuniary and professional perspective, Allen had every reason to remain at Clovis until the Company secured that approval.

240. First, by resigning from his position just before rociletinib's approval, Allen forfeited at least 25% of his lucrative performance pay, which, presumably, would only have become more lucrative after approval as a function of the ensuing surge in Clovis' stock price.[6]

241. Second, rociletinib's approval would have represented an important professional accomplishment for Allen: the Company's first major victory, having finally gotten a drug to market after the devastating failure of its pancreatic cancer drug, CO-101.

242. Accordingly, Allen's departure just a few months before rociletinib was supposed to be approved and brought to market is highly suspicious and raises a strong

[6] In March 2015, Allen received 35,000 Clovis stock options. Based on analysts' forward guidance valuing Clovis at $130 per share upon FDA approval of rociletinib, Allen's options would have been worth almost $2 million once the NDA passed agency muster. By leaving in June 2015, he forfeited all 35,000 options. Had Allen remained with Clovis, over 36% of those options, about 13,500 shares would have vested by March 2016.

inference that by the spring of 2015, at the latest, Clovis' internal rociletinib data indicated to Allen that it was virtually certain the drug would lose its battle with Tagrisso.

C. Clovis Suddenly Accelerated The Development Timeline For Its Pipeline Drugs

243. Over the course of the Class Period, Defendants' false and misleading statements enabled the Company to raise nearly $600 million in investor capital, including a $300 million public equity offering in July 2015. The Company used the proceeds from these offerings to dramatically accelerate the development of its remaining pipeline drugs because they knew (but concealed) the fact that rociletinib was in reality performing very poorly in the TIGER trials, with poor confirmed ORRs and disastrous side effects.

244. As discussed above, because Clovis had no revenue generating products on the market the Company was heavily dependent on capital raised from investors to keep the Company afloat. In order to keep the lifeline of capital in place, Clovis desperately needed to persuade investors that rociletinib was a promising drug with blockbuster potential. As negative rociletinib efficacy data began to crystalize by the start of the Class Period, it became even more urgent for Clovis to keep investors interested in rociletinib in order to keep Clovis' stock price inflated, maintain investor interest, and to keep the influx of capital flowing so as to secure the time and money to develop the Company's two other pipeline products, rucaparib a treatment for ovarian cancer, and lucitanib, a treatment for breast cancer.

245. Investors viewed rucaparib, which was in a series of pivotal trials at the start of the Class Period, as particularly promising, but understood that its timeline for approval was later than rociletinib. For example, Piper Jaffray analysts rated Clovis "Overweight" based on "continued expectations for clinical data successes and eventually meaningful

market shares for both rociletinib and rucaparib." Moreover, as Clovis began to release positive data from its early rucaparib studies throughout the Class Period, investor enthusiasm continued to grow.

246. As late as October 31, 2013, Clovis told investors that the data from the ongoing phase II study of rucaparib, ARIEL2, would not "start to become meaningful [until] the end of 2015," and that the Company "may not be very public with those data" until that time. Moreover, as of June 2014, Clovis did not plan to file an NDA for rucaparib before the second half of 2017.

247. Once negative ORR data began to materialize at the start of the Class Period, however, the Company completely reversed that position. On Clovis' August 7, 2014 earnings call, for instance, Allen told investors that "[o]ur intention in the fall . . . is to show our preliminary clinical data from the ARIEL2 study." Indeed, the Company ***twice*** presented updated rucaparib data from ARIEL2 during the fall of 2014, and, notably, Defendants, including Mahaffy, provided investors with rosy characterizations of the data on both occasions.

248. Throughout that fall, Clovis' rucaparib program was "advancing rapidly," such that by January 2015, Clovis had, in Defendants' own words "substantially accelerate[d]" the program "by at least a year," with the drug's NDA to be submitted on the heels of the rociletinib filing. That Clovis management's decision to dramatically accelerate the rucaparib program coincided with the emergence of disappointing confirmed rociletinib ORR data gives rise to a strong inference that they were aware of the negative data and understood its implications for rociletinib's commercial viability.

IX. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

249. In addition to the statements set forth above, Clovis and the Executive Defendants made a number of other materially false and misleading statements and omissions during the Class Period. These included (1) false and misleading statements concerning the results of Clovis' clinical trials, including the purported ORRs observed in those trials; (2) false and misleading statements touting the strength of the reported rociletinib efficacy results, including false and misleading statements favorably comparing Clovis' reported rociletinib ORR results to those reported for Tagrisso; and (3) false and misleading statements concerning rociletinib's safety profile, including the incidence of serious QT prolongation and treatment modification in the Company's clinical trial data.

250. Including, and in addition to, the materially false and misleading statements and omissions set forth above, Defendants made the following materially false and misleading statements and omissions during the Class Period.

A. False and Misleading Statements At The May 2014 ASCO Meeting Conference

1. May 31, 2014 Statements

251. The Class Period begins on May 31, 2014. On that day Clovis issued a press release, filed with the SEC on a Form 8-K signed by Mast, announcing "updated findings from the Phase 1 and early Phase 2 portions of its ongoing" TIGER-X study. In a section entitled "Evidence of Activity," Clovis' press release claimed "23 partial responses (PRs) have been observed [in the TIGER-X data] to date, for a 58 percent objective response rate (ORR)." Clovis' press release quoted Mahaffy, who stated, "We are extremely pleased with the consistency of the efficacy demonstrated to date, the growing evidence of a

lengthy duration of benefit and that CO-1686 is so well-tolerated with a manageable side effect profile."

252. Also on May 31, 2014, Defendants publicly presented those same data to doctors, investors, and analysts at the 2014 ASCO annual conference in Chicago, Illinois. Clovis' presentation, the contents of which were subject to the Company's final approval, stated, "Promising activity seen [with rociletinib] across all dose levels of Phase 1/2 trial; 58% ORR in biopsy-proven, heavily pretreated centrally confirmed, T790M+ patients."

253. Additionally, on May 31, 2014, Allen and Mahaffy held a conference call on behalf of Clovis to discuss Clovis' ASCO presentation with investors. On the teleconference, Allen emphasized that "the primary outcome for Phase II is Objective Response Rate with duration of response ***using RECIST 1.1***," and stated that "the current objective response rate in biopsy program, patients with centrally-confirmed T790M disease is 58%."

254. As set forth above, Defendants' May 31, 2014 statements touting the data they presented at the 2014 ASCO meeting successfully persuaded analysts and investors that rociletinib was in a favorable position to compete with Tagrisso and that the two drugs possessed a similar efficacy profile.

255. These statements were materially false and misleading when made. It was false and misleading for Clovis, Mahaffy, and Allen to state that rociletinib had achieved "a 58 percent objective response rate" in Clovis' data, and to characterize these results as "demonstrat[ing]" the "consistency of [rociletinib's] efficacy" and providing evidence of rociletinib's "[p]romising activity," while failing to disclose that the reported ORR included unconfirmed responses; that the endpoint reported would not be used by the

medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that rociletinib's confirmed ORR in those data was significantly lower than the confirmed ORR Astra-Zeneca reported for Tagrisso.

256. Indeed, as discussed above, the illegitimate unconfirmed 58% ORR Defendants reported overstated rociletinib's true ORR by at least 26%, while the confirmed ORR Astra-Zeneca reported for Tagrisso was likely at least 22% higher than rociletinib's unreported confirmed ORR.

257. Likewise, Clovis' and Allen's claims that the ORR results presented in their public statements "us[ed] RECIST 1.1" and reflected the same endpoint prespecified as the "primary outcome for Phase II" of the TIGER-X trial were false because both RECIST 1.1 and the TIGER-X protocol required Defendants to report a confirmed objective response rate, which they did not do.

2. June and August 2014 Statements Touting The Data Presented At The 2014 ASCO Conference

258. On June 23, 2014, Clovis issued a press release announcing it had enrolled its first patient in the TIGER-2 study. In that press release, Clovis reiterated the data it had presented at the May 31, 2014 ASCO meeting. Specifically, Clovis claimed, "23 partial responses (PRs) [in 40 patients had been] observed as of early May, for a 58 percent objective response rate (ORR)."

259. On August 7, 2014, Clovis issued a press release, filed with the SEC on a Form 8-K signed by Mast, announcing the Company's second quarter financial results. Clovis' press release once again touted the results presented at the 2014 ASCO meeting. Clovis stated in the press release, "Highlights from the data presented for evaluable,

centrally-confirmed T790M positive patients treated at a therapeutic dose of rociletinib included a 58 percent objective response rate . . . ."

260. Also on August 7, 2014, Mahaffy, Allen, and Mast, on behalf of Clovis, held a conference call with investors to discuss the Company's second quarter financial results. On that call, Mahaffy stated, "At ASCO we announced the most recent update of rociletinib completed clinical data, which continues to demonstrate that rociletinib is a very active and well-tolerated drug." Mahaffy then cited the same ORR results cited in the Company's press release and likewise characterized them as "[t]he highlights of the data presented at ASCO."

261. As set forth above, analysts responded positively to Defendants' August 7, 2014 statements touting the data they presented at the 2014 ASCO conference.

262. These statements were materially false and misleading when made. It was false and misleading for Clovis and Mahaffy to state that Clovis had observed "a 58 percent objective response rate" associated with rociletinib in its data, and to claim those data "demonstrate[d] that rociletinib is a very active drug," while failing to disclose that the reported ORR included unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that rociletinib's confirmed ORR in those data was significantly lower than the confirmed ORR Astra-Zeneca reported for Tagrisso.

263. Indeed, as discussed above, the illegitimate unconfirmed 58% ORR Defendants reported overstated rociletinib's true ORR by at least 26%, while the confirmed

ORR Astra-Zeneca reported for Tagrisso was likely at least 22% higher than rociletinib's unreported confirmed ORR.

3. The September 9, 2014 Morgan Stanley Healthcare Conference

264. On September 9, 2014, Mahaffy participated in the Morgan Stanley Healthcare Conference on behalf of Clovis. At that conference, a securities analyst asked Mahaffy about the rociletinib ORR data the Company presented at the 2014 ASCO meeting as compared with the ORR data Astra-Zeneca had presented for Tagrisso: "I think you and your main competitor [Astra-Zeneca] showed similar response rates. Maybe you could just sort of talk to us about what you think are the key differences between the drugs and where you may or may not have a competitive advantage?" Mahaffy replied, "I think what you see is a similar response rate [between rociletinib and Tagrisso]."

265. These statements were materially false and misleading when made. It was false and misleading for Mahaffy to claim that the data presented at the 2014 ASCO conference showed rociletinib had "a similar response rate" to Tagrisso, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso. Indeed, as discussed above, the illegitimate unconfirmed 58% ORR Defendants reported overstated rociletinib's true ORR by at least 26%, while the confirmed ORR Astra-Zeneca reported for Tagrisso was likely at least 22% higher than rociletinib's unreported confirmed ORR.

266. Mahaffy's comparison misled investors into believing that identical endpoints were being presented and compared for the two drugs, and overstated

rociletinib's efficacy and the validity, reliability, and robustness of the ORR data Defendants reported.

4. Clovis' Third Quarter 2014 Earnings Announcement

267. On November 6, 2014, Clovis issued a press release, filed with the SEC on a Form 8-K signed by Mast, announcing the Company's third quarter financial results. In that press release, Clovis once again touted the results presented at the 2014 ASCO meeting. Clovis also stated "As reported at ASCO earlier this year, rociletinib has demonstrated compelling efficacy in a heavily pre-treated Western population of patients with acquired resistance to currently available EGFR inhibitors."

268. That same day, Clovis held a conference call with investors, attended by Mahaffy, Mast, and Allen, to discuss its third quarter 2014 results. On that call, Mahaffy told investors that Clovis' upcoming presentation at the ENA medical conference would "focus primarily on our selected dose of 625 milligrams twice daily, where we see ***very compelling activity*** with an improved safety profile."

269. These statements were materially false and misleading when made. It was false and misleading for Clovis and Mahaffy to claim that the ORR data presented at the 2014 ASCO meeting "demonstrated [rociletinib's] compelling efficacy" and that the Company observed "very compelling activity" in its 625mg data, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rates Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

270. Indeed, as discussed above, the illegitimate unconfirmed 58% ORR Defendants reported overstated rociletinib's true ORR by at least 26%, while the confirmed ORR Astra-Zeneca reported for Tagrisso was likely at least 22% higher than rociletinib's unreported confirmed ORR.

B. False and Misleading Statements Made In Connection With Clovis' Presentation Of Rociletinib Data At The November 2014 ENA Conference

271. On November 18, 2014, Defendants issued a press release presenting updated rociletinib efficacy data from the phase II expansion of the TIGER-X study. That press release stated:

> **Evidence of Activity**
>
> The objective response rate (ORR) in 27 evaluable T790M-positive patients receiving either 625 or 500mg BID was 67%. The ORR was comparable in the 625mg BID and the 500mg BID dose groups.
>
> In 11 evaluable T790M-negative patients treated at 625 or 500mg BID, a 36% ORR and median PFS of 7.5 months were observed. This activity in the non-target T790M-negative patient group is surprising . . . .

272. Clovis' press release continued, quoting Mahaffy as follows: "These data demonstrate the very encouraging activity and tolerability observed with rociletinib at our go-forward dose of 625mg BID, and our step-down dose of 500mg BID . . . . We are now expanding beyond our initial focus on T790M-positive patients and are very enthusiastic about our expansion into . . . an all-comer population of patients with acquired TKI resistance, including both T790M-positive and T790M-negative patients . . . ."

273. On November 21, 2014, Clovis presented those updated data at the ENA conference. Clovis' presentation, which was prepared and approved by the Company, included the following slide:

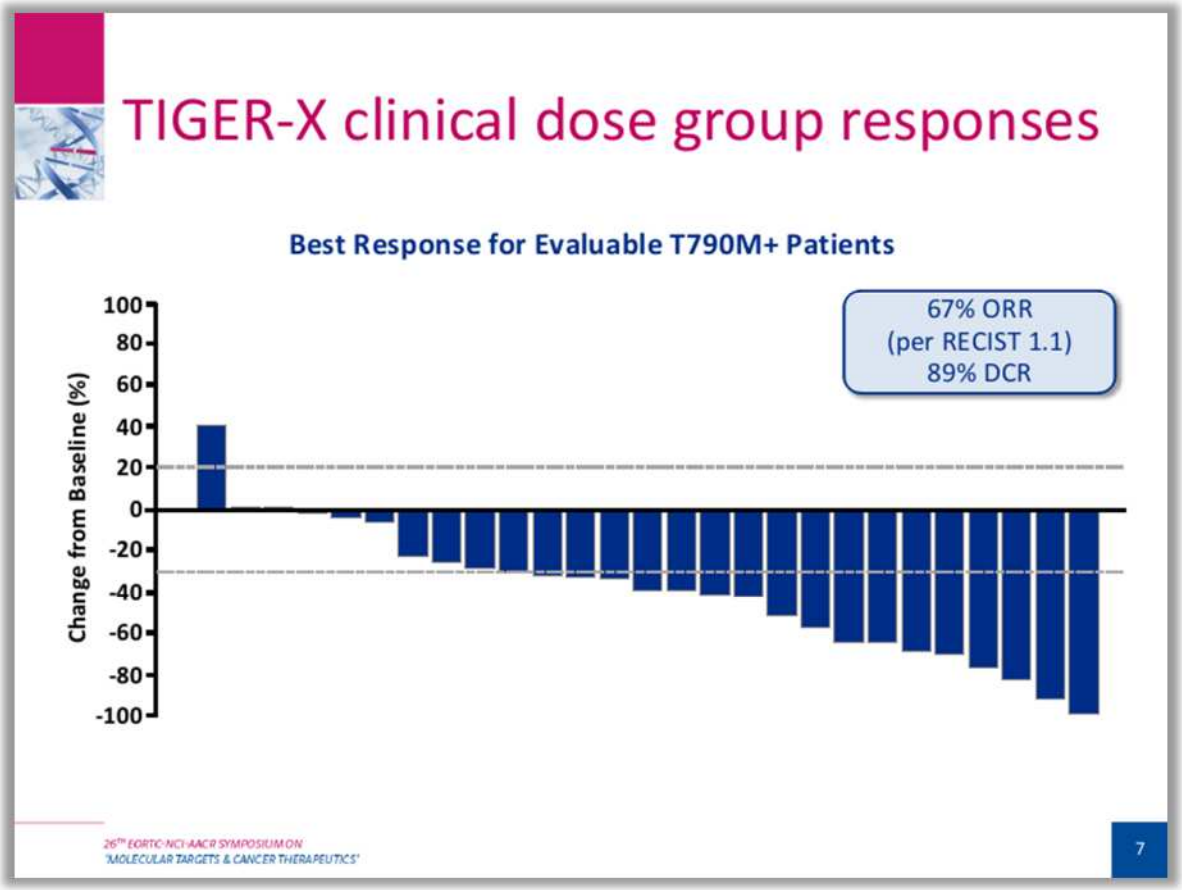


Figure 6. Excerpt from Clovis' rociletinib presentation at the November 2014 ENA conference.

274. Defendants' presentation at the ENA conference further stated, "Early evidence of activity was observed with durable RECIST responses, particularly in T790M+ patients."

275. That same day, Mahaffy and Allen, on behalf of Clovis, held a conference call with investors to discuss the rociletinib data presented at the ENA conference. On that call, Allen stated, "In the T790M-positive patients, we presented an impressive 67% response rate . . . . These data are highly consistent with the Phase 1 data presented previously."

276. Allen further stated on that same call, "Moving to the encouraging data we've observed in T790M-negative patients, we and our investigators have really been struck by this activity, a response rate of 36% . . . ." Mahaffy also highlighted these data: "I'd also like to focus your attention on the encouraging benefit seen in T790M-negative patients. What we presented today are admittedly a smaller number of [T790M-negative] patients [as compared with the number of T790M-positive patients presented], but the data are compelling, with a 36% response rate . . . ."

277. Also on that November 21, 2014 investor call, a WallachBeth securities analyst asked Defendants about "the efficacy in T790M mutation-negative patients. I'm trying to think about it commercially. How can you take advantage of that?" Mahaffy responded,

> We actually think it could represent a pretty meaningful point of differentiation and benefit to patients. We've had a number of interactions with clinicians, both in the community setting and in the academic setting, where the response to the data that you now saw for the first time today is[, "]That's really exciting because I want to use it in everybody.["]

278. On that November 21, 2014 investor call, Mahaffy further stated, "We're very encouraged to see continued strong response rates and durability of benefit from rociletinib."

279. As set forth above, Defendants statements on November 18 and 21, 2014 touting the data they presented at the 2014 ENA conference persuaded analysts and other market participants that rociletinib's efficacy profile was "impressive" and that the drug was highly competitive with Tagrisso.

280. These statements were materially false and misleading when made. It was false and misleading for Clovis, Mahaffy, and Allen to state that Clovis had observed an ORR of "67%" among "T790M-positive patients receiving either 625 or 500mg BID" in

its updated TIGER-X data; that "[t]he ORR was comparable in the 625mg and the 500mg dose groups"; and to characterize these results as "impressive," "strong response rates," and "durable," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses (which, among other things, could not support a claim that responses were "durable"), unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

281. Indeed, as discussed above, the illegitimate unconfirmed 67% ORR Defendants reported overstated rociletinib's true ORR by at least 40%, while the 61% confirmed ORR Astra-Zeneca had most recently reported for Tagrisso at the 2014 ESMO conference was likely at least 27% higher than rociletinib's unreported confirmed ORR.

282. Further, Clovis' statements that the Company had observed a "67% ORR (***per RECIST 1.1***)" and "durable ***RECIST*** responses" in its updated TIGER-X data were false: RECIST 1.1 required Defendants to report a confirmed objective response rate; instead, Defendants reported a post-hoc and scientifically illegitimate efficacy endpoint that included unconfirmed responses.

283. It was also materially false and misleading for Clovis, Mahaffy, and Allen to claim that Clovis had observed "a 36% ORR" among "T790M-negative patients treated at 625mg or 500mg BID," and to characterize these results as "compelling," "surprising," and showing an "encouraging benefit," while failing to disclose that Clovis' presentation

of rociletinib efficacy data included mostly unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

284. It was also materially false and misleading for Clovis and Mahaffy to claim that the supposed "encouraging benefit" seen in TIGER-X patients who tested negative for the T790M mutation "could represent a pretty meaningful point of differentiation" for rociletinib relative to Tagrisso and to tout the Company's "interactions with clinicians" about these data, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

C. False and Misleading Statements Made In The First Quarter Of 2015

1. The January 12 And February 12, 2015 Investor Conferences

285. On January 12, 2015, Mahaffy, on behalf of Clovis, participated in J.P. Morgan's 33rd Annual Healthcare Conference, attended by analysts and investors. At that conference, Clovis once again trumpeted the rociletinib efficacy data presented at the ENA conference, claiming, in the Company's investor conference slides, that they had observed a "67% ORR (per RECIST 1.1)" in "Evaluable T790M+ Patients" in the 500mg or 625mg

dose groups. Clovis' slides also presented new data, which it claimed demonstrated "Striking Activity in T790M-negative patients." Specifically, Clovis' slides stated that "RECIST ORR = 42% overall" and "RECIST ORR = 50% in patients treated with 625mg BID immediately off prior TKI."

286. At that January 12, 2015 investor conference, Mahaffy stated, "These are the data we showed most recently at the [ENA] meeting at our selected dose. We showed a response rate of 67% in the T790M positive population . . . . So, really good combination of efficacy and durability . . . . So ***clearly we have a very active compound in the targeted population of T790M positive TKI failures***."

287. At that conference, Mahaffy further stated:

> What continues to be fascinating about about [sic] this drug, is that ***we have striking activity in the T790M negative patients***. This is an update from the data that we presented at the [ENA] meeting. So, these are data that include about 20 patients who are treated at either 625 mg or 500 mg dose. And what you see in T7 -- in central negative T790M negative patients is ***a 42% overall response rate, and at the 625 mg dose, our response rate is 50%***.
>
> * * *
>
> And in fact most notable, ***our response rate in patients who immediately failed the TKI is 50%*** . . . . So, ***these are really compelling data for what is a significant unmet medical need***.

288. On February 12, 2015, Mast, on behalf of Clovis, participated in the Leerink Global Healthcare Conference. At that conference, Mast reiterated Clovis' claims about rociletinib's efficacy in TKI-resistant T790M-negative patients to analysts and investors:

> [W]e have seen some early but very encouraging data response rates to this T790M negative patient population we showed at [sic] just a month ago, we showed some updated data that had about a 50% response rate out of 19 patients, so admittedly a small patient population, but about 50% response rate in patients who are coming right off of a TK-I first line patient and onto rociletinib. If these data continue to play out in [a] larger patient population, that will be a very significant distinguishment from the competing drugs.

289. Mast later equated rociletinib's efficacy with Tagrisso's efficacy in the all-important T790M-positive population: "from an efficacy perspective, we may have a lot of similarities but we think we have a distinguishable side effect profile."

290. On that same call, Mast also touted rociletinib's safety profile, stating "the primary side effect that comes with rociletinib that is easily managed is hyperglycemia . . . . Particularly with the efficacy we see and rociletinib is monotherapy with what we believe is a ***very manageable side effect profile***, we think this can really be the backbone, therapy for this class of drugs."

291. As set forth above, analysts responded positively to Defendants' January 12 and February 12, 2015 statements touting the data they presented at the 2014 ENA conference and the updated data in T790M-negative patients presented at the J.P. Morgan Healthcare Conference.

292. These statements were materially false and misleading when made. It was false and misleading for Clovis, Mahaffy, and Mast to state that Clovis had observed an ORR of "67%" among "T790M-positive patients" in the key 500mg and 625mg dose groups; to characterize these results as "very encouraging"; to claim these results demonstrated that rociletinib provided "a really good combination of efficacy and durability" and was "clearly" a "very active compound"; and to claim Clovis' data showed that "from an efficacy perspective, [rociletinib] may have a lot of similarities" with Tagrisso, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly

lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

293. Indeed, as discussed above, the illegitimate unconfirmed 67% ORR Defendants reported overstated rociletinib's true ORR by at least 40%, while the 61% confirmed ORR Astra-Zeneca had most recently reported for Tagrisso at the 2014 ESMO conference was likely at least 27% higher than rociletinib's unreported confirmed ORR.

294. It was also materially false and misleading for Clovis, Mahaffy, and Mast to claim that in T790M-negative patients, Clovis' TIGER-X data showed "RECIST ORR = 42% overall" and a "RECIST ORR = 50%" in the 625mg dose group, to characterize these results as evidence of "striking activity" and as "really compelling data for what is a significant unmet medical need," and to claim the data indicated a potential "very significant distinguishment from" Tagrisso, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

295. Indeed, as discussed above, while Defendants reported 8 "responses" among T790M-negative patients in the 625mg dose group in these data, even as of November 16, 2015, only 7 patients in that dose group had confirmed responses. Accordingly, Defendants improperly included unconfirmed responses in the ORR results

presented in T790M-negative patients during the Class Period. Moreover, there is no more than a 3% chance Clovis had observed even 7 confirmed responses among T790M-negative patients in the 625mg dose group in this dataset.

296. Further, Clovis' claims that the Company was presenting ORRs as defined by RECIST criteria were materially false and misleading: RECIST 1.1 required Defendants to report a confirmed objective response rate; instead, Defendants reported a post-hoc and scientifically illegitimate efficacy endpoint that included mostly unconfirmed responses.

297. Finally, it was materially false and misleading for Mast and Clovis to claim Clovis' data showed that the "primary side effect that comes with rociletinib that is easily managed is hyperglycemia" and that rociletinib had a "very manageable side effect profile," while failing to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso. Indeed, Clovis' data showed that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required, and prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib.

2. Clovis' Full-Year 2014 And Fourth Quarter 2014 Earnings Announcement

298. On February 25, 2015, Clovis issued a press release, filed with the SEC on a Form 8-K signed by Mast, announcing its full year 2014 financial results, and filed those results with the SEC on Form 10-K, signed by Mahaffy and Mast. In its press release, Clovis repeated the results Defendants had presented at the January 12, 2015 J.P. Morgan

Healthcare Conference, including that: "Data presented in late 2014 demonstrated an objective response rate (ORR) of 67 percent in 27 evaluable T790M-positive patients receiving either 625mg or 500mg BID (the clinical dose group). The ORR was comparable in the 625mg BID and 500mg BID dose groups." The press release continued, "In addition, data for 19 T790M-negative patients receiving either 625mg or 500mg BID were presented in January 2015. An ORR of 42 percent was observed in these patients . . . . Based on this observed activity, the Company is now actively exploring rociletinib as treatment for T790M-negative patients, where a significant unmet medical need exists."

299. In the Company's Form 10-K, Clovis stated, "Data presented at a medical conference in late 2014 demonstrated an objective response rate ("ORR") of 67% [for rociletinib] in 27 evaluable T790M-positive patients receiving either 625mg or 500mg BID. The ORR was comparable in the 625mg BID and 500mg BID dose groups."

300. Also on February 25, 2015, Clovis held its fourth quarter and year-end 2014 conference call with investors. Mahaffy, Allen, and Mast participated in that conference call on Clovis' behalf. On that call, Mahaffy repeated the efficacy results presented in the Company's press release: "In November 2014 at the ENA meeting in Barcelona, data from our TIGER-X and TIGER-2 studies demonstrated an objective response rate of 67% in 27 evaluable T790M-positive patients, receiving either 625 mg or 500 mg BID, and what we refer to as the clinical dose group . . . . [W]e continue to see activity in [the T790M-negative] patient population as well. In 19 patients in the T790M-negative clinical dose group we reported a 42% overall response rate."

301. On that same February 25, 2015 conference call, Mahaffy stated, "we believe these data demonstrate the safety and effectiveness of rociletinib in a real-world

patient population, seen from the US market point of view . . . .Data presented to date demonstrates that rociletinib is well tolerated . . . . The only common grade 3/4 toxicity recorded was hypoglycemia [sic], which occurred at 14% of patients and was readily managed with an oral hypoglycemic agent [sic]."

302. As set forth above, in response to Defendant's February 25, 2015 statements, analysts publicly reported their views about rociletinib's "impressive" efficacy, and were reassured about rociletinib's safety and its competitiveness with Tagrisso.

303. These statements were materially false and misleading when made. It was false and misleading for Clovis and Mahaffy to state that Clovis had observed an ORR of "67%" among "T790M-positive patients receiving either 625 or 500mg BID" in its TIGER-X data; that "[t]he ORR was comparable in the 625mg BID and the 500mg BID dose groups"; and to claim that "these data demonstrate the . . . effectiveness of rociletinib in a real-world patient population," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

304. Indeed, as discussed above, the illegitimate unconfirmed 67% ORR Defendants reported overstated rociletinib's true ORR by at least 40%, while the 61% confirmed ORR Astra-Zeneca had most recently reported for Tagrisso at the 2014 ESMO conference was likely at least 27% higher than rociletinib's unreported confirmed ORR.

305. It was also materially false and misleading for Clovis and Mahaffy to claim that Clovis' TIGER-X data showed an "ORR of 42%" in T790M-negative patients, while failing to disclose that the ORR reported included mostly unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

306. Indeed, as discussed above, while Defendants reported 8 "responses" among T790M-negative patients in the 625mg dose group in these data, even as of November 16, 2015, only 7 patients in that dose group had confirmed responses. Accordingly, Defendants improperly included unconfirmed responses in the ORR results presented in T790M-negative patients during the Class Period. Moreover, there is no more than a 3% chance Clovis had observed even 7 confirmed responses among T790M-negative patients in the 625mg dose group in this dataset.

307. Finally, it was materially false and misleading for Clovis and Mahaffy to claim Clovis' data "demonstrate" that rociletinib is "safe[]" and "well-tolerated," while failing to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso. Indeed, Clovis' data showed that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required, and

prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib. Moreover, it was misleading for Mahaffy to claim that "[t]he only common grade 3/4 toxicity recorded was hypoglycemia [sic]," when 13% of rociletinib patients in the recommended 625mg dose group experienced grade 3 or 4 QT prolongation, and 12% of such rociletinib patients experienced a QT interval greater than 500 ms (compared with 0.2% of Tagrisso patients).

3. The March 4, 2015 TAT Medical Conference

308. On March 4, 2015 Clovis presented rociletinib efficacy data from phase II of the TIGER-X study at the TAT medical conference. Clovis' presentation, the contents of which were subject to the Company's final approval, stated that "Promising activity seen [with rociletinib] across all doses used in Phase 1/2 trial – 67% ORR in T790M+ patients – durable responses." Clovis' presentation also repeated the data in T790M-negative patients the Company had presented in January 2015. Clovis claimed its TIGER-X data showed "RECIST ORR = 42% overall" and a "RECIST ORR = 50%" among patients in the 625mg dose group and characterized these results as evidence of "striking activity."

309. Clovis' TAT presentation also stated, "The only grade 3/4 adverse event observed in >5% of patients was hyperglycemia, readily managed with oral Rx."

310. These statements were materially false and misleading when made. It was false and misleading for Clovis to state that it had observed a "67% ORR in T790M+ patients" in its TIGER-X data, and to characterize those results as showing "promising activity" and "durable responses," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses (which, among other things, could not support a claim that responses were "durable"), unlike the results presented for Tagrisso; that the endpoint reported was not prespecified and would not be

used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

311. Indeed, as discussed above, the illegitimate unconfirmed 67% ORR Defendants reported overstated rociletinib's true ORR by at least 40%, while the 61% confirmed ORR Astra-Zeneca reported for Tagrisso was likely at least 27% higher than rociletinib's unreported confirmed ORR.

312. It was also materially false and misleading for Clovis to claim that in T790M-negative patients, the Company's TIGER-X data showed "RECIST ORR = 42% overall" and a "RECIST ORR = 50%" among patients in the 625mg dose group, and to characterize these results as evidence of "striking activity," while failing to disclose that the ORR reported included mostly unconfirmed responses; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rates Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

313. Indeed, as discussed above, while Defendants reported 8 "responses" among T790M-negative patients in the 625mg dose group in these data, even as of November 16, 2015, only 7 patients in that dose group had confirmed responses. Accordingly, Defendants improperly included unconfirmed responses in the ORR results presented in T790M-negative patients during the Class Period. Moreover, there is no more

than a 3% chance Clovis had observed even 7 confirmed responses among T790M-negative patients in the 625mg dose group in this dataset.

314. Finally, it was materially false and misleading for Clovis and Mahaffy to claim that "The only grade 3/4 adverse event observed in >5% of patients was hyperglycemia, readily managed with oral Rx," when 13% of rociletinib patients in the recommended 625mg dose group experienced grade 3 or 4 QT prolongation, and 12% of such rociletinib patients experienced QTc greater than 500 ms (compared with 0.2% of Tagrisso patients).

D. False And Misleading Statements Made In The *New England Journal of Medicine*

315. On April 30, 2015, Defendants published rociletinib efficacy data from the TIGER-X trial in the *NEJM*, in article titled, *Rociletinib in EGFR-Mutated Non-Small-Cell Lung Cancer*. Five Clovis employees, including Allen, coauthored the *NEJM* article. Clovis drafted and edited the manuscript and approved the final published *NEJM* article. Defendants published the following table as Table 2 in the *NEJM* article:

Table 2. Best Response, Objective Response, and Disease Control.*

Variable	Any Dose of Rociletinib	Free Base, 900 mg Twice Daily	Hydrogen Bromide Salt			
			500 mg Twice Daily	625 mg Twice Daily	750 mg Twice Daily	1000 mg Twice Daily
			number/total number (percent)			
Patients with centrally confirmed T790M-positive tumors						
Best response						
Partial response	27/46 (59)	6/8 (75)	3/6 (50)	5/9 (56)	10/19 (53)	3/4 (75)
Stable disease	16/46 (35)	2/8 (25)	2/6 (33)	2/9 (22)	9/19 (47)	1/4 (25)
Progressive disease	3/46 (7)	0/8	1/6 (17)	2/9 (22)	0/19	0/4
Objective response	27/46 (59)	6/8 (75)	3/6 (50)	5/9 (56)	10/19 (53)	3/4 (75)
Disease control	43/46 (93)	8/8 (100)	5/6 (83)	7/9 (78)	19/19 (100)	4/4 (100)
Patients with centrally confirmed T790M-negative tumors						
Best response						
Partial response	5/17 (29)	0/2	0/2	2/6 (33)	3/7 (43)	NA
Stable disease	5/17 (29)	2/2 (100)	0/2	0/6	3/7 (43)	
Progressive disease	7/17 (41)	0/2	2/2 (100)	4/6 (67)	1/7 (14)	
Objective response	5/17 (29)	0/2	0/2	2/6 (33)	3/7 (43)	NA
Disease control	10/17 (59)	2/2 (100)	0/2	2/6 (33)	6/7 (86)	

* Tumor response was assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST), version 1.1. Objective response was defined as a complete response or a partial response. Disease control was defined as a complete response, a partial response, or stable disease for more than 6 weeks. Six patients (five with T790M-positive tumors and one with a T790M-negative tumor) could not be evaluated according to RECIST.

Figure 7. Table 2 from Clovis' April 30, 2015 *NEJM* article, *Rociletinib in EGFR-Mutated Non-Small-Cell Lung Cancer*.

316. Likewise, Defendants stated in the *NEJM* article that "The response rate among 46 patients with centrally confirmed T790M-positive tumors was 59% (95% confidence interval [CI], 45[%] to 73[%])." Similarly, Defendants stated that "T790M-positive patients treated with rociletinib in our study had a sustained clinical benefit. A response rate of 59% with prolonged disease control was noted."

317. These statements were materially false and misleading when made. It was false and misleading for Clovis and Allen to report the ORR results set forth in Table 2 of the *NEJM* article, and to characterize those results as showing "a sustained clinical benefit,"

while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib was significantly lower than the confirmed ORR presented for Tagrisso.

318. Indeed, as discussed above, the illegitimate unconfirmed 59% ORR Defendants reported overstated rociletinib's true ORR by at least 28%, while the 54% confirmed ORR Astra-Zeneca reported for Tagrisso at the April 2015 ELCC conference was likely at least 17% higher than rociletinib's unreported confirmed ORR.

E. False And Misleading Statements Made In Connection With Clovis' First Quarter 2015 Earnings Announcement

319. On May 6, 2015, Clovis issued a press release, filed with the SEC on a Form 8-K signed by Mast, announcing its first quarter 2015 financial results. In the press release, Clovis repeated the results presented in its April 30, 2015 *NEJM* article: "In the forty-six evaluable patients who possessed the T790M mutation and were treated with a therapeutic dose of rociletinib, overall response rate (ORR) was 59 percent."

320. Also on May 6, 2015, Clovis held its first quarter 2015 conference call with investors. Mahaffy, Allen, and Mast participated in that conference call on Clovis' behalf. On that call, Mahaffy, discussing Clovis' presentations of rociletinib efficacy data, stated, "all of our presentations have demonstrated [rociletinib's] compelling and consistent activity and safety in patients with EGFR mutant non-small cell lung cancer." Mahaffy further stated, "[W]e've shown encouraging response rates and progression free survival in the centrally confirmed T790M-negative patient population."

321. On that same call, Mahaffy stated, "we believe our data demonstrate the safety and activity of rociletinib in a uniquely relevant patient population from a US market point of view. . . . Overall, rociletinib is ***well tolerated with treatment related adverse events generally infrequent and mild, with the only grade 3 adverse event of note, hyperglycemia***, which when observed and requiring treatment is typically managed with a commonly prescribed single oral agent."

322. These statements were materially false and misleading when made. It was false and misleading for Clovis to state that it had observed a 59% ORR among T790M-positive patients in its TIGER-X data, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported was not prespecified and would not be used by the medical community or regulatory agencies to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

323. Indeed, the illegitimate unconfirmed 59% ORR Defendants reported overstated rociletinib's true ORR by at least 28%, while the 54% confirmed ORR Astra-Zeneca reported for Tagrisso at the April 2015 ELCC conference was likely at least 17% higher than rociletinib's unreported confirmed ORR.

324. It was also materially false and misleading for Clovis and Mahaffy to claim that "all" of Clovis' rociletinib "presentations have demonstrated [the drug's] compelling and consistent activity" and that the data presented "show[ed] encouraging response rates"

in T790M-negative patients, while failing to disclose that the ORR reported in "all of [Clovis'] presentations" included mostly unconfirmed responses; that the endpoint reported in "all of [Clovis' rociletinib] presentations" would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in the Company's data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

325. Finally, it was materially false and misleading for Clovis and Mahaffy to claim Clovis' data "demonstrate" rociletinib's "safety," that rociletinib is "well tolerated with treatment related adverse events generally infrequent and mild," and that "the only grade 3 adverse event of note [was] hyperglycemia," while failing to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso; that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required; that prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib; and that adverse side effects were causing patients to interrupt, modify, or discontinue therapy at an alarming rate.

326. Moreover, it was materially false and misleading for Mahaffy to claim that "the only grade 3 adverse event of note, hyperglycemia," when 12% of rociletinib patients

experienced grade 3 or 4 QT prolongation and 13% of rociletinib patients experienced a QT interval greater than 500 ms (compared with 0.2% of Tagrisso patients).

F. False And Misleading Statements Made In Connection With Clovis' Presentation Of Rociletinib Data At The 2015 ASCO Conference

327. On May 31, 2015, Clovis presented additional rociletinib efficacy data from phase II of the TIGER-X study at the 2015 annual ASCO medical conference. Clovis' presentation, the contents of which were subject to the Company's final approval, included the following slide:

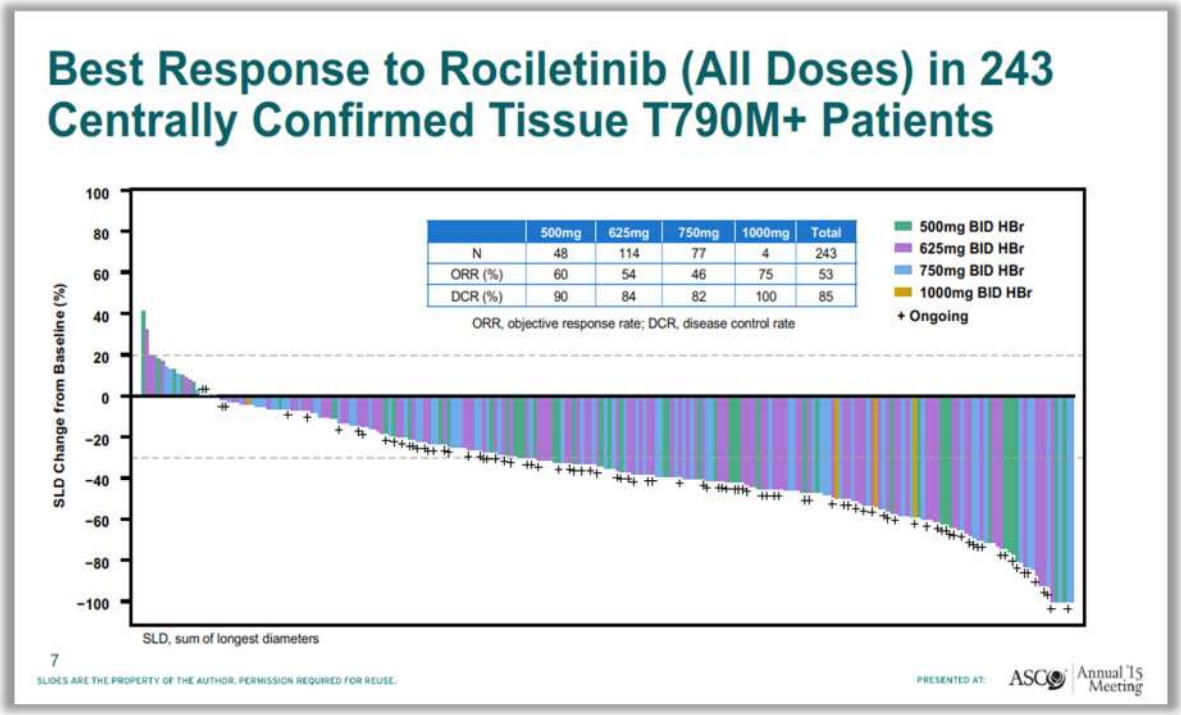


Figure 8. Except from Clovis' presentation at the May 31, 2015 ASCO medical conference.

328. Likewise, Defendants' presentation stated, "Rociletinib demonstrates compelling activity and is a well-tolerated agent at the recommended dose (500mg BID)

in US/EU mutant EGFR NSCLC patients with PD [progressive disease] after immediate prior TKI – ORR of 60% . . . in centrally confirmed tissue T790M+ patients at this dose."

329. Defendants' presentation also claimed that the Company had observed "ORR [of] 37%" associated with rociletinib in "[c]entral T790M [n]egative [p]atients" across all doses, and a 50% ORR among T790M-negative patients taking 625mg of rociletinib.

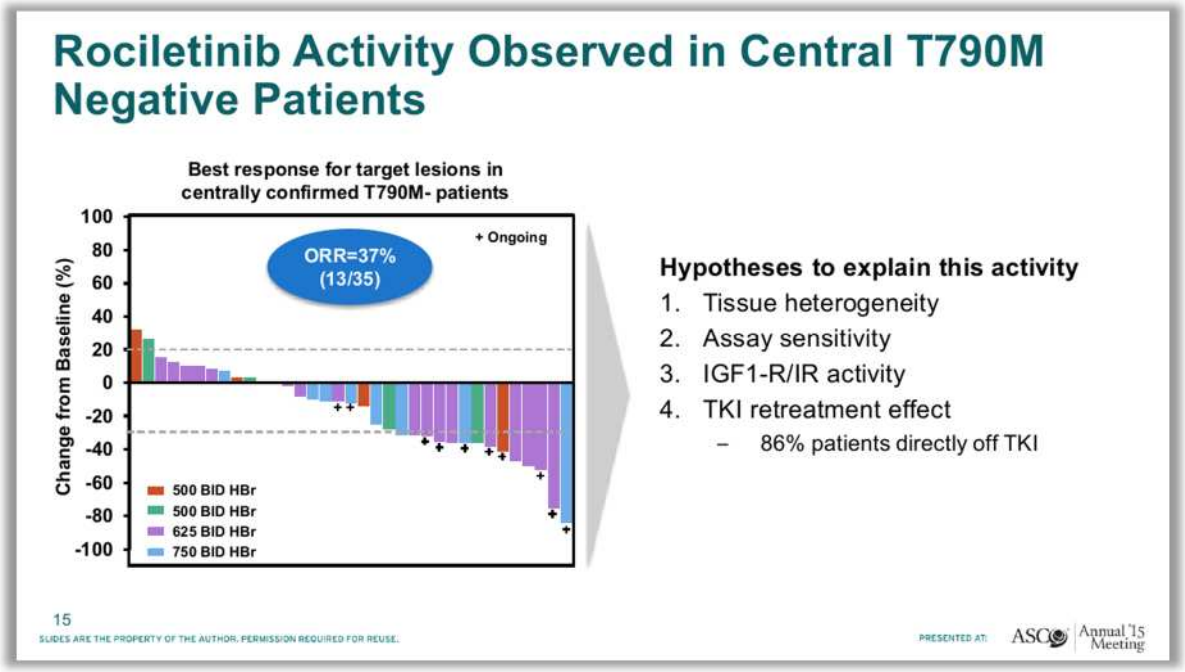


Figure 9. Except from Clovis' presentation at the May 31, 2015 ASCO medical conference.

330. Also on May 31, 2015, Clovis issued a press release announcing these same results. Clovis' press release claimed that "Clovis Oncology's Rociletinib (CO-1686) Phase 2 Study Results Demonstrate Consistent and Promising Clinical Activity." The press release went on to claim that in these phase II data, rociletinib achieved a "60% overall response rate (ORR) . . . in heavily pretreated centrally confirmed tissue T790M-positive

patients," and "[c]ompelling activity in T790M-negative disease with 37% ORR observed."

331. The May 31, 2015 press release also quoted Mahaffy's claim that "'[t]o show ***responses and durability of this magnitude*** in a very advanced U.S. patient population, of whom nearly half have a history of CNS metastases, is ***extremely encouraging*** . . . . These maturing data ***confirm rociletinib's compelling activity*** in patients with the most advanced stage of mutant EGFR NSCLC.'"

332. Finally, the May 31, 2015 press release, quoting one of doctors running the TIGER-X study, claimed that:

> "The maturing data for rociletinib ***confirm*** in a large patient population what we have seen in our early clinical experience . . . . Rociletinib has shown ***very encouraging and durable activity*** in the most advanced mutant EGFR lung cancer patients, including in a large population of patients with CNS metastases. Importantly, the data continue to show activity in both T790M-positive and T790M-negative patients, which gives us a potential treatment option for all patients who have progressed on their initial EGFR targeted therapy."

333. Also on May 31, 2015, Mahaffy and Allen, on behalf of Clovis, held a conference call with investors to present these additional phase II data. On the investor call, Allen stated, "[W]e have very consistently shown an objective response rate of around 60% in centrally confirmed tissue T790M positive patients." Allen further stated, "Importantly and interestingly, we have consistently observed response rates greater than 35% in centrally confirmed T790M negative patients."

334. On that same May 31, 2015 call, Allen stated, "I will simply highlight that at the go-forward dose of 500 milligrams, we have an objective response of 60%." Allen further stated, "We now have 35 patients who test central negative [for the T790M

mutation] using our FDA approved diagnostic test. And the response rate remains high at 37%."

335. Also on that call, Allen, in answering a question about Clovis' efficacy presentation, highlighted to investors and analysts that the Company was adhering to RECIST 1.1 standards in evaluating and reporting ORRs in its rociletinib data: "You cannot be evaluable for response [i.e., ORR] until you have had two scans. Because, ***obviously, that is the definition for RECIST objective response***."

336. Additionally, on that May 31, 2015 call Allen stated, "So our conclusions regarding rociletinib: it is a novel and unique EGFR tyrosine kinase inhibitor with FDA breakthrough therapy designation. We have seen these ***consistent responses with durable patient benefit in now a large, very advanced Western patient population*** using our commercial drug formulation."

337. Finally, on that May 31, 2015 call Allen claimed that rociletinib "is a very well tolerated oral cancer therapeutic with an extremely low discontinuation rate due to adverse events. And at 500 milligrams, which is our go forward dose, discontinuations are found in only 2.5% of patients. . . . It is a very well tolerated agent, as exemplified by only 2.5% discontinuations from adverse events."

338. As set forth above, Defendants' May 31, 2015 statements touting the efficacy data they had presented at the 2015 ASCO meeting reassured investors and analysts that rociletinib remained competitive with Tagrisso, which, as Astra-Zeneca had announced just a few weeks earlier, achieved a 54% confirmed ORR. Moreover, as set forth above, Defendants' statements also persuaded analysts that rociletinib had a safety profile that would allow the drug to garner market share and compete with Tagrisso.

Analysts were convinced that rociletinib and Tagrisso each had manageable, non-overlapping toxicities that as with efficacy, essentially placed the drugs in commercial equipoise.

339. These statements were materially false and misleading when made. It was false and misleading for Clovis and Allen to state that Clovis had "very consistently" observed an "ORR of 60% . . . in centrally confirmed tissue T790M+ patients at [the recommended 500mg] dose" in their updated TIGER-X data; to claim Clovis had observed the ORRs set forth in Figure 9; to characterize these efficacy results as demonstrating rociletinib's "very encouraging and durable activity," "confirming" its "compelling activity," and showing "consistent responses with durable patient benefit in now a large, very advanced Western patient population"; and to claim that "responses and durability of this magnitude in a very advanced U.S. patient population, of whom nearly half have a history of CNS metastases, is extremely encouraging," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses (which, among other things, could not support a claim that responses were "durable"), unlike the results presented for Tagrisso; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

340. Indeed, as discussed above, the illegitimate unconfirmed ORRs Defendants reported overstated rociletinib's true ORR by at least 56%, while the confirmed ORR

Astra-Zeneca reported for Tagrisso was likely at least 50% higher than rociletinib's unreported confirmed ORR.

341. It was also materially false and misleading for Clovis to claim that in T790M-negative patients, the Company's TIGER-X data showed a "high" ORR of 37% for rociletinib across all doses and a 50% ORR in patients in the 625mg cohort, while failing to disclose that the ORR reported included mostly unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rates Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

342. Indeed, as of November 16, 2015 only 7 T790M-negative patients taking 625mg of rociletinib had confirmed responses. Yet, months earlier at the May 2015 ASCO conference, Defendants claimed that 9 such patients were "responsive." Accordingly, Defendants' own statements show they improperly included unconfirmed responses in the ORR results presented in T790M-negative patients during the Class Period. Moreover, there is no more than a 9% chance Clovis had observed even 7 confirmed responses among T790M-negative patients in the 625mg dose group in the Company's ASCO dataset.

343. Further, Defendants' claims that Clovis was presenting ORRs that satisfied "the definition for RECIST objective response" were false: RECIST 1.1 required Defendants to report a confirmed objective response rate; instead, Defendants reported a post-hoc and scientifically illegitimate efficacy endpoint that included mostly unconfirmed responses.

344. Finally, Allen's claims that rociletinib "is a very well tolerated oral cancer therapeutic with an extremely low discontinuation rate due to adverse events," and that the rate of discontinuation due to adverse events at the 500mg dose group only 2.5% were false and misleading because Clovis' rociletinib safety data showed that 12% of both the patients in the 500mg dose group and across all doses discontinued rociletinib therapy due to adverse events. In addition, Clovis' safety data showed that ***65%*** of all rociletinib patients either interrupted therapy (56%) or reduced dosage (51%) as a result of adverse events, including ***60%*** of patients in the 500mg dose group. In addition, it was misleading for Allen to characterize rociletinib as "very well tolerated," without disclosing the drug's increased cardiovascular risk.

G. False And Misleading Statements In The Third Quarter Of 2015

1. Clovis' Second Quarter 2015 Earnings Announcement

345. On August 6, 2015, Clovis issued a press release, filed with the SEC on a Form 8-K signed by Mast, announcing its second quarter 2015 financial results. In the press release, Clovis repeated the rociletinib efficacy results it presented at the 2015 ASCO conference, claiming Clovis' clinical trial data showed a "60% overall response rate (ORR) . . . in heavily pretreated centrally confirmed tissue T790M-positive patients at the 500mg BID dose," and a "37% ORR in centrally confirmed tissue T790M-negative patients."

346. Also on August 6, 2015, Clovis held its second quarter 2015 earnings call with investors. Mahaffy and Mast participated in that conference call on Clovis' behalf. On that call, Mahaffy, discussing Clovis' rociletinib NDA, stated, "Our submissions include data from two single-arm studies, TIGER-X and TIGER-2. ***These data sets have continued to demonstrate compelling and consistent activity*** and tolerability in patients with T790M-positive mutant EGFR non-small cell lung cancer." Mahaffy further stated,

"Interestingly, as we have discussed previously, we've shown encouraging response rates in the centrally confirmed T790M-negative population, as well."

347. On that same August 6, 2015 call, Mahaffy also touted rociletinib's safety profile, claiming that "[o]verall, rociletinib is well-tolerated" and that "the only grade 3 adverse reaction or lab abnormality reported in greater than 5% of patients was hyperglycemia."

348. These statements were materially false and misleading when made. It was false and misleading for Clovis and Mahaffy to state that the Company had observed a "60% overall response rate (ORR) . . . in heavily pretreated centrally confirmed tissue T790M-positive patients at the 500mg BID dose" in the data submitted to the FDA and foreign regulators, and that "these data sets have continued to demonstrate compelling and consistent activity" for rociletinib in T790M-positive patients, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

349. Indeed, as discussed above, the illegitimate unconfirmed ORRs Defendants reported overstated rociletinib's true ORR by at least 56%, while the confirmed ORR Astra-Zeneca reported for Tagrisso was likely at least 50% higher than rociletinib's unreported confirmed ORR.

350. It was also materially false and misleading for Clovis to claim that the Company's TIGER-X data showed a "37% ORR in centrally confirmed tissue T790M-negative patients," and to characterize those results as "encouraging," while failing to disclose that the ORR reported included mostly unconfirmed responses; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

351. Finally, it was misleading for Mahaffy to claim that "[o]verall, rociletinib is well-tolerated," while failing to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso; that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required, and prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib; and that adverse side effects were causing patients to interrupt, modify, or discontinue therapy at an alarming rate. Moreover, it was misleading for Mahaffy to claim that "the only grade 3 adverse reaction or lab abnormality reported in greater than 5% of patients was hyperglycemia," when 12% of rociletinib patients experienced grade 3 or 4 QT prolongation and 13% of rociletinib patients experienced a QT interval greater than 500 ms (compared with 0.2% of Tagrisso patients).

2. The 2015 World Conference On Lung Cancer

352. On September 7, 2015, Clovis presented updated rociletinib efficacy data at the 2015 World Conference on Lung Cancer. Clovis' presentation, the contents of which was subject to the Company's final approval, claimed that Clovis' TIGER-X data showed rociletinib's "ORR in centrally confirmed tissue T790M-positive pts (n=48) enrolled at the 500mg BID dosing level was 60%." Clovis further claimed its TIGER-X data showed "rociletinib's ORR in centrally confirmed tissue and plasma T790M-negative pts was 35% and 45%, respectively."

353. As set forth above, Defendants' statements successfully reassured analysts that rociletinib's efficacy profile was "compelling," that the drug remained in competitive deadlock with Tagrisso, and that Clovis would split the $3 billion market for "third generation" TKIs equally with Astra-Zeneca.

354. These statements were materially false and misleading when made. It was false and misleading for Clovis and Mahaffy to state that the Company had observed a 60% ORR in "centrally confirmed tissue T790M-positive patients" taking 500mg of rociletinib in the data submitted to the FDA and foreign regulators, while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

355. Indeed, as discussed above, the illegitimate unconfirmed ORRs Defendants reported overstated rociletinib's true ORR by at least 56%, while the confirmed ORR Astra-Zeneca reported for Tagrisso was likely at least 50% higher than rociletinib's unreported confirmed ORR.

356. It was also materially false and misleading for Clovis to claim that "rociletinib's ORR in centrally confirmed tissue and plasma T790M-negative pts was 35% and 45%, respectively" in the Company's TIGER-X data, while failing to disclose that the ORR reported included mostly unconfirmed responses; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

3. The September 17, 2015 Morgan Stanley Healthcare Conference

357. On September 17, 2015, Mahaffy participated in the annual Morgan Stanley Healthcare Conference on behalf of Clovis. At that conference, Mahaffy once again highlighted the rociletinib efficacy data the Company had presented in patients who tested negative for the T790M mutation, claiming Clovis' data "showed a 37% response rate in the T790M negative population":

> And we have probably presented data on the T790M negatives over the course of the last 12 to 18 months at various medical meetings. It started with single digit numbers of patients, which could have clearly been noise to 20 odd patients that may well also have been noise. But when you get up into a 40 plus number of patient population, it feels like there is probably something there. It's also true that ***that is in contrast with our competitor who does not show this type of activity in the [T790M] negative [patients]***.

> So if the explanation was limited to tumor heterogeneity or an assay issue feels like that would be equally balanced for these very similar drugs.

358. These statements were materially false and misleading when made. It was false and misleading for Clovis to claim that rociletinib "showed a 37% response rate in the T790M negative population" in the Company's TIGER-X data; to assure investors that these ORR results were not "noise" and that there was "probably something there"; and to claim that these results are "in contrast with our competitor who does not show this type of activity in the [T790M] negative [patients]," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

4. The September 27 And 28, 2015 European Cancer Congress

359. On September 27 and 28, 2015, at the 2015 European Cancer Congress, Clovis presented the rociletinib efficacy data it had presented at the 2015 ASCO conference. Clovis' presentation, the contents of which was subject to the Company's final approval, claimed that Clovis' TIGER-X data showed rociletinib's "RECIST ORR >50% in centrally confirmed tissue T790M-positive patients at therapeutic doses" and that rociletinib's "[o]bjective response rate (ORR) in centrally confirmed tissue T790M-positive patients (n=48) enrolled at the 500mg BID dosing level was 60%." Clovis also claimed that its TIGER-X data showed that "ORR among pts without and with a history of

CNS mets was 58% and 45%, respectively," and therefore, "rociletinib response rate does not appear affected by history of CNS disease."

360. With regards to rociletinib's safety, Clovis' September 28, 2015 presentation at the European Cancer Congress claimed that "Rociletinib is generally well tolerated[,] 2.5% of patients discontinued study due to treatment-related adverse events (4% overall)."

361. These statements were materially false and misleading when made. It was false and misleading for Clovis to state that its TIGER-X data showed rociletinib's "RECIST ORR >50% in centrally confirmed tissue T790M-positive patients at therapeutic doses"; that rociletinib achieved an ORR of 60% in 500mg patients; and that the "ORR among pts without and with a history of CNS [metastasis] was 58% and 45%, respectively," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

362. It was also false and misleading for Clovis to use the ORRs reported for patients with and without a history of CNS metastasis to support its claim that "rociletinib response rate does not appear affected by history of CNS disease," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported would not

be used by the medical and regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

363. Finally, Clovis' claim that "Rociletinib is generally well tolerated[,] 2.5% of patients discontinued study due to treatment-related adverse events (4% overall)," was false and misleading because Clovis' rociletinib safety data showed that 12% of rociletinib patients discontinued rociletinib therapy due to adverse events, with 21% discontinuing overall (including patients whose tumors grew notwithstanding rociletinib therapy). In addition, Clovis' safety data showed that ***65%*** of all rociletinib patients either interrupted therapy (56%) or reduced dosage (51%) as a result of adverse events, including ***60%*** of patients in the 500mg dose group.

H. False And Misleading Statements Made In The Fourth Quarter Of 2015

1. Clovis' Third Quarter 2015 Earnings Announcement

364. On November 5, 2015, Clovis issued a press release, filed with the SEC on a Form 8-K signed by Mast, announcing its third quarter 2015 financial results. In the press release, Clovis directed investors to the false and misleading presentations the Company disseminated in connection with its presentation of rociletinib efficacy data at the WCLC and at ECC medical conferences in September 2015. Specifically, the press release stated,

> Rociletinib was the subject of several posters and presentations during the third quarter, including updates of data from the TIGER-X study in EGFR mutant, T790M-positive patients with a history of CNS involvement, as well as EGFR mutant, T790M-negative patients as determined by tissue as

> well as plasma testing. Posters and presentations for all Clovis products in development presented during the third quarter may be viewed at http://clovisoncology.com/products-companion-diagnostics/scientific-presentations/.

365. Also on November 5, 2015, Clovis held its third quarter 2015 earnings call with investors. Mahaffy and Mast participated in that conference call. On that call, Mahaffy reminded investors that Clovis had "provided updates of [rociletinib] data at both the World Conference on Lung Cancer and ESMO [the ECC conference] in September," and directed investors to those presentations on Clovis' website.

366. The presentations to which Defendants Clovis and Mahaffy directed investors, described in ¶¶352 and 359-60, and which they incorporated by reference in their statements, were materially false and misleading, for the reasons set forth in ¶¶354-56 and 361-63, including that they failed to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the endpoint reported would not be used by the medical and regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso.

367. Moreover, Defendants have affirmatively admitted that at the time these statements were made, they had already provided the FDA with an analysis showing that confirmed ORRs for T790M-positive patients in the phase II rociletinib data submitted to regulators were 28% for the recommended 500mg dose and 34% for the 625mg dose. Accordingly, Clovis' and Mahaffy's statements were misleading because they failed to disclose that the ORRs to which they directed investors included mostly unconfirmed

responses; that the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that rociletinib's confirmed ORR for T790M-positive patients in those data was significantly lower than, the confirmed ORR Astra-Zeneca reported for Tagrisso; and that Clovis' reported results in T790M-negative patients overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

368. Clovis' and Mahaffy's statements were materially false and misleading when made because Mahaffy failed to disclose that Clovis had already submitted to the FDA, but had not shared with investors, data significantly altering the image of rociletinib's efficacy and commercial viability Defendants' prior public statements had created and promoted. Moreover, Mahaffy failed to disclose the analysis of confirmed responses Clovis had already provided to the FDA, which showed that rociletinib's ORR was approximately 50% lower than had been previously reported and that it was far less effective than Tagrisso.

2. The November 10, 2015 Credit Suisse Healthcare Conference

369. On November 10, 2015, Mast participated in the Credit Suisse Healthcare Conference on Clovis' behalf. At that conference, Mast presented rociletinib ORR data to investors, stating, "You see we have equal and very robust response rates across all the different doses, and an overall response rate of just over 50% . . . . Most of that majority of patients received some sort of clinical benefit from taking rociletinib."

370. Also at that conference, Mast further highlighted the rociletinib efficacy data in patients who tested negative for the T790M mutation:

> Now, as I mentioned earlier, this drug was designed really specifically for T790[M] positive patients, but as we've gone through our clinical development activity, one of the more interesting aspects that we learned is seeing some response in T790[M]-negative patients. So, here again you see data that was presented at ASCO, and for these 30-odd patients showing a ***response rate in excess of 30%*** . . . . So, this is very interesting to us. ***This is not something that has been seen in other third-generation TKIs that are under development***.

371. Finally, Defendant Mast also touted rociletinib's safety profile. Mast stated;

> ***The drug is also well tolerated. The only grade 3 or 4 adverse event that has been identified in more than 10% of patients is hyperglycemia***. This is a condition that is ***readily managed with oral agents***. It is oftentimes asymptomatic, not always, but oftentimes. And one that when monitored . . . and managed earlier on, we certainly had more success in lowering the rate and treating those symptoms . . . . [A]t the 500 milligram dose, the QTc prolongation of grade 3 or higher was only 2.5%.

372. These statements were materially false and misleading when made. It was false and misleading for Clovis and Mast to claim that rociletinib showed an "overall response rate of just over 50%," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses, unlike the results presented for Tagrisso; that the Company had already provided the FDA with an analysis showing that confirmed ORRs for T790M-positive patients in the phase II rociletinib data submitted to regulators were 28% for the recommended 500mg dose and 34% for the 625mg dose; and that the confirmed ORR associated with rociletinib in the TIGER-X data was significantly lower than the confirmed ORR presented for Tagrisso. Likewise, it was materially false and misleading for Clovis and Mast to claim that "most of that majority of patients received some sort of clinical benefit from taking rociletinib," when, in fact, the confirmed ORR data the Company had already reported to the FDA affirmatively showed that "most" patients did not "respond" to rociletinib, as that term is defined by the RECIST 1.1 criteria and by Clovis' own study protocols.

373. It was also materially false and misleading for Clovis and Mast to claim that rociletinib was associated with a "response rate in excess of 30%" among T790M-negative patients enrolled in TIGER-X, and that the ORR result observed in these patients "is not something that has been seen in other third-generation TKIs that are under development [i.e., Tagrisso]," while failing to disclose that Clovis' presentation of rociletinib efficacy data included mostly unconfirmed responses; the endpoint reported was not prespecified and would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

374. Moreover, it was materially false and misleading for Clovis and Mast to claim that rociletinib was "well-tolerated," while failing to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso; that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required, and prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib; and that adverse side effects were causing patients to interrupt, modify, or discontinue therapy at an alarming rate.

375. Finally, it was materially false and misleading for Mast to claim that the "only grade 3 or 4 adverse event that has been identified in more than 10% of patients is

hyperglycemia" when Clovis' data showed that 12% of rociletinib patients experienced grade three or higher QT prolongation. Likewise, it was materially false and misleading for Mast to claim that "QTc prolongation of grade 3 or higher was only 2.5%" in the 500mg group when 8% of such patients experienced grade 3 or 4 QT prolongation and 12% of such patients experienced QTc prolongation greater than 500 ms.

I. False and Misleading Statements At The January 13, 2016 J.P. Morgan Healthcare Conference

376. On January 13, 2016, Mahaffy attended the annual J.P. Morgan Healthcare Conference on Clovis' behalf. At that investor conference, Mahaffy again touted rociletinib's safety profile, and continued to suggest that rociletinib and Tagrisso were essentially in equipoise in terms of safety, with the choice between the drugs coming down to a choice between easily-managed hyperglycemia (with rociletinib) and rash (with Tagrisso). Mahaffy, stated

> [Rociletinib] doesn't have rash. It doesn't have diarrhea. Does have hyperglycemia. And ***I think the greater differentiator, and the greater decision a physician will make about their patient, is*** whether, for instance, that patient is afraid of getting hyperglycemia, and therefore would be more appropriate for the competitor; or, ***if that patient had had a terrible rash experience on Tarceva and doesn't want to see rash ever again, then that patient's going to be more appropriate to go on 1686***. We'll compete just fine . . . . A community oncologist, of course, treats any number of tumor types, and as a consequence uses a broader spectrum of drugs, and they have a lot of experience with a tremendous amount of steroid use. They do in the academic setting too; but a tremendous amount of steroid use. MTOR inhibitors; PI3 kinase inhibitors; now including Keytruda, which has generated quite a bit of hyperglycemia. They're used to it, and they think they can manage it quite easily. But ***they hate rash***. They hate rash, because they see the patients, and the patients hate rash. So, ***I think we have some advantages***.

377. Mahaffy further stated that QT prolongation in rociletinib patients was "well-managed -- readily managed. We've had very, very few arrhythmic events, for instance, associated with the QT prolongation."

378. As set forth above, analysts were persuaded that despite rociletinib's inferior efficacy relative to Tagrisso, its favorable safety profile might still allow it to garner some market share as a second-line therapy for patients who could not tolerate Tagrisso.

379. These statements were materially false and misleading when made. It was misleading for Clovis and Mahaffy to claim that rociletinib "doesn't have rash. It doesn't have diarrhea. Does have hyperglycemia," that rociletinib "will compete fine" and "may have some advantages" because of its safety profile, that rociletinib had a differentiated safety profile from, but not inferior to, Tagrisso, that the "greatest differentiator between rociletinib and Tagrisso" was a choice between easily-managed hyperglycemia and rash, and that the safety data indicated that there was no other substantial safety-related reason for doctors who felt comfortable managing hyperglycemia to choose Tagrisso.

380. These statements were materially false and misleading and failed to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso; that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required, and prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib; and that adverse side effects were causing patients to interrupt, modify, or discontinue therapy at an alarming rate.

381. It was also materially false and misleading for Clovis and Mahaffy to state that "QT prolongation in rociletinib patients was "well-managed -- readily managed.

We've had very, very few arrhythmic events, for instance, associated with the QT prolongation," while failing to disclose that at least 13% of rociletinib patients discontinued treatment, interrupted therapy, or reduced their dosage as a result of QT prolongation, that 13% of rociletinib patients experienced cardiac arrhythmias, and that at least one patient who experience QT prolongation died after subsequently experiencing a cardiac arrhythmia.

X. LOSS CAUSATION

382. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class. Throughout the Class Period, Clovis' stock price was artificially inflated as a result of Defendants' materially false and misleading statements and omissions, which were widely disseminated to the securities markets, securities analysts, and investors and created false impressions concerning, among other things, (i) rociletinib's efficacy, including its efficacy relative to Tagrisso; (ii) rociletinib's safety profile, including its cardiovascular safety; (iii) rociletinib's commercial viability, including its commercial viability relative to Tagrisso; (iv) the strength of the empirical evidence supporting claims about rociletinib's efficacy; (v) the "durability" of reported responses; (vi) the confirmed character of the ORR results Defendants reported during the Class Period; (vii) the clinical and empirical meaningfulness of the ORR results reported during the Class Period; and (viii) the extent to which the ORR results reported during the Class Period reflected the ORR endpoint as defined in RECIST standards and incorporated into relevant Clovis clinical trial protocols, and the endpoint that the medical community and regulators would use to assess rociletinib's efficacy.

383. As a result of Defendants' materially false and misleading statements and omissions, and concealments of known material risks, Plaintiffs and other members of the Class purchased Clovis common stock and call options at artificially inflated prices and wrote put options at artificially deflated prices. Plaintiffs and other members of the Class were thus damaged when the truth concealed by Defendants' misstatements was revealed on November 16, 2015 and April 8, 2016 and the artificial inflation affecting Clovis' common stock price dissipated.

384. Two separate disclosures revealed to the market the false and misleading character of Defendants' statements and omissions, and the truth about rociletinib's commercial viability, its overall risk/benefit profile, and its ability to compete with Tagrisso.

385. First, as described above, on November 16, 2015, Clovis disclosed to investors that the efficacy results Defendants presented throughout the Class Period were "based primarily on unconfirmed responses," and that rociletinib's true ORR was approximately half the rate previously reported and significantly lower than the ORR Astra-Zeneca reported for Tagrisso. In response to these disclosures, Clovis common stock declined by 70%, falling from $99.43 per share to $30.24 per share, on heavy trading volume of over 30 million shares (compared to 824,233 shares average volume over the prior three months), and wiping out approximately $2.7 billion in shareholder value.

386. However, Clovis' November 16, 2015 disclosures did not reveal the whole truth to the marketplace about rociletinib's commercial viability and overall risk/benefit profile. While Clovis' disclosures made clear that rociletinib was less efficacious than Tagrisso, the Company did not disclose that rociletinib was also less safe than Tagrisso.

Indeed, even after Clovis' November 16, 2015 disclosures, the Company continued to make false and misleading statements that concealed the truth about rociletinib's safety profile from investors. As alleged above, analysts continued to believe that rociletinib would capture some market share as a second-line therapy for those patients who could not tolerate Tagrisso. Accordingly, even after Clovis' November 16, 2015 disclosures, Clovis stock remained artificially inflated.

387. Second, on April 8, 2016, as discussed above, the market learned that rociletinib's safety profile was far worse than previously reported, and substantially inferior to Tagrisso's. Following Defendants' April 8, 2016 disclosures, Clovis' stock fell by 17%, from $20.43 per share to $15.77 per share, on heavy trading volume of over 8 million shares.

388. The declines in Clovis' stock price on November 16, 2015 and April 8, 2016 were a direct and proximate result of Defendants' fraudulent conduct being revealed to investors and to the market. The timing and magnitude of Clovis' stock price declines negate any inference that the economic losses and damages suffered by Plaintiffs and the other members of the Class were caused by changed market conditions or macroeconomic factors.

389. It was entirely foreseeable that Defendants' materially false and misleading statements and omissions discussed herein would artificially inflate the price of Clovis common stock. It was also foreseeable to Defendants that the revelation of the truth about Defendants' inclusion of unconfirmed responses in reported rociletinib efficacy results, about the magnitude of rociletinib's true confirmed ORR rate, and about rociletinib's adverse safety profile would cause the price of the Company's common stock to drop as

the artificial inflation caused by Defendants' misstatements and omissions was removed. Thus, the stock price declines described above were directly and proximately caused by Defendants' materially false and misleading statements and omissions.

XI. PRESUMPTION OF RELIANCE

390. At all relevant times, the market for Clovis' common stock was efficient for the following reasons, among others:

(a) Clovis' common stock met the requirements for listing, and was listed and actively traded on Nasdaq, a highly efficient and automated market;

(b) Clovis common stock traded at high weekly volumes;

(c) As a regulated issuer, Clovis filed periodic reports with the SEC and Nasdaq;

(d) Clovis was eligible to file registration statements with the SEC on Form S-3;

(e) Clovis regularly communicated publicly with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(f) Clovis was followed by numerous securities analysts employed by major brokerage firms who wrote reports, which were distributed to those brokerage firms' sales force and certain customers. Each of these reports was publicly available and entered the public securities marketplace.

391. As a result of the foregoing, the market for Clovis common stock promptly digested current information regarding Clovis from all publicly available sources and reflected such information in Clovis' stock price. Under these circumstances, all purchasers of Clovis common stock and call options, and sellers of Clovis put options, during the Class Period suffered similar injury through their transactions in Clovis

securities at distorted prices reflecting Clovis' artificially inflated common stock price, and a presumption of reliance applies.

392. In addition, Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the claims asserted herein are predicated in part upon material omissions of fact that Defendants had a duty to disclose.

XII. INAPPLICABILITY OF THE STATUTORY SAFE-HARBOR

393. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward looking statements under certain circumstances do not apply to any of the false and misleading statements pleaded in this Complaint.

394. None of the statements complained of herein was a forward-looking statement. Rather, they were historical statements or statements of purportedly current facts and conditions at the time the statements were made, including statements about the ORR results of Clovis' clinical trials of rociletinib, how those results compared with clinical trial results reported by Clovis' competitors, Clovis' compliance with RECIST in reporting rociletinib efficacy data, and rociletinib's safety profile, among others.

395. To the extent that any of the false and misleading statements alleged herein can be construed as forward looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. As set forth above in detail, then existing facts contradicted Defendants' statements regarding rociletinib's efficacy results, how those results compared with clinical trial results reported by Clovis' competitors, Clovis' compliance with RECIST in reporting rociletinib efficacy data, and rociletinib's safety profile, among others. Given the then-existing facts contradicting Defendants' statements,

any generalized risk disclosures made by Clovis were not sufficient to insulate Defendants from liability for their materially false and misleading statements.

396. To the extent that the statutory safe harbor does apply to any forward looking statements pleaded herein, Defendants are liable for those false forward looking statements because at the time each of those statements was made, the particular speaker knew that the particular forward looking statement was false, and/or the false forward looking statement was authorized and/or approved by an executive officer of Clovis who knew that the statement was false when made.

XIII. CLASS ACTION ALLEGATIONS

397. Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) on behalf of a class consisting of all those who (i) purchased or otherwise acquired Clovis common stock or (ii) purchased or otherwise acquired call options or sold/wrote Clovis put options, between May 31, 2014 and April 7, 2016, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of Clovis 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.

398. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Clovis common shares were actively traded on the Nasdaq exchange. As of February 24, 2014, just before the start of the Class Period, Clovis had approximately 33,899,587 shares of common stock outstanding. Clovis issued more than four million additional shares as part of its July 2015 Offering. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of

members of the proposed Class. Class members may be identified from records maintained by Clovis or its transfer agent(s), and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

399. Plaintiffs' claims are typical of Class members' claims, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

400. Plaintiffs will fairly and adequately protect Class members' interests and have retained competent counsel experienced in class actions and securities litigation.

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

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about rociletinib clinical trial results and rociletinib's efficacy and safety;

(c) whether Defendants acted with scienter; and

(d) to what extent the members of the Class have suffered damages, as well as the proper measure of damages.

402. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable. Additionally, the damage suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation makes it impossible for such members to individually redress the wrong done to them. There will be no difficulty in the management of this action as a class action.

XIV. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5 PROMULGATED THEREUNDER (Against Defendant Clovis And The Executive Defendants)

403. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

404. This Count is asserted on behalf of all members of the Class against Defendants Clovis and the Executive Defendants (Mahaffy, Mast, Allen, and Ivers-Read) for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. These Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Clovis securities by disseminating materially untrue and misleading statements and/or concealing material adverse facts, which caused Plaintiffs and other members of the Class to purchase Clovis securities at artificially inflated prices.

405. Throughout the Class Period, Clovis and the Executive Defendants, individually and in concert, directly and indirectly, by the use of means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Plaintiffs and the Class; made various untrue and/or misleading 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.

406. These Defendants' materially false and misleading statements and omissions were made with scienter, made in connection with the purchase or sale of Clovis' securities, and were intended to and did, as alleged herein, (a) deceive the investing public,

including Plaintiffs and the other members of the Class; (b) artificially create, inflate, and maintain the market for and market price of the Company's securities; and (c) cause Plaintiffs and other members of the Class to purchase Clovis securities at artificially inflated prices.

407. Clovis and the Executive Defendants had a duty to promptly disseminate accurate and truthful information with respect to Clovis' business and its products and to correct any previously issued statements that had become materially misleading or untrue.

408. Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Clovis common stock and call options, and wrote put options at artificially deflated prices, which inflation/deflation was removed from the respective securities when the true facts became known. Plaintiffs and the Class would not have purchased Clovis securities at the prices they paid, or at all, if they had been aware that the market price of Clovis common stock had been artificially and falsely inflated by these Defendants' false and misleading statements.

COUNT II

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT (Against The Executive Defendants)

409. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

410. This Count is asserted on behalf of all members of the Class against each of the Executive Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

411. During their tenures as officers and/or directors of Clovis, each of the Executive Defendants was a controlling person of the Company within the meaning of Section 20(a) of the Exchange Act. By reason of their positions of control and authority as officers and/or directors of Clovis, these Defendants had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. These Defendants were able to and did control, directly and indirectly, the content of the public statements made by Clovis during the Class Period, thereby causing the dissemination of the false and misleading statements and omissions of material facts as alleged herein.

412. As more fully described above, in their capacities as senior corporate officers of the Company, the Executive Defendants had direct involvement in the day-to-day operations of the Company, in reviewing and managing the Company's regulatory and legal compliance, and in its public reporting of rociletinib clinical trial data, including drafting, reviewing, and approving statements concerning those data. The Executive Defendants made numerous false and misleading statements on Clovis' behalf at investor conferences, in press releases, on earnings calls, and in medical journals.

413. Defendants Mahaffy and Mast signed the Company's SEC filings during the Class Period. Defendant Allen, as Clovis' CMO, was directly involved in providing false and misleading clinical trial data to, and approving the false statements disseminated by, Clovis during the Class Period. Each of the Executive Defendants owned Clovis stock during the Class Period, and Defendant Mahaffy was a member of the Company's board of directors. As a result of the foregoing, the Executive Defendants, as a group and

individually, were controlling persons of Clovis within the meaning of Section 20(a) of the Exchange Act.

414. As set forth above, Clovis violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Clovis and as a result of their own aforementioned conduct, the Executive Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Plaintiffs and the other members of the Class who purchased or otherwise acquired Clovis securities. Moreover, as detailed above, during the respective times these Defendants served as officers and/or directors of Clovis, each of these Defendants was culpable for the material misstatements and omissions made by Clovis, including misstatements concerning the ORR results of Clovis' clinical trials of rociletinib, how those results compared with clinical trial results reported by Clovis' competitors, Clovis' compliance with RECIST in reporting rociletinib efficacy data, and rociletinib's safety profile, among others, as set forth above.

415. As a direct and proximate result of these Defendants' conduct, Plaintiffs and the other members of the Class suffered damages in connection with their transactions in Clovis securities.

XV. SECURITIES ACT ALLEGATIONS

416. In Counts Four through Five below (the "Securities Act Claims"), Plaintiffs assert strict liability and negligence claims based on Sections 11, 12(a)(2), and 15 of the Securities Act. Plaintiffs incorporate the above paragraphs by reference, but expressly disclaim any allegations of scienter or fraud for these Securities Act claims, except that any

challenged statements of opinion or belief are alleged to have been materially misstated statements of opinion or belief.

417. The Securities Act Claims arise out of Clovis' $298.4 million secondary public offering of approximately 4.1 million shares of Clovis common stock conducted on or about July 14, 2015 (defined above as "the July 2015 Offering"). The July 2015 Offering was conducted pursuant to a June 11, 2013 shelf registration statement filed with the SEC on Form S-3, and incorporated a prospectus and prospectus supplement filed with the SEC on July 9, 2015; Clovis' 2014 Annual Report on Form 10-K filed with the SEC on February 27, 2015; the Company's first quarter 2015 Form 10-Q filed with the SEC on May 8, 2015; Clovis' Definitive Proxy Statement on Schedule 14A and additional proxy soliciting materials, filed with the SEC on April 30, 2015; the Company's Forms 8-K filed on June 15 and June 22, 2015 (collectively, "the Registration Statement").

418. Clovis' prospectus supplement filed July 9, 2015 provides that common stock would be offered at $78.00 per share in the July 2015 Offering. Clovis' prospectus for the July 2015 Offering also makes clear the Offering was a firm commitment offering, pursuant to which Clovis "agreed to sell to the underwriters, and each underwriter has severally agreed to purchase" Clovis stock at the offering price, less underwriting discounts and underwriting commissions.

419. This action was brought within one year after the discovery of the untrue statements and omissions (and within one year after such discovery should have been made in the exercise of reasonable diligence) and within three years of the July 2015 Offering.

A. The Securities Act Plaintiff

420. Named Plaintiff the City of St. Petersburg Employees' Retirement System ("St. Petersburg" or "Named Plaintiff") is a public retirement system that provides defined

benefit pension payments to the retired public employees of St. Petersburg, Florida. As set forth in the certification attached as Exhibit A to this Complaint and St. Petersburgh's trading records attached as Exhibit B, St. Petersburg purchased Clovis common stock during the Class Period, including Clovis shares in, and traceable to, the Company's July 2015 Offering, and suffered damages as a result of the violations of federal securities laws alleged herein.

421. Specifically, as detailed in Exhibits A and B, St. Petersburgh entered a purchase order for 956 shares of Clovis common stock directly from lead underwriter JPM on July 9, 2015 (the date the prospectus for the July 2015 Offering was filed), which settled on July 14, 2015 (the exact date of the July 2015 Offering). St. Petersburgh purchased these shares for $78.00 per share – the ***exact*** offering price for the July 2015 Offering. St. Petersburgh paid no commission on its purchases, which would have been impossible if the purchases had been made in the aftermarket.

B. The Securities Act Defendants

1. Defendant Clovis

422. Defendant Clovis is a biopharmaceutical company headquartered in Boulder, Colorado. The Company was founded in 2009 and has been publicly traded since November 2011. Clovis' business focuses on acquiring, developing, and commercializing oncology products worldwide. During the Class Period, the Company marketed no drug products, but had three drugs in development: rociletinib, rucaparib, and lucitanib. Clovis stock trades on the Nasdaq under the symbol CLVS.

2. The Executive Defendants

423. Defendant Patrick Mahaffy is a co-founder of Clovis and has served as its CEO and Chairman of its board of directors since the Company's inception in 2009.

424. Defendant Erle T. Mast is a co-founder of Clovis and served as its Executive Vice President and CFO since the Company's inception in 2009 until his resignation on March 31, 2016.

425. Defendant Andrew Allen is a co-founder of Clovis and served as the Company's CMO and Executive Vice President for Clinical and Pre-clinical Development and Pharmacovigilance from the Company's inception in 2009 until his resignation on June 22, 2015.

426. Defendant Gillian Ivers-Read is a co-founder of Clovis and has served as its CRO and Executive Vice President for Technical Operations since the Company's inception in 2009.

427. Defendants Mahaffy, Mast, Allen, and Ivers-Read are collectively referred to herein as the "Executive Defendants."

3. The Underwriter Defendants

428. Defendant J.P. Morgan Securities LLC ("JPM") was lead underwriter of Clovis' July 2015 Offering, and, not including its overallotment, sold and distributed 50% of the common stock offered (1,762,821 shares), worth over $137.5 million, earning a commission of more than $7.5 million.

429. Defendant Credit Suisse Securities (USA) LLC ("Credit Suisse") was an underwriter of Clovis' July 2015 Offering, and, not including its overallotment, sold and distributed 30% of the common stock offered (1,057,692 shares), worth approximately $82.5 million, earning a commission of more than $4.5 million.

430. Defendant Stifel, Nicolaus & Company, Incorporated ("Stifel") was an underwriter of Clovis' July 2015 Offering, and, not including its overallotment, sold and

distributed 10% of the common stock offered (352,564 shares), worth approximately $27.5 million, earning a commission of more than $1.5 million.

431. Defendant Mizuho Securities USA Inc. ("Mizuho") was an underwriter of Clovis' July 2015 Offering, and, not including its overallotment, sold and distributed 10% of the common stock offered (352,564 shares), worth approximately $27.5 million, earning a commission of more than $1.5 million.

432. Defendants JPM, Credit Suisse, Stifel, and Mizuho are collectively referred to herein as the "Underwriter Defendants."

4. The Venture Capital Defendants

433. Defendants NEA Partners, 13 L.P., NEA 13 GP, LTD, Scott D. Sandell and Forest Baskett (the "NEA Defendants") along with Clovis Director M. James Barrett, are a part of New Enterprise Associates, a venture capital firm that beneficially owned 6.7% of Clovis' shares at the time the company conducted its July 2015 Offering. At the time of that offering, an affiliated partnership, New Enterprise Associates 13, L.P. held the Clovis shares beneficially owned by New Enterprise Associates. NEA Partners, 13 L.P. was the sole general partner of New Enterprise Associates 13, L.P.; NEA 13 GP, LTD was the sole general partner of NEA Partners, 13 L.P. Sandell and Baskett, along with Barrett, are members of NEA 13 GP, LTD.

434. At the time of the July 2015 Offering, the NEA Defendants and Barrett held all dispositive and voting power with respect to all Clovis shares held by New Enterprise Associates 13, L.P. By virtue of their significant stake in Clovis, their voting power qua shareholder, and their representation, through Barrett, on Clovis' board of directors, the NEA Defendants had the power to control, and did control, Clovis in its conduct of the July 2015 Offering.

435. Defendant Aberdare Ventures IV, L.P. ("Aberdare") is a venture capital firm that beneficially owned 2.5% of Clovis' shares at the time the company conducted its July 2015 Offering. Clovis Director Paul Klingenstein founded Aberdare, and at the time of Clovis' July 2015 Offering, was (and still is) its managing director, as well as managing director of Aberdare GP IV, LLC, the sole general partner of Aberdare (a position he likewise still holds). At the time of the July 2015 Offering, Aberdare and Klingenstein held all dispositive and voting power with respect to all Clovis shares held by Aberdare. By virtue of its significant stake in Clovis, its voting power qua shareholder, its representation, through Klingenstein, on Clovis' board of directors, and as a party to a 2009 investor rights agreement with Clovis, entitling Aberdare to, among other things, registration right and access to Company information, Aberdare had the power to control, and did control, Clovis in its conduct of the July 2015 Offering.

436. NEA Defendants and Aberdare are collectively referred to herein as the "Venture Capital Defendants." As alleged below, the Complaint asserts only control person claims under Section 15 of the Securities Act against the Venture Capital Defendants.

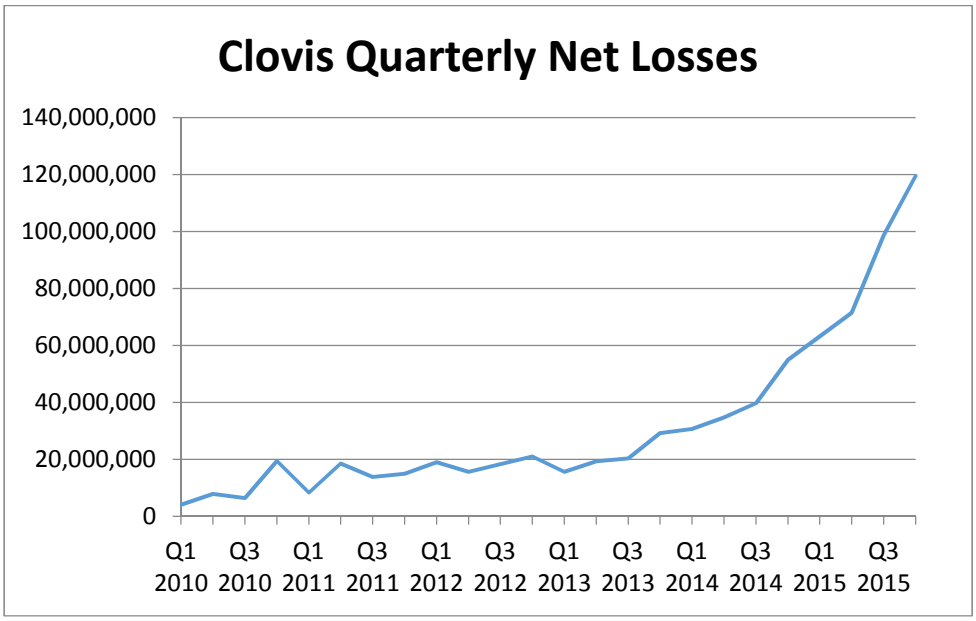
C. Background To The Securities Act Claims

437. The following facts summarize and supplement those alleged above.

438. As alleged above, on or about July 14, 2015, Clovis raised nearly $300 million through its July 2015 Offering of 4.1 million shares of Clovis common stock.

439. The July 2015 Offering came at a critical time for Clovis. As a result of Clovis' dramatic expansion of its development programs in late 2014 and early 2015, by mid-2015, Clovis' operating costs had increased significantly and the Company was again in need of an infusion of investor capital to stay afloat.

440. As Defendants began to realize (but concealed) that rociletinib was performing poorly in its clinical trials, they caused Clovis to accelerate the development program for rucaparib. The ramp-up in the development program for rucaparib had a significant negative impact on Clovis' cash position, as shown in the chart below. Indeed, Clovis had a $55 million net loss in the fourth quarter of 2014, up from $29 million in the same quarter the prior year. Clovis' losses continued to balloon over the next two quarters: $63 million and $72 million, respectively. With the rociletinib NDA filing around the corner and the drug's disastrous confirmed ORR results and safety problems likely to become public in the months thereafter, Defendants knew that the July 2015 Offering was one of the last chances Clovis would have to raise on favorable terms the capital needed to bring rucaparib through development.



441. Thanks to Clovis' false and misleading statements about rociletinib's efficacy and safety, the July 2015 Offering was highly successful, with the offering's underwriters fully exercising their overallotment option. As discussed above, the offering

provided Clovis with the capital it needed to fully finance the development of rucaparib, at least through the anticipated filing of the drug's NDA in mid-2016. Again, as Mahaffy told investors on August 6, 2015, "Importantly, with the $298 million equity offering we completed in July, we're well-capitalized to pursue our development and commercial objectives."

442. Defendants JPM, Credit Suisse, Stifel, and Mizuho acted as the underwriters of the July 2015 Offering by selling and distributing the Clovis common stock offered to the investing public. They were obligated under federal securities laws to conduct a reasonable investigation into the truthfulness and accuracy of the various statements contained in or incorporated by reference into the Registration Statement. Any reasonable investigation would have entailed a review of the efficacy and safety data concerning rociletinib, Clovis' most critical pipeline drug and a drug that was the focus of enormous investor attention and concern at the time of the July 2015 Offering. Such a review, in turn, would have revealed that the Registration Statement contained false and misleading statements, as alleged below. None of the Underwriter Defendants made a reasonable investigation into the truthfulness and accuracy of the Registration Statement.

1. False Statements In The Prospectus Supplement

443. The Registration Statement reiterated the false and misleading ORR results Defendants had presented at the May 31, 2015 ASCO conference. Specifically, under the heading "Evidence of Activity," the Registration Statement claimed data from the "TIGER-X Phase 2 clinical trial of rociletinib" showed the drug was associated with "60 percent ORR" among T790M-positive patients taking the "recommended dose of 500mg." The Registration Statement further claimed that "across all doses, a 53 percent ORR" was "observed" in those data.

444. The Registration Statement additionally claimed that the "[c]linical benefit" observed in these data was "durable."

445. Finally, the Registration Statement claimed that "[r]ociletinib activity was also observed in 35 evaluable T790M-negative patients treated at all doses." Specifically, the Registration Statement claimed "[a] 37 percent ORR was observed with a range of 32 to 39 percent across doses studied. Eighty-six percent of these patients were treated with rociletinib directly after TKI therapy, so a TKI re-treatment effect is unlikely to be the driver of this activity."

446. These statements were materially false and misleading and omitted material information at the time of the Offering. It was materially false and misleading for the Registration Statement to state that Clovis had observed a "60 percent ORR" among T790M-positive patients taking the "recommended dose of 500mg," and that "across all doses, a 53 percent ORR" was "observed," while failing to disclose that the ORRs reported included mostly unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that rociletinib's confirmed ORR in those data was significantly lower than the confirmed ORR Astra-Zeneca reported for Tagrisso.

447. Indeed, there is less than a 5% chance that rociletinib's confirmed ORR in T790M-positive patients taking either the recommended 500mg or 625mg dose exceeded 36%. Accordingly, the illegitimate and unconfirmed ORRs Defendants reported likely overstated rociletinib's true ORR by at least 56%, while the confirmed ORR Astra-Zeneca

reported for Tagrisso was likely at least 50% higher than rociletinib's unreported confirmed ORR.

448. Likewise, it was materially misleading for the Registration Statement to state that "rociletinib activity was also observed" in T790M-negative patients, specifically a "37 percent ORR was observed with a range of 32 to 39 percent across doses studied," while failing to disclose that the ORR reported included mostly unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that Clovis' reported results overstated the magnitude and clinical meaningfulness of the difference in efficacy between rociletinib and Tagrisso in those patients.

449. Indeed, as of November 16, 2015 only 7 T790M-negative patients taking 625mg of rociletinib had confirmed responses. Yet, months earlier, in the Registration Statement, Defendants claimed that 9 such patients were "responsive." Accordingly, Defendants improperly included unconfirmed responses in the ORR results presented in T790M-negative patients during the Class Period. Moreover, there is no more than a 9% chance Clovis had observed even 7 confirmed responses among T790M-negative patients in the 625mg dose group in these data.

450. Further, it was materially false and misleading for the Registration Statement to claim that the "[c]linical benefit" observed in these data was "durable," when, the responses reported were unconfirmed and, therefore could not support claims of "durability," and, moreover, by July 14, 2015, Clovis' data showed that most of the

reported responses failed to be confirmed and were therefore affirmatively ***not*** "durable."[7] It was also materially false and misleading for the Registration Statement to claim that "a TKI re-treatment effect is unlikely to be the driver of" rociletinib's purported "activity" in T790M-negative patients (and suggesting that the driver of the observed ORR is rociletinib's efficacy in such patients) without disclosing that the reported ORR was, in fact, driven by Clovis' inclusion of unconfirmed responses in the result.

451. The Registration Statement also made false and misleading claims about rociletinib's safety profile. Specifically, the Registration Statement stated,

> The data presented at ASCO continue to demonstrate rociletinib is well tolerated. In the 500mg dose group, the most common treatment-related adverse events, or AEs, reported in greater than 10 percent of all patients included hyperglycemia, diarrhea and nausea. Across all doses, most AEs were grade 1 or 2 in severity. The only common grade 3 treatment-related AE was hyperglycemia, which was observed in 17 percent of patients treated with rociletinib 500mg (20/119), 24 percent of patients treated with the 625mg dose (56/236), 36 percent of patients treated with the 750mg dose (34/95) and 33 percent of patients treated with the 1000mg dose (2/6).

452. These statements were materially false and misleading and omitted material information at the time of the Offering. It was materially misleading for the Registration Statement to claim that the data Clovis presented at the 2015 ASCO conference "demonstrate rociletinib is well tolerated," while failing to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso; that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required, and

[7] Because all the responses reported at the 2015 ASCO conference were observed on or before April 27, 2015, Clovis would have confirmed or disconfirmed them no later than June 15, 2015.

prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib; and that adverse side effects were causing patients to interrupt, modify, or discontinue therapy at an alarming rate.

453. Moreover, it was materially misleading for the Registration Statement to claim that the "only common [i.e., an incidence of 10% or more] grade 3 treatment-related [adverse event] was hyperglycemia," when 12% of rociletinib patients experienced grade 3 or 4 QT prolongation and 13% of rociletinib patients experienced a QT interval greater than 500 ms (compared with 0.2% of Tagrisso patients).

2. False Statements In Clovis' 2014 Form 10-K

454. The Registration Statement also incorporated Clovis' 2014 Form 10-K, filed with SEC on February 27, 2015. In that Form 10-K, Clovis reiterated the materially false and misleading efficacy results Defendants had presented at the 2014 ENA medical conference. Specifically, in that Form 10-K, Clovis stated, "Data presented at a medical conference in late 2014 demonstrated an objective response rate ('ORR') of 67% [for rociletinib] in 27 evaluable T790M-positive patients receiving either 625mg or 500mg BID. The ORR was comparable in the 625mg BID and 500mg BID dose groups."

455. These statements were materially false and misleading and omitted material information at the time of the Offering. It was materially misleading for the Registration Statement to claim that Clovis had observed the ORR results described above while failing to disclose that those reported results included mostly unconfirmed responses; that the endpoint reported would not be used by the medical or regulatory communities to assess the efficacy of rociletinib; that rociletinib's confirmed ORR in those data was significantly lower than the unconfirmed rate Defendants touted; and that rociletinib's confirmed ORR

in those data were significantly lower than the confirmed ORR Astra-Zeneca reported for Tagrisso. Indeed, there is less than a 5% chance that the unreported confirmed ORR in the key 500mg and 625mg dose groups exceeded 48%. Accordingly, the illegitimate and unconfirmed 67% ORR Defendants reported likely overstated rociletinib's true ORR by at least 40%, while the 61% confirmed ORR Astra-Zeneca had most recently reported for Tagrisso at the 2014 ESMO conference was likely at least 27% higher than rociletinib's unreported confirmed ORR.

456. Clovis' 2014 Form 10-K, which was incorporated into the Registration Statement by reference, also made false and misleading claims about rociletinib's safety profile. Specifically, the Form 10-K stated, "Safety data presented to date demonstrate that rociletinib is well-tolerated . . . . Most adverse events were grade 1 or 2 in severity; the only grade 3/4 treatment-related adverse event observed in more than one patient was hyperglycemia (14 percent)."

457. These statements were materially false and misleading and omitted material information at the time of the July 2015 Offering. It was materially misleading for the Registration Statement to claim that the data Clovis presented at the 2015 ASCO conference "demonstrate rociletinib is well tolerated," while failing to disclose that Clovis' rociletinib safety data showed the drug significantly increased the risk of "serious or life threatening" adverse cardiovascular events – specifically, QT prolongation – more than any other competing therapy and far more than Tagrisso; that rociletinib's propensity to increase cardiovascular risk was so significant that a "Boxed Warning" was required, and prescribing physicians would need to implement an extensive "risk mitigation" plan in order to safeguard patients to whom they administered rociletinib; and that adverse side

effects were causing patients to interrupt, modify, or discontinue therapy at an alarming rate. Moreover, it was materially misleading for the Registration Statement to claim that "the only grade 3/4 treatment-related adverse event observed in more than one patient was hyperglycemia (14 percent)" when 12% of rociletinib patients experienced grade 3 or 4 QT prolongation and 13% of rociletinib patients experienced a QT interval greater than 500 ms (compared with 0.2% of Tagrisso patients).

XVI. CLAIMS FOR RELIEF UNDER THE SECURITIES ACT

COUNT III

FOR VIOLATIONS OF SECTION 11 OF THE SECURITIES ACT (Against Clovis, Mahaffy, Mast, And The Underwriter Defendants)

458. This Count is based on Defendants' statutory liability for false and materially misleading statements or omissions in the Registration Statement. This Count does not sound in fraud, and any allegations of knowing or reckless misrepresentations and/or omissions in the Registration Statement are excluded from this Count, except that any challenged statements of opinion or belief are alleged to have been materially misstated statements of opinion or belief.

459. This Count is asserted by Named Plaintiff St. Petersburg against Clovis, Mahaffy (who signed the Registration Statement), Mast (who signed the Registration Statement), and the Underwriter Defendant for violations of Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of all persons who acquired shares of Clovis common stock pursuant to the Registration Statement.

460. As alleged above, the Registration Statement contained untrue statements and omissions of material fact concerning, among other things, the efficacy results observed in clinical trials of rociletinib and rociletinib's safety profile.

461. As the issuer of the registered securities, Clovis is strictly liable for the untrue statements of material fact and material omissions described herein.

462. None of the other Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were accurate and complete in all material respects. Had they exercised reasonable care, they would have known of the material misstatements and omissions alleged herein.

463. Class members did not know, nor in the exercise of reasonable diligence could they have known, that the Registration Statement contained untrue statements of material fact and omitted to state material facts required to be stated or necessary to make the statements identified above not misleading when they purchased or acquired the registered securities. As a direct and proximate result of the acts and omissions of the Defendants named in this Count in violation of the Securities Act, the Class suffered substantial damage in connection with its purchase of Clovis common stock sold through the Offering.

464. This claim is brought within one year of discovery of the untrue statements and omissions in the Registration Statement and within three years of its effective date.

465. By reason of the foregoing, the Defendants named in this Count are liable under Section 11 of the Securities Act to members of the Class who purchased or otherwise acquired the securities sold pursuant and/or traceable to the Registration Statement.

COUNT IV

FOR VIOLATIONS OF SECTION 12(a)(2) OF THE SECURITIES ACT (Against Clovis And The Underwriter Defendants)

466. Plaintiffs reallege every allegation contained above as if fully set forth herein, only to the extent, however, that such allegations do not allege fraud, scienter or the intent of the defendants to defraud Plaintiffs or members of the Class.

467. This Count is based on Defendants' statutory liability for false and materially misleading statements or omissions in the Registration Statement. This Count does not sound in fraud, and any allegations of knowing or reckless misrepresentations and/or omissions in the Registration Statement are excluded from this Count, except that any challenged statements of opinion or belief are alleged to have been materially misstated statements of opinion or belief.

468. This Count is asserted by Named Plaintiff St. Petersburg against Clovis and the Underwriter Defendants for violations of Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77l(a)(2), on behalf of all persons who acquired shares of Clovis common stock pursuant to the Registration Statement.

469. Clovis and the Underwriter Defendants were sellers, offerors, and/or solicitors of purchasers of the shares offered pursuant to the Registration Statement.

470. As alleged above, the Registration Statement contained untrue statements and omissions of material fact concerning, inter alia, the efficacy results observed in clinical trials of rociletinib and rociletinib's safety profile.

471. By means of the Registration Statement (as well as instruments of transportation and communication in interstate commerce and the mails), Defendants named in this Count, through the July 2015 Offering, which was a public offering, solicited and sold Clovis common stock to members of the Class.

472. As the issuer of the registered securities, Clovis is strictly liable for the untrue statements of material fact and material omissions described herein.

473. None of the Underwriter Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were accurate and complete in all material respects. Had they exercised reasonable care, these Defendants would have known of the material misstatements and omissions alleged herein.

474. Class Members purchased Clovis stock pursuant to the materially untrue or misleading Registration Statement. Class members did not know, nor in the exercise of reasonable diligence could they have known, that the Registration Statement contained untrue statements of material fact and omitted to state material facts required to be stated or necessary to make the statements identified above not misleading when they purchased such securities.

475. This action is brought within one year of the date when Plaintiffs discovered or reasonably could have discovered the facts upon which this Count is based, and within three years of the date that the securities upon which this Count is brought were sold to the public.

476. By reason of the foregoing, Clovis and the Underwriter Defendants are liable for violations of §12(a)(2) of the Securities Act to Class members who purchased securities sold pursuant to the Registration Statement. Such Class members also have the right to rescind and recover the consideration paid for such securities upon tender of their stock to Clovis and the Underwriter Defendants, and to recover rescissory damages to the extent they have already sold such securities.

COUNT V

FOR VIOLATIONS OF SECTION 15 OF THE SECURITIES ACT (Against Mahaffy, Mast, And The Venture Capital Defendants)

477. Plaintiffs reallege every allegation contained above as if fully set forth herein, only to the extent, however, that such allegations do not allege fraud, scienter or the intent of the defendants to defraud Plaintiffs or members of the Class. This Claim does not sound in fraud, and any allegations of knowing or reckless misrepresentations and/or omissions in the Registration Statement are specifically excluded from this Count, except that any challenged statements of opinion or belief made in connection with the July 2015 Offering is alleged to have been a materially misstated statement of opinion or belief when made and at the time of the Offering.

478. This Count is asserted by Named Plaintiff St. Petersburg against Defendants Mahaffy and Mast, and the Venture Capital Defendants for violations of Section 15 of the Securities Act, 15 U.S.C. § 77o, on behalf of all persons who acquired shares of Clovis common stock pursuant to the Registration Statement.

479. As set forth in Counts Four and Five above, Clovis is strictly liable under §§ 11 and 12(a)(2) for untrue statements and omissions of material fact in the Registration Statement.

480. Defendants Mahaffy, Mast, and the Venture Capital Defendants, by virtue of their positions, voting power, ownership, rights as against Clovis, and/or specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Clovis within the meaning of § 15 of the Securities Act. These Defendants also had the power and influence, and exercised the same, to cause Clovis to engage in the acts

described herein, including by causing Clovis to conduct the July 2015 Offering pursuant to the Registration Statement.

481. Specifically, with respect to the Venture Capital Defendants, the NEA Defendants held all dispositive and voting power with respect to 6.7% of Clovis' shares at the time the company conducted the July 2015 Offering. By virtue of their significant stake in Clovis, their voting power qua shareholder, and their representation, through Barrett, on Clovis' board of directors, the NEA Defendants had the power to control, and did control, Clovis in its conduct of the July 2015 Offering.

482. Likewise Aberdare exercised all dispositive and voting power with respect to 2.5% of Clovis' shares at the time the company conducted the July 2015 Offering. By virtue of its significant stake in Clovis, its voting power qua shareholder, its representation, through Klingenstein, on Clovis' board of directors, and as a party to a 2009 investor rights agreement with Clovis, entitling Aberdare to, among other things, registration right and access to Company information, Aberdare had the power to control, and did control, Clovis in its conduct of the July 2015 Offering.

483. By virtue of the conduct alleged herein, Defendants Mahaffy and Mast, and the Venture Capital Defendants are liable for the aforesaid wrongful conduct and are liable, to the same extent that Clovis is liable under Sections 11 and 12(a)(2) of the Securities Act, to members of the Class who purchased Clovis common stock pursuant and/or traceable to the Registration Statement.

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages and equitable relief in favor of Plaintiffs and the other Class members against all Defendants,

jointly and severally, for all damages sustained as a result of Defendants' wrongful conduct, in an amount to be proven at trial, including interest thereon;

(c) As to the Claims alleged under the Securities Act, awarding rescission or a recessionary measure of damages as appropriate;

(d) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(e) Such other and further relief as the Court may deem just and proper.

XVII. JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury in this action of all issues so triable.

BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP

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Local Counsel for Lead Plaintiff M.Arkin (1999) LTD and Arkin Communications LTD

EXHIBIT A

AMENDED CERTIFICATION AND AUTHORIZATION OF LEAD PLAINTIFF

I, Tammy Jerome, on behalf of Employees' Retirement System of the City of St. Petersburg, Florida ("St. Petersburg Employees"), hereby certify, as to the claims asserted under the federal securities laws, that:

1. I am authorized in my capacity as Chairperson of St. Petersburg Employees to execute this Certification on behalf of St. Petersburg Employees.

2. St. Petersburg Employees did not purchase the securities that are the subject of this action at the direction of counsel, or in order to participate in any action arising under the federal securities laws.

3. St. Petersburg Employees is willing to serve as a representative party on behalf of the Class, including providing testimony at deposition and trial, if necessary.

4. St. Petersburg Employees' transactions in Clovis Oncology, Inc. common stock are set forth in the Schedule A attached hereto.

5. St. Petersburg Employees has sought to serve and was appointed as lead plaintiff and representative party on behalf of a class in the following actions under the federal securities laws filed during the three-year period preceding the date of this Certification: *None*

6. St. Petersburg Employees has sought to serve as a lead plaintiff and representative party on behalf of a class in the following actions under the federal securities laws filed during the three-year period preceding the date of this Certification, but either withdrew its motion for lead plaintiff, was not appointed lead plaintiff or the lead plaintiff decision is still pending: *None*

7. St. Petersburg Employees will not accept any payment for serving as a representative party on behalf of the Class beyond St. Petersburg Employees' pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the Class, as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct.
Executed this 29 day of April 2016.

Employees' Retirement System of
the City of St. Petersburg, Florida

Tammy Jerome

Tammy Jerome, Chairperson

SCHEDULE A

Employees' Retirement System of the City of St. Petersburg, Florida

Transactions in Clovis Oncology, Inc.

Class Period: May 31, 2014 through April 8, 2016

Beg. Hold. 0

Common Stock Purchases		
Date	**Shares**	**Price**
07/09/15	956	$78.00
07/09/15	126	$78.80
07/09/15	88	$78.85
07/20/15	90	$86.12
08/25/15	77	$69.45
08/26/15	216	$68.95
08/27/15	187	$75.00
08/31/15	20	$78.43
08/31/15	230	$78.26
09/30/15	90	$91.97

Common Stock Sales		
Date	**Shares**	**Price**
11/16/15	1,020	$29.13
11/16/15	1,060	$30.29

EXHIBIT B

WELLS FARGO

SCHEDULE OF SECURITY ACQUISITIONS
FOR THE PERIOD JULY 1, 2015 THROUGH JULY 31, 2015

ST PETE ERS/WEL
ACCOUNT NUMBER [redacted]2409

DATE	PAR VALUE/SHARES	DESCRIPTION	BROKER COMMISSION	CASH	COST VALUE
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
		CLOVIS ONCOLOGY INC CUSIP 189464100			
7/09/15	956.000	PURCHASED 956 SHARES/UNITS AT $78.00 ON TRADE DATE 7/09/15 TO SETTLE 7/14/15 JP MORGAN SECURITIES, INC COMMISSION $0.00 956 SHARES AT 78.00 USD	0.00	74,568.00-	74,568.00

CERTIFICATE OF SERVICE

I, Abraham Alexander, an attorney, hereby certify that on February 22, 2017, I caused a true and correct copy of the foregoing AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS AND JURY TRIAL DEMAND to be filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

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

Dated: February 22, 2017

s/ Abe Alexander
Abe Alexander