IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Raymond P. Moore

Civil Action No. 15-02546-RM-MEH
Consolidated with Civil Action Nos. 15-02547-RM-MEH,
15-02697-RM-MEH, 16-00459-RM-MEH

SONNY P. MEDINA, *et al.*,

Plaintiffs,

v.

CLOVIS ONCOLOGY, INC., *et al.*,

Defendants.

OPINION AND ORDER

On November 19, 2015, plaintiff Sonny P. Medina ("Medina") filed a Class Action Complaint ("the initial complaint") against defendants Clovis Oncology, Inc. ("Clovis") and Patrick J. Mahaffy ("Mahaffy"), alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) & 78t(a), and Rule 10b-5 promulgated by the Securities and Exchange Commission, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"). (ECF No. 1.) Soon thereafter, two other cases were filed against Clovis and Mahaffy, as well as Erle T. Mast ("Mast"), in this District, and one further case was filed in the Northern District of California against the same three defendants.

On February 18, 2016, this Court consolidated the instant case with the two other cases filed in this District, and appointed M.Arkin (1999) LTD and Arkin Communications LTD (collectively, "plaintiffs") as lead plaintiffs, pursuant to 15 U.S.C. § 78u-4(a)(3). (ECF No. 43.) On May 23, 2016, after the case filed in the Northern District of California was transferred to this District, the Court consolidated that action with the instant one. (ECF No. 77.) Following the entry of an Order setting a pre-discovery schedule (ECF No. 58), the stage was set for the filing of plaintiffs' consolidated class action complaint.

On May 6, 2016, plaintiffs, now joined by the City of St. Petersburg Employees' Retirement System ("St. Petersburg") as a "named plaintiff," filed a Consolidated Class Action Complaint for Violations of the Federal Securities Laws ("the Consolidated Complaint"), asserting claims of (1) fraud under the Exchange Act against Clovis, Mahaffy, Mast, Andrew Allen ("Allen"), and Gillian Ivers-Read ("Ivers-Read") (collectively, Mahaffy, Mast, Allen, and Ivers-Read, the "Executive Defendants"), and (2) strict liability and negligence under the Securities Act of 1933, 15 U.S.C. §§ 77a *et seq.,* ("the Securities Act") against Clovis, the Executive Defendants, J.P. Morgan Securities LLC ("JPM"), Credit Suisse Securities (USA) LLC ("Credit Suisse"), Stifel, Nicolaus & Company, Incorporated ("SNC"), Mizuho Securities USA Inc. ("Mizuho") (collectively, JPM, Credit Suisse, SNC, and Mizuho, the "Underwriter Defendants"), NEA Partners, 13 L.P., NEA 13 GP, LTD, Scott D. Sandell ("Sandell"), Forest Baskett ("Baskett") (collectively, NEA Partners, 13 L.P.; NEA 13 GP, LTD; Sandell; and Baskett, the "NEA Defendants"), and Aberdare Ventures IV, L.P.

("Aberdare") (collectively, the NEA Defendants and Aberdare, the "Venture Capital Defendants"). (ECF No. 65.)[1]

On July 27, 2016, three motions to dismiss the Consolidated Complaint were filed. (ECF Nos. 98, 103, 105.) The motions to dismiss were filed by (1) Clovis and the Executive Defendants (collectively, the "Clovis Defendants") (ECF No. 105), (2) the Venture Capital Defendants (ECF No. 98), and (3) the Underwriter Defendants (ECF No. 103). On the same day, the Clovis Defendants also filed a Motion Requesting Judicial Notice ("the motion for judicial notice"). (ECF No. 104.) The Clovis Defendants, the Venture Capital Defendants, and the Underwriter Defendants move for dismissal pursuant to Fed.R.Civ.P. 8, 9(b), and/or 12(b)(6) ("Rule 8," "Rule 9(b)," and "Rule 12(b)(6)").

On September 23, 2016, plaintiffs filed a global response in opposition to each of the motions to dismiss (ECF Nos. 120, 121),[2] and a response to the motion for judicial notice (ECF No. 119), in which plaintiffs too requested judicial notice be taken of certain documents. On October 11, 2016, the Clovis Defendants filed a reply in support of the motion for judicial notice. (ECF No. 122.) Three days later, briefing ended when the Clovis Defendants, the Venture Capital Defendants, and the Underwriter Defendants, respectively, each filed replies in support of their motions to dismiss. (ECF Nos. 123-125.)

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[1] Unless otherwise noted, in this Opinion, the Court uses the page number assigned by the CM/ECF system in the top right-hand corner of the relevant pleading, rather than any other page number that may appear elsewhere in said pleading.

[2] For some reason, plaintiffs filed two responses to the three motions to dismiss. (ECF Nos. 120, 121.) Although the second filed response indicates that it is "Corrected," given that the page lengths of the two responses are identical and the Court has not been made aware of the correction(s) that occurred in the second filed response, the Court does not know what correction(s) occurred. In any event, the Court will use the second filed response as the operative document.

I. Pleading Standards

A. Rule 12(b)(6)

In evaluating a motion to dismiss under Rule 12(b)(6), a court must accept as true all well-pleaded factual allegations in the complaint, view those allegations in the light most favorable to the non-moving party, and draw all reasonable inferences in the plaintiff's favor. *Brokers' Choice of America, Inc. v. NBC Universal, Inc.*, 757 F.3d 1125, 1135-36 (10th Cir. 2014); *Mink v. Knox*, 613 F.3d 995, 1000 (10th Cir. 2010). In the complaint, the plaintiff must allege a "plausible" entitlement to relief. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-556, 127 S.Ct. 1955 (2007). "Asking for plausible grounds … does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [prohibited conduct]." *Id*. at 556. Conclusory allegations, however, are insufficient. *Cory v. Allstate Ins.*, 583 F.3d 1240, 1244 (10th Cir. 2009). A complaint warrants dismissal if it fails "*in toto* to render [plaintiff's] entitlement to relief plausible." *Id*. at 569 n.14.

B. Rule 8, Rule 9(b), and the Private Securities Litigation Reform Act

Under Rule 8, a pleading need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). However, under Rule 9(b), when fraud or mistake are alleged, the pleader "must state with particularity the circumstances constituting fraud or mistake." Fed.R.Civ.P. 9(b).

Added to this mix, are the special pleading standards required by the Private Securities Litigation Reform Act ("the PSLRA"), 15 U.S.C. §§ 78u-4 *et seq*. The PSLRA requires that, when a plaintiff alleges the making of an untrue statement of material fact, or the omission of a material fact that was necessary in order to make the statement not misleading, "the complaint shall specify

each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). The PSLRA further requires that, when proof of a particular state of mind is required to recover money damages, the plaintiff must, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id*. § 78u-4(b)(2)(A).

While alleged violations of Section 10(b) of the Exchange Act are subject to the heightened pleading requirements of the PSLRA, *In re Level 3 Commc'ns, Inc. Sec. Litig.*, 667 F.3d 1331, 1333 (10th Cir. 2012), alleged violations of Sections 11 and 12(a)(2) of the Securities Act do not fall under the statute's pleading requirements. *Falkowski v. Imation Corp.*, 309 F.3d 1123, 1133 (9th Cir. 2002), *abrogated on other grounds as explained in Proctor v. Vishay Intertechnology Inc.*, 584 F.3d 1208, 1219-20 (9th Cir. 2009). Arguably, though, the heightened pleading standards of Rule 9(b) would apply to such alleged violations of the Securities Act if the allegations are premised upon fraud. *See Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1251-52 (10th Cir. 1997) ("[a]ssuming without deciding" that, if a claim was premised upon fraud, Rule 9(b)'s pleading requirements would apply).

II. Factual Background

Before summarizing the pertinent factual background for the motions to dismiss, it is necessary to resolve the motion for judicial notice. With that motion, the Clovis Defendants request that the Court take judicial notice of 55 documents. (ECF No. 104.) In their response to the motion

for judicial notice, plaintiffs ask that a further seven documents be judicially noticed.[3] (ECF No. 119.) Given that the Consolidated Complaint is 149 pages and 481 paragraphs long, taking judicial notice of a further 62 documents (some much longer than others) could be considered excessive, or, conversely, appropriate.

Nonetheless, the parties do not quibble about the noticing of most of the documents. The Clovis Defendants do not object to plaintiffs seven exhibits, and plaintiffs object to just 16 of the 55 exhibits submitted by the Clovis Defendants. Of those objections, the Court need not spend much time, except in one instance. Plaintiffs object to all of the exhibits on the grounds that they are being used to either establish the truth of a matter or make "sweeping" claims about what the financial market as a whole believed. (ECF No. 119 at 4-7.) The Clovis Defendants, however, disavow any such purposes in their reply (ECF No. 122 at 4-5), and the Court would not consider any of the exhibits presented by the parties for those purposes. Instead, the Court will consider the exhibits as evidence that they exist and of their contents. (*See id*.)

One exception is Exhibit R attached to the motion for judicial notice (ECF No. 104-19). According to the Clovis Defendants, this is "a copy of an abstract presenting certain interim results for rociletnib. The abstract was published by the European Journal of Cancer in conjunction with a presentation at the EEORTC NCI AACR ("ENA") medical conference in November 2014." (ECF No. 122 at 6.) This may be so, but it is not evident from the document itself. Notably, there is no marking on the document to reflect that it was published by the European Journal of Cancer or to show that it was published in conjunction with a presentation at a medical conference in November

[3] Although an Exhibit H was attached to plaintiffs' response, plaintiffs did not actually seek leave for that exhibit to be judicially noticed. (*See* ECF No. 119 at 8.)

2014. (*See* ECF No. 104-19.) The Court notes that the document does have a title and a list of authors, and its content does appear to contain test data. (*See id*.) That being said, without any indication in the document that it was presented at the medical conference as the Clovis Defendants contend, those elements could be present in any document containing test data. In a footnote, the Clovis Defendants assert that the document is "publicly available on the European Journal of Cancer's website for anyone to verify that Exhibit R is what it purports to be." (ECF No. 122 at 6 n.4.) Again, that may be true, but it is not this Court's role to perform that investigation. As a result, having not been presented with a basis to find that Exhibit R "is what it purports to be," the Court DENIES the motion for judicial notice to the limited extent that judicial notice will not be given to Exhibit R. In all other respects, the motion for judicial notice is GRANTED.

With those findings, the Court now assumes the truth of the following pertinent, non-conclusory allegations from the Complaint and the exhibits that have been given judicial notice. In addition, the Court notes that further facts are set forth for the first time in the 'Discussion' section of this Opinion for ease of reference.

A. The Clovis Defendants

Clovis is a biopharmaceutical company headquartered in Boulder, Colorado. (ECF No. 65 at ¶ 37.) Clovis was founded in 2009, and it has been publicly traded since November 2011. Clovis' business focuses upon acquiring, developing, and commercializing oncology products worldwide. From May 31, 2014 through April 7, 2016 ("the Class Period"), Clovis marketed no drug products, but had three drugs in development. Those drugs were: rociletnib, rucaparib, and lucitanib. (*Id*.)

Mahaffy was a co-founder of Clovis, and has served as its Chief Executive Officer and Chairman since 2009. (*Id*. at ¶ 38.) Mast was also a co-founder of Clovis, and served as its

Executive Vice President and Chief Financial Officer from 2009 until his resignation on March 31, 2016. (*Id*. at ¶ 39.) Allen was another co-founder of Clovis, and served as its Chief Medical Officer and Executive Vice President for Clinical and Preclinical Development and Pharmacovigilance from 2009 until his resignation on June 22, 2015. (*Id*. at ¶ 40.) Ivers-Read was another co-founder of Clovis, and has served as its Chief Regulatory Officer and Executive Vice President for Technical Operations since 2009. (*Id*. at ¶ 41.)

B. Rociletnib

By far the most important of Clovis' three drugs under development during the Class Period was rociletnib. (*Id*. at ¶ 53.) Rociletnib was presented to investors as a breakthrough therapy in the treatment of lung cancer. (*Id*.) It was also presented as poised to dominate an untapped $3 billion marketplace for lung cancer therapies aimed at patients who develop resistance to front-line treatments. (*Id*. at ¶ 54.)

The front-line treatment for lung cancer is a class of drugs known as "tyrosine kinase inhibitors" (or "TKIs"). (*Id*. at ¶ 55.) Patients treated with TKIs overwhelmingly develop a resistance to treatment within one year. (*Id*. at ¶ 56.) In 60% of those cases, resistance to treatment is caused by a secondary mutation called "T790M" mutation. Rociletnib was supposed to provide an effective treatment for patients who exhibited resistance to TKIs due to the T790M mutation. (*Id*.)

Prior to the start of the Class Period, rociletnib was the primary developmental drug targeting the marketplace for the T790M positive mutation. (*Id*. at ¶ 63.) In late 2013, a drug from another pharmaceutical company, Astra Zeneca, called "[t]agrisso" began to emerge as a potential rival to rociletnib. (*Id*. at ¶¶ 3, 63.) Investor concerns about tagrisso's commercial threat came into focus

on September 23, 2013, when Astra Zeneca reported a small set of promising data: two confirmed partial responses in six patients evaluated at tagrisso's lowest dose.[4] (*Id*. at ¶ 64.) An unspecified number of defendants were aware of the threat posed by tagrisso. (*See id*. at ¶ 65.) On an October 31, 2013 earnings call, Mahaffy acknowledged that "[w]e are in a race. They are a very able competitor with an active drug." (*Id*.)

C. Trial Protocols for Rociletnib

In order to receive approval from the Food and Drug Administration ("the FDA"), Clovis enrolled rociletnib in a series of clinical tests, including a multi-year safety and efficacy trial called "TIGER-X." (ECF No. 65 at ¶ 4.) TIGER-X generated the entirety of the rociletnib data reported during the Class Period, and formed the principal basis of the rociletnib New Drug Application ("NDA") that was filed with the FDA. (*Id*. at ¶ 4.)

Phase 1 trials are conducted to evaluate a drug's safety in humans. (*Id*. at ¶ 66.) Phase 2 trials are conducted to evaluate efficacy of a drug. (*Id*.) An unspecified number of defendants understood that investors were focused upon the Phase 2 rociletnib efficacy results. (*Id*. at ¶ 65.) One of the key metrics that doctors, regulators, and investors were focused upon was the "objective response rate" (or "ORR") exhibited in trials. (*Id*. at ¶ 5.) ORR describes the percentage of patients who experience clinically meaningful tumor shrinkage when treated with a drug. Oncologists and researchers view ORR as a particularly meaningful measure of a drug's efficacy. (*Id*. at ¶ 68.) In order for rociletnib to become a commercial success, it needed to show an ORR that compared favorably to tagrisso's. (*Id*. at ¶ 70.)

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[4] The concept of "partial responses," as well as other forms of response as they relate to the efficacy of a drug, will be discussed in more detail *infra*. Partial responses are also referred to as "PR" by the parties and in this Opinion.

The rules for calculating ORR are set forth in cancer trial standards known as the Response Evaluation Criteria in Solid Tumors ("RECIST"). (*Id*. at ¶ 5.) RECIST was first published in 2000, and later updated with criteria known as RECIST version 1.1. (ECF No. 104-10 at 229-230.)[5] RECIST version 1.1 states that "[c]onfirmation of response is required for trials with response primary endpoint," and "[c]omplete or partial responses may be claimed only if criteria for each are met at a subsequent time point as specified in the protocol (generally 4 weeks later)." (*Id*. at 228, 235.)

Before a drug trial begins, a drug company is required to specify in "clinical trial protocol" how the trial will be conducted, how trial data will be analyzed, and how success will be defined and measured. (*Id*. at ¶ 73.) Clovis developed, approved, and agreed to abide by protocols for TIGER-X. (*Id*. at ¶ 74.) Clovis incorporated RECIST into the clinical trial protocol for TIGER-X, and repeatedly stated during the Class Period that it was adhering to RECIST standards. (*Id*. at ¶¶ 6, 76.) Clovis' adherence to RECIST gave investors confidence in its reported results. (*Id*. at ¶ 77.)

TIGER-X protocols established a schedule for performing confirmatory tumor scans. (*Id*. at ¶ 79.) In Phase 2, except in certain circumstances, rociletnib was to be administered daily in 21-day cycles until disease progression. (Ex. 1 at 32.)[6] CT scans were "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 [complete response] or PR [partial response] is noted at Cycle 7 or beyond, confirmatory scans must be performed 4-6 weeks later."

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[5] For this exhibit, the Court uses the page numbers assigned by the document itself.

[6] Although plaintiffs cite to the website where the TIGER-X clinical trial protocols are available, a copy of the same has not been provided to the Court. Attached to this Opinion, the Court includes a copy of those protocols as "Exhibit 1," and will cite to the same as "Ex. 1 at ___." The Court will use the page number provided at the bottom, center of each page.

(*Id*. at 92.) Members of the medical community, like investors, understood that Clovis was reporting confirmed objective response rates at medical conferences conducted during the Class Period. (*Id*. at ¶ 91.)

D. Clovis' Contacts with the FDA and the New Drug Application

In anticipation of filing the NDA for rociletnib, Clovis met privately with the FDA on June 9, 2015. (*Id*. at ¶ 135.) At this meeting, Clovis reported an ORR of 50% for patients taking the 500mg dose of rociletnib. (*Id*.) On June 24, 2015, Clovis filed a rolling NDA submission for rociletnib, which was primarily based upon efficacy data from Phase 2 of TIGER-X. (*Id*. at ¶ 138.) The rolling NDA submission was finalized on August 3, 2015. (*Id*. at ¶ 146.)

In October 2015, pursuant to an FDA request, defendants privately submitted rociletnib data showing a confirmed ORR of 28% in T790M positive patients taking the 500mg dose of rociletnib, and a confirmed ORR of 34% for patients taking the 625mg dose. (*Id*. at ¶¶ 152-153.)

E. Clovis' Funding

In addition to rociletnib, Clovis was also developing rucaparib, a treatment for ovarian cancer, and lucitanib, a treatment for breast cancer. (*Id*. at ¶ 61.) Although Clovis had these three drugs in development, it generated no sales revenue during the Class Period. During the Class Period, Clovis' operating expenses were more than $475 million: $84 million in 2013; $172 million in 2014; and $230 million in the first nine months of 2015. In order to fund those operating expenses, Clovis relied on its ability to raise capital from investors. (*Id*.) Specifically, Clovis raised $287.5 million in a September 9, 2014 private placement of senior notes, and $298 million in a July 2015 secondary offering. (*Id*. at ¶ 62.)

F. The July 2015 Secondary Offering

Shortly after filing the NDA, Clovis conducted the July 2015 secondary offering by offering 4.1 million shares at $78 per share. (*Id*. at ¶ 139.) The July 2015 offering raised more than $316 million, with net total proceeds to Clovis of approximately $298 million. (*Id*. at ¶ 140.) The July 2015 offering was conducted pursuant to a shelf registration statement filed with the SEC, in which Clovis disclosed that it intended to use the proceeds for, *inter alia*, expenses associated with the potential launches of rociletnib and rucaparib. (*Id*. at ¶ 141.) Clovis needed these funds, as its operating costs had significantly increased. (*Id*. at ¶ 142.) Clovis had a $55 million net loss in the fourth quarter of 2014, and, in the next two quarters, Clovis' losses were $63 million and $72 million, respectively. (*Id*.)

The prospectus supplement for the July 2015 secondary offering made statements regarding rociletnib's efficacy, including that data from TIGER-X showed a 60% ORR at the 500mg dose, and, across all doses of rociletnib, a 53% ORR. (*Id*. at ¶ 144.) The prospectus supplement further stated that Clovis' data showed "the only common grade 3 [side effect] was hyperglycemia." (*Id*. at ¶ 145.) On August 6, 2015, during a conference call with investors, Mahaffy stated that, following the July 2015 secondary offering, Clovis was "well-capitalized to pursue our development and commercial objectives." (*Id*. at ¶ 146.)

G. False or Misleading Statements

The following statements are alleged to be false or misleading when made, essentially, because (1) Clovis failed to disclose that its presentation of efficacy data was based upon unconfirmed responses, (2) rociletnib's confirmed ORR was significantly lower than the unconfirmed rate and tagrisso's rate, (3) rociletnib's safety data showed the drug significantly

increased the risk of serious or life threatening cardiovascular events including QT prolongation, and/or (4) adverse side effects from rociletnib caused patients to interrupt, modify, or discontinue therapy. (*See, e.g.*, *id*. at ¶¶ 322, 324-326.)[7]

On the first day of the Class Period (May 31, 2014), Clovis issued a press release, filed with the Securities and Exchange Commission ("the SEC") on a form signed by Mast, announcing updated findings from Phase 1 and early Phase 2 portions of TIGER-X. (*Id*. at ¶ 251.) Clovis claimed 23 partial responses, resulting in an ORR of 58%. (*Id*.) On the same day, Clovis presented the same data to doctors, investors, and analysts at the 2014 ASCO conference. (*Id*. at ¶ 252.) Still on the same day, Allen and Mahaffy held a conference call to discuss the ASCO presentation with investors. (*Id*. at ¶ 253.) During the call, Allen stated that the current ORR in patients with "centrally-confirmed T790M disease is 58%." (*Id*.) These statements persuaded analysts and investors that rociletnib was in a favorable position to compete with tagrisso. (*Id*. at ¶ 254.)

On June 23, 2014, Clovis issued a press release, reiterating the data it had presented on May 31, 2014. (*Id*. at ¶ 258.) On August 7, 2014, Clovis issued another press release, filed with the SEC on a form signed by Mast, announcing its second quarter financial results. (*Id*. at ¶ 259.) This press release announced again the data presented on May 31, 2014. (*Id*.) The same data was also announced by Mahaffy on a conference call with investors on the same day. (*Id*. at ¶ 260.)

On September 9, 2014, Mahaffy participated in the Morgan Stanley Healthcare Conference on behalf of Clovis. (*Id*. at ¶ 264.) In response to an analyst's question, Mahaffy stated that he thought rociletnib and tagrisso had similar response rates. (*Id*.) Mahaffy's comparison misled investors into believing that tagrisso and rociletnib were using identical endpoints. (*Id*. at ¶ 266.)

[7] The concepts of "adverse side events" and "QT prolongation" will be more fully discussed *infra*.

On November 6, 2014, Clovis announced its third quarter financial results, and filed the same with the SEC on a form signed by Mast, and also stated that rociletnib had demonstrated compelling efficacy. (*Id*. at ¶ 267.)

On November 18, 2014, an unspecified number of defendants issued a press release presenting updated rociletnib efficacy data from a Phase 2 expansion of TIGER-X. (*Id*. at ¶ 271.) That press release stated that the ORR "in 27 evaluable T790M-positive patients receiving either 625 or 500mg BID was 67%." In addition, the press release stated that "[i]n 11 evaluable T790M-negative patients treated at 625 or 500mg BID, a 36% ORR and median PFS [progression free survival] of 7.5 months were observed. This activity in the non-target T790M-negative patient group is surprising." (*Id*.) On November 21, 2014, Clovis presented the same data at the November 2014 ENA conference. (*Id*. at ¶ 273.) Clovis' presentation at the ENA conference stated that "[e]arly evidence of activity was observed with durable RECIST responses, particularly in T790M+ patients." (*Id*. at ¶ 274.) On the same day, Mahaffy and Allen held a conference call with investors, and, during the call, Allen stated that, in T790M positive patients, Clovis had presented "an impressive 67% response rate," and a response rate of 36% in T790M negative patients. (*Id*. at ¶¶ 275, 276.) On the same call, Mahaffy stated that he thought the response rate in T790M negative patients could represent "a pretty meaningful point of differentiation and benefit to patients." (*Id*. at ¶ 277.) These statements persuaded analysts and other market participants that rociletnib's efficacy profile was impressive and that the drug was highly competitive with tagrisso. (*Id*. at ¶ 279.)

On January 12, 2015, Mahaffy, on behalf of Clovis, participated in J.P. Morgan's 33rd Annual Healthcare Conference, and, at that conference, Clovis "trumpeted" the data presented at the ENA conference. (*Id*. at ¶ 285.) Clovis also presented new data with respect to T790M negative

patients, stating "RECIST ORR = 42% overall" and "RECIST ORR = 50% in patients treated with 625mg BID immediately off prior TKI." (*Id*.) Mahaffy stated that the data for T790M negative patients was "compelling data for what is a significant unmet medical need." (*Id*. at ¶ 287.)

On February 12, 2015, Mast, on behalf of Clovis, participated in the Leerink Global Healthcare Conference, and reiterated the data presented at the 2015 J.P. Morgan conference concerning T790M negative patients. (*Id*. at ¶ 288.) Mast further stated that rociletnib and tagrisso had a similar efficacy profile, but rociletnib had a "distinguishable side effect profile." (*Id*. at ¶ 289.) Mast stated that rociletnib's primary side effect was "easily managed hyperglycemia." (*Id*. at ¶ 290.) Analysts responded positively to the data presented at the January and February 2015 conferences. (*Id*. at ¶ 291.)

On February 25, 2015, Clovis issued a press release, filed with the SEC on a form signed by Mast, announcing full year 2014 financial results, which were also filed with the SEC on a form signed by Mast and Mahaffy. (*Id*. at ¶ 298.) The press release repeated the results presented at the 2015 J.P. Morgan conference. (*Id*.) On the same day, during a conference call with investors, Mahaffy repeated the efficacy data from the press release. (*Id*. at ¶ 300.) Mahaffy also stated that "[t]he 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]." (*Id*. at ¶ 301.) In response to these statements, analysts publicly reported their views about rociletnib's impressive efficacy, and were reassured about the drug's safety and its competitiveness with tagrisso. (*Id*. at ¶ 302.)

On March 4, 2015, Clovis presented efficacy data from Phase 2 of TIGER-X at the TAT medical conference. (*Id*. at ¶ 308.) Clovis reported a 67% ORR in T790M positive patients across all doses used in "Phase ½," and repeated the data concerning T790M negative patients from January

2015. (*Id*.) Clovis also stated that "[t]he only grade 3/4 adverse event observed in >5% of patients was hyperglycemia, readily managed with oral Rx." (*Id*. at ¶ 309.)

On April 30, 2015, an unspecified number of defendants published rociletnib efficacy data from TIGER-X in an article in the New England Journal of Medicine ("the NEJM Article"). (*Id*. at ¶ 315.) Five Clovis employees, including Allen, co-authored the article. (*Id*.) Therein, the unspecified defendants reported "[t]he response rate among 46 patients with centrally confirmed T790M-positive tumors was 59% …." (*Id*. at ¶ 316.)

On May 6, 2015, Clovis issued a press release, filed with the SEC on a form signed by Mast, announcing its first quarter financial results for 2015, and repeated the results presented in the NEJM Article. (*Id*. at ¶ 319.) During a conference call with investors on the same day, Mahaffy stated that "treatment related adverse events [for rociletnib were] generally infrequent and mild, with the only grade 3 adverse event of note, hyperglycemia …." (*Id*. at ¶ 321.)

On May 31, 2015, Clovis presented additional rociletnib efficacy data at the 2015 ASCO medical conference. (*Id*. at ¶ 327.) Clovis reported an ORR of 60% for T790M positive patients taking the 500mg dose of rociletnib, and an ORR of 50% for T7900M negative patients taking the 625mg dose. (*Id*. at ¶¶ 328-329.) On the same day, Clovis issued a press release, announcing the same results, and held a conference call with investors. (*Id*. at ¶¶ 330, 333.) During the conference call, Allen stated that Clovis had "consistently shown an objective response rate of around 60% in centrally confirmed tissue T790M positive patients," as well as "consistently observed response rates greater than 35% in centrally confirmed T790M negative patients." (*Id*. at ¶ 333.) Allen also stated, with respect to evaluating responses, that "[y]ou cannot be evaluable for response [i.e., ORR] until you have had two scans. Because, obviously, that is the definition for RECIST objective response."

(*Id*. at ¶ 335.). Allen further stated that rociletnib was "a very well tolerated oral therapeutic with an extremely low discontinuance rate due to adverse events. And at 500 milligrams, which is our go forward dose, discontinuations are found in only 2.5% of patients." (*Id*. at ¶ 337.) These statements reassured investors that rociletnib remained competitive with tagrisso, which, as announced by Astra Zeneca a few weeks earlier, had achieved a 54% confirmed ORR. (*Id*. at ¶ 338.) The statements also persuaded analysts that rociletnib had a safety profile that would allow it to garner market share and compete with tagrisso. (*Id*.)

On August 6, 2015, Clovis issued a press release, filed with the SEC on a form signed by Mast, announcing its second quarter financial results for 2015, and repeated the efficacy results presented at the 2015 ASCO conference. (*Id*. at ¶ 345.) On the same day, Clovis held a conference call with investors, during which Mahaffy stated that "the only grade 3 adverse reaction or lab abnormality reported in greater than 5% of patients was hyperglycemia." (*Id*. at ¶ 347.)

On September 7, 2015, Clovis presented updated rociletnib efficacy data at the 2015 World Conference on Lung Cancer. (*Id*. at ¶ 352.) Clovis reported an ORR of 60% in T790M positive patients taking the 500mg dose of rociletnib. (*Id*.) Clovis' presentation reassured analysts that rociletnib's efficacy profile was compelling, and that the drug remained in competitive deadlock with tagrisso. (*Id*. at ¶ 353.) On September 17, 2015, Mahaffy, on behalf of Clovis, participated in the Morgan Stanley Healthcare Conference. (*Id*. at ¶ 357.) Mahaffy stated that data showed a 37% response rate in T790M negative patients, which he said was "in contrast with our competitor who does not show this type of activity …." (*Id*.) On September 27 and 28, 2015, at the European Cancer Congress, Clovis presented the efficacy data presented at the 2015 ASCO conference. (*Id*. at ¶ 359.)

On November 5, 2015, Clovis issued a press release, filed with the SEC on a form signed by Mast, announcing its third quarter financial results, and directed investors to the presentations it had made at the September 7 and September 27-28, 2015 conferences. (*Id*. at ¶ 364.) Mahaffy did the same thing on a conference call with investors on the same day. (*Id*. at ¶ 365.) At the time these statements were made, an unspecified number of defendants had provided the FDA with an analysis showing that confirmed objective response rates for T790M positive patients were 28% for the 500mg dose and 34% for the 625mg dose of rociletnib. (*Id*. at ¶ 367.)

On November 10, 2015, Mast, on behalf of Clovis, participated in the Credit Suisse Healthcare Conference. (*Id*. at ¶ 369.) Mast presented rociletnib data showing "an overall response rate of just over 50%," and, for T790M negative patients, "30-odd patients showing a response rate in excess of 30%." (*Id*. at ¶¶ 369-370.) Mast also stated that "[t]he only grade 3 or 4 adverse event that has been identified in more than 10% of patients is hyperglycemia," and, at the 500mg dose, "the QTc prolongation of grade 3 or higher was only 2.5%." (*Id*. at ¶ 371.)

On November 16, 2015, Clovis revealed that the objective response rates reported throughout the Class Period were "based primarily on unconfirmed responses." (*Id*. at ¶ 161.) An unspecified number of defendants disclosed that rociletnib's ORR was 28% among T790M positive patients taking the 500mg dose, and 34% for those taking the 625mg dose. (*Id*.) Investors and market commentators were shocked by these disclosures. (*Id*. at ¶ 163.) On November 16, 2015, Clovis' stock price fell by 70%, from $99.43 per share to $30.24 per share, wiping out approximately $2.7 billion in shareholder value. (*Id*. at ¶ 170.) The stock price did not decline further because investors continued to believe that rociletnib had a favorable safety profile that would allow it to gain at least some market share for patients who could not tolerate tagrisso. (*Id*. at ¶ 172.)

On January 13, 2016, Mahaffy, on behalf of Clovis, attended the 2016 J.P. Morgan Healthcare Conference. (*Id*. at ¶ 376.) Mahaffy stated that QT prolongation in rociletnib patients was "well managed," and that the drug had, had "very few arrhythmic events…." (*Id*. at ¶ 377.) Analysts were persuaded that, despite rociletnib'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. (*Id*. at ¶ 378.)

On April 8, 2016, the FDA and Clovis released safety data for rociletnib in anticipation of an April 12, 2016 meeting of the FDA's Oncological Drug Advisory Committee ("the ODAC"). (*Id*. at ¶ 176.) This data showed that rociletnib significantly increased the risk of serious or life threatening adverse cardiovascular events (specifically, QT prolongation). An unspecified number of defendants had known about this information since at least January 2015. (*Id*.) The safety data also showed that 56% of rociletnib patients interrupted treatment, 51% reduced their dosage, and 12% discontinued treatment altogether. (*Id*. at ¶ 178.) Analysts and market commentators reacted by revising their prior valuations to reflect zero revenue attributable to rociletnib. (*Id*. at ¶ 179.) Following these disclosures, Clovis' stock price fell 17%, from $20.43 per share to $15.77 per share. (*Id*. at ¶ 182.)

On April 12, 2016, the ODAC met to discuss the rociletnib NDA, voting 12 to 1 to delay FDA action until Clovis could provide evidence that rociletnib's overall risk/benefit profile merited approval. (*Id*. at ¶ 183.) The ODAC concluded that rociletnib failed to show any clinically meaningful advantage over available therapies, especially tagrisso. (*Id*.) On May 5, 2016, Clovis announced that it had withdrawn the NDA for rociletnib, and terminated enrollment in all ongoing rociletnib studies. (*Id*. at ¶ 185.)

III. Discussion

The Court will address the three motions to dismiss individually. First, the Court will address the Clovis Defendants' motion to dismiss, next will follow the Venture Capital Defendants' motion to dismiss, followed last (but by no means least) the Underwriter Defendants' motion to dismiss.

A. The Clovis Defendants' Motion to Dismiss

The Court makes the following initial observations. The vast majority of the collective motions to dismiss, and plaintiffs' joint response to those motions to dismiss, is dedicated to the dispute with the Clovis Defendants. Of that dispute, the vast majority of the parties' pleadings are devoted to two elements of plaintiffs' claim under Section 10(b) of the Exchange Act. The Court can understand why—because those elements constitute the very heart of the overarching controversy: whether the Clovis Defendants' statements were false or misleading; and whether the Clovis Defendants' acted with intent to defraud or with recklessness. On those issues, the parties agree on very little, if anything. Based upon the Court's review of the Consolidated Complaint, the motions to dismiss, response, and accompanying exhibits, though, resolution of these disputes cannot be achieved at this stage of proceedings.

As alleged in the Consolidated Complaint, the Clovis Defendants engaged in clinical trials to test, *inter alia*, the safety and efficacy of rociletnib. One of these trials was called "TIGER-X," and the purpose of Phase 2 of that trial was to test the efficacy of rociletnib. A drug's efficacy is ordinarily determined by its "objective response rate" or "ORR"—the higher the ORR, the better. Here, a "response" means a reduction (or elimination) of a cancerous tumor. The more favorable

responses, i.e., the more patients with reduced or eliminated tumors, the higher the ORR, and, purportedly, the more efficacious a drug. That is the goal at least.

The root of the parties' dispute appears to be *when* a "response" needs to be confirmed, and whether the fact that a response is not confirmed need be disclosed to the investing public. Assuming the accuracy of the Consolidated Complaint's allegations and the material cited therein, though, there is at least one other important matter to be discovered. Notably, the Consolidated Complaint cites the clinical trial protocols for TIGER-X. In other words, the rules governing the TIGER-X trial. In those protocols were built rules governing the assessment of tumors for purposes of testing the efficacy of rociletnib. Specifically, the TIGER-X protocols stated that tumor assessments would be performed "at screening; at the end of Cycles 2, 4, and 6 (between Days 14 and 21); every 3 cycles after Cycle 6 (between Days 14 and 21); and at the end-of-study visit." (Ex. 1 at 52.) Moreover, each "Cycle" lasted 21 days. (ECF No. 104-24 at 2.)

Plaintiffs allege that, unbeknownst to them, the objective response rates reported by the Clovis Defendants reflected initial or unconfirmed responses. When in the timeline of the TIGER-X study that these "initial" responses were assessed is unclear. The answer to that question may prove important, but, for now, it is enough to say that it was some time after screening. After an initial response was assessed, a further tumor assessment was made either six weeks (two cycles), nine weeks (three cycles) later, or, in the event an initial response was not assessed until Cycle 7 or beyond, four to six weeks later. Thus, pursuant to TIGER-X's own protocols, every initial response should have been followed-up at some point thereafter, and, depending on whether a patient withdrew from testing, on more than one occasion. Except for two hypothetical situations discussed

in more detail *infra*, these follow-up assessments should have definitively established whether a patient's "initial" response was confirmed or unconfirmed.

In other words, based upon the Court's understanding of the alleged facts, there should be hard data to prove or disprove plaintiffs' allegations in this case. By hard data, the Court means the results of the tumor assessments required by the TIGER-X's protocols. Either those results will show what plaintiffs allege: that initial responses were not followed up by further favorable responses, and these less favorable responses were knowingly left undisclosed. Or the results will show what the Clovis Defendants allege, which, as far as the Court can tell, is something not all that clear, but, at the very least, it is something not suggesting knowing nondisclosure of negative results. Based upon the arguments put forward by the parties, the Court sees no reason why this case should be dismissed *before* the actual data from Phase 2 of TIGER-X is disclosed, especially when those results could provide a definitive answer to the questions raised by this case or come very close to doing so.

1. Section 10(b) of the Exchange Act

To state a claim under Section 10(b) of the Exchange Act, the plaintiff must allege that:

> (1) the defendant made an untrue or misleading statement of material fact, or failed to state a material fact necessary to make statements not misleading; (2) the statement complained of was made in connection with the purchase or sale of securities; (3) the defendant acted with scienter, that is, with intent to defraud or recklessness; (4) the plaintiff relied on the misleading statements; and (5) the plaintiff suffered damages as a result of his reliance.

In re Level 3 Commc'ns, 667 F.3d at 1333. Moreover, the heightened pleading requirements of the PSLRA apply to the first and third elements. *Id*.

In addition, in the Tenth Circuit, courts evaluate "the facts alleged in a complaint to determine whether, taken as a whole, they support a reasonable belief that the defendant's statements identified by the plaintiff were false or misleading." *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1099 (10th Cir. 2003). This approach involves an evaluation of the following factors:

> (1) the level of detail provided by the facts stated in a complaint; (2) the number of facts provided; (3) the coherence and plausibility of the facts when considered together; (4) whether the source of the plaintiff's knowledge about a stated fact is disclosed; (5) the reliability of the sources from which the facts were obtained; and (6) any other indicia of how strongly the facts support the conclusion that a reasonable person would believe that the defendant's statements were misleading.

Id. When an analysis of these factors leads to the conclusion that "a reasonable person would believe that the defendant's statements were false or misleading, the plaintiff has sufficiently pled with particularity facts supporting his belief in the misleading nature of the defendant's statements." *Id*.

Here, the Clovis Defendants and plaintiffs focus their attentions exclusively on the first and third elements of a Section 10(b) claim: i.e., whether the Clovis Defendants' statements were false or misleading; and whether the Clovis Defendants' acted with intent to defraud or with recklessness. Moreover, due to the nature of the allegations in the Consolidated Complaint, discussion of the first and third elements is interwoven to some extent because plaintiffs allege that the Clovis Defendants acted with scienter due, in part, to their knowing disclosure of misleading information. Thus, in order to assess whether the Clovis Defendants acted with scienter, the Court must also assess whether the alleged information was misleading—the same inquiry for the first element. Accordingly, the Court will begin with that inquiry: whether the alleged information—here, the objective response rates for rociletnib that the Clovis Defendants disclosed in their public communications—was misleading.

a. False or Misleading Statements

Based upon the allegations in the Consolidated Complaint, the Court believes that the answer to this question is 'yes'. Plaintiffs' essential allegation in this regard is that, when the Clovis Defendants disclosed the objective response rate for rociletnib during the Class Period, the rate was based upon "unconfirmed" responses. (*See, e.g.*, ECF No. 65 at ¶ 255.) Plaintiffs allege that this was misleading because an ORR based upon "unconfirmed" responses would not be accepted by the regulator, did not comply with RECIST, and was not consistent with industry standards. (*Id*. at ¶¶ 255, 257.) Plaintiffs further allege that the information was misleading because rociletnib's confirmed ORR was "significantly lower" than the ORR actually reported by the Clovis Defendants. (*Id*. at ¶ 255.) The Clovis Defendants counter that it was not clear until after "virtually all" of the challenged statements were made that the regulator would not accept an ORR based upon unconfirmed responses, RECIST did not preclude the reporting of unconfirmed responses, and the Clovis Defendants' interpretation of RECIST was reasonable. (ECF No. 105 at 36-37, 44-46.)

The first issue is whether RECIST required confirmed responses during the TIGER-X trial. According to plaintiffs, when the primary "endpoint" of a study is response, RECIST requires that responses be confirmed. (ECF No. 120 at 24.) The Clovis Defendants argue that RECIST "did not appear to require confirmation of responses in the circumstances of the TIGER-X trial." (ECF No. 105 at 46.) The Clovis Defendants base this argument on the principle that, because they were reporting results from an "ongoing" study, confirmation may not "necessarily occur" until the conclusion of the same. (*Id*.) At this stage, the Court agrees with plaintiffs' interpretation of RECIST.

RECIST is the oncology field's attempt to standardize criteria for evaluating efficacy in clinical trials. (ECF No. 65 at ¶ 75; *see also* ECF No. 104-10 at 229). In 2009, RECIST was revised, and it is to this revised version that the parties refer. From the outset of the article explaining the revised RECIST guidelines ("the EJC Article") (*see* ECF No. 104-10 ("New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1)")), it is clear that response confirmation is part of RECIST's guidelines. Notably, one of the "Highlights of revised RECIST 1.1" is that "Confirmation of response is required for trials with response primary endpoint …." (*Id*. at 228.)

Here, it is not disputed that the purpose or "primary endpoint" for Phase 2 of the TIGER-X trial was response. To the extent it is disputed, it should not be—the trial's protocols state clearly that "overall response rate" was a "primary endpoint" of Phase 2. (*See* Ex. 1 at 74; *see also* ECF No. 104-24 at 4 ("In phase 2, the primary end points were response rate and duration of response.")). In addition, as far as the Court can discern, the principle of requiring confirmation when response is a primary endpoint does not appear to be disputed. Instead, the Clovis Defendants appear to focus their argument on *when* confirmation is required, and, on the apparent notion that the moment of confirmation may occur so late in a study that it may never actually happen at all. (*See* ECF No. 105 at 66 ("there was no date-certain by which Clovis would know whether a response had confirmed or would never confirm.")). The Clovis Defendants appear to base this argument upon the interplay of something called "best overall response" and a hypothetical question asked in the "[f]requently asked questions" section of the EJC Article. (*See* ECF No. 105 at 11, 67; ECF No. 124 at 13.)

Before embarking down that rabbit hole, however, it is important to give some meaning to various terms of art used in the parties' pleadings. Specifically, the concepts of "complete response,"

"partial response," "stable disease," and "progressive disease." RECIST provides that "complete response" or "CR" means the "[d]isappearance of all target lesions," "partial response" or "PR" means "[a]t least a 30% decrease in the sum of diameters of target lesions," "progressive disease" or "PD" means "[a]t least a 20% increase in the sum of diameters of target lesions," and "stable disease" or "SD" means "[n]either sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD." (ECF No. 104-10 at 232-233.)

Returning to the Clovis Defendants' argument about when or whether confirmation can be achieved, the Court disagrees with the principles upon which it appears to rest. First, in their "Statement of Facts," the Clovis Defendants assert that RECIST does not require confirmation by consecutive scans, and that a CR or PR can be confirmed "by any scan showing another response before progressive disease is documented," citing pages 233 and 235 of the EJC Article. (ECF No. 105 at 19.) As an initial matter, the Court notes its frustration at the Clovis Defendants' frequent decision to cite to a page or pages from their exhibits without pinpointing the specific language upon which they are relying. In the current example, this citing decision leaves the Court staring at two pages from an exhibit hoping to find the language supporting the Clovis Defendants' argument when that language is clearly not evident simply from reading the document. More specifically, the Clovis Defendants cite to page 235 of the EJC Article for the proposition that confirmation by consecutive scans is not required under RECIST. To what language on page 235 is a mystery left for this Court to unravel. Arguably, it could be the language saying that a CR or PR may be claimed only if the criteria for each are met "at a subsequent time point". After all, "subsequent" does not necessarily mean next in time. This is undercut somewhat, though, by the immediately following language that the subsequent time point is "as specified in the protocol (generally 4 weeks later)." Given that a

subsequent time point for assessment in the TIGER-X protocol was in the region of four to six weeks (*see* Ex. 1 at 92), the foregoing language in the EJC Article would not seem to leave much room for non-consecutive scans.

There is potentially more fruitful language, however, elsewhere on page 235. Notably, the EJC Article explains that repeated "NE" (or not evaluable) assessments may "complicate" best response determinations, and that it would be "reasonable to consider a patient with time point responses of PR-NE-PR as a confirmed response." This would seem to fit squarely in the Clovis Defendants' argument that confirmation can be achieved with non-consecutive scans, given that the next-in-time scan in the foregoing language did not confirm the initial scan, but the initial scan could still be confirmed by the third-in-time scan. There is a similar principle in the hypothetical question posed at the end of the EJC Article and upon which the Clovis Defendants rely. (*See* ECF No. 124 at 13.) In that question it is asked whether "sequential scans" are required to confirm a PR if a patient has a "32% decrease in sum cycle 2, a 28% decrease cycle 4 and a 33% decrease cycle 6"? (ECF No. 104-10 at 246.) In other words, this question is asking whether borderline responses of PR-SD-PR can result in a confirmed PR. The EJC Article answers that yes it can, explaining that "[i]t is not infrequent that tumor shrinkage hovers around the 30% mark. In this case, most would consider PR to have been confirmed looking at this overall case. Had there been two or three non-PR observations between the two time point PR responses, the most conservative approach would be to consider this case SD." (*Id.*)

These principles are all well and good as far as they go, but they go nowhere near as far as the Clovis Defendants assert or how far they need to go in order to make their interpretation of RECIST reasonable. To start with, there is no assertion, or even suggestion, that the hypothetical

scenarios *supra* existed with respect to any of the patients involved in the TIGER-X study. In other words, there is no suggestion that the reason the Clovis Defendants held onto initial responses of PR (and continued to disclose patients as being PR) was because the next-in-time scan was either NE or a borderline case of SD, and the Clovis Defendants were waiting to see if the third scan would return to PR. To be clear, it is to those scenarios, and those scenarios only, that the hypotheticals are addressed. Importantly, the answer to the hypothetical question specifically states that "[h]ad there been two or three non-PR observations between the two time point PR responses, the most conservative approach would be to consider this case SD." This would appear to foreclose the Clovis Defendants' second, and more fundamental principle, that a CR or PR can be confirmed by *any* scan showing another response before progressive disease is documented. (*See* ECF No. 105 at 19.) This argument from the Clovis Defendants appears to suggest that as long as a patient's responses are bookended by a CR or PR, whatever happens in the meantime is irrelevant. That is simply not the case, given that the EJC Article states that two or three non-PR observations, such as a combination of two or three not evaluables or stable diseases, should lead to a SD response, even when a patient's responses are bookended by partial responses.[8]

In any event, based upon the allegations in the Consolidated Complaint, the Court has no reason to find that either one of the hypothetical situations is applicable here. To the extent it is, as the Court has already stated (and will continue to state), there is one very good way to know: through production of the results of Phase 2 of the TIGER-X trial. If those results do happen to show that

[8] The Clovis Defendants also cite to page 233 of the EJC Article for the proposition that a CR or PR can be confirmed by any scan showing another response. (*See* ECF No. 105 at 19 n.49.) As with page 235, the Clovis Defendants do not try to point the Court in the direction of the applicable language from page 233, and, unlike the Court's attempts to find supporting language on page 235, the Court has tried but could not find anything to support this proposition on page 233. In the future, the Court suggests that the Clovis Defendants quote the applicable language, so as to avoid further confusion and wasting of time.

the Clovis Defendants were presented with initial responses of PR, followed by NE or borderline SD, and were waiting to see if the next-in-time scan was a PR, then the Clovis Defendants may (or may not) have a reasonable basis for making the public disclosures at issue in this case. That, however, is not the situation presented in the Consolidated Complaint, and shows why dismissal at this stage is inappropriate.

The Clovis Defendants' next argument in support of their interpretation of RECIST is that a CR or PR "may not be determined until all data for that patient is known at the conclusion of the study," which, purportedly, leaves open whether confirmation is required in "ongoing" trials. (ECF No. 105 at 19.) This argument confuses confirmation with the concept of "best overall response." The Clovis Defendants are correct that the EJC Article does contain the language "once all the data for the patient is known." (*See* ECF No. 104-10 at 234.) However, this relates to the determination of "best overall response." (*See id*.) "Best overall response" is defined by RECIST as "the best response recorded from the start of the study treatment until the end of treatment taking into account any requirement for confirmation." (*Id*.) In that light, requiring that all data be known makes sense before describing a response as the "best" one for the entire study. And that concept is also good as far as it goes, but it does not, as the Clovis Defendants appear to suggest, suspend the need for confirmation.[9]

[9] The Court further notes that the TIGER-X protocols did *not* evaluate best overall response in this manner. Notably, the TIGER-X protocols stated that best overall response "is the best response from the start of the treatment *until disease progression/recurrence* …." (Ex. 1 at 91 (emphasis added)). Of course, "disease progression/recurrence" may not take place until the end of a study, but, as far as the Court can discern, this is not the situation presented in this case. Instead, the TIGER-X protocols appear to have specifically provided for measuring best overall responses *before* the conclusion of a study. In addition, the same protocol provided that a patient's best response assignment would depend upon the achievement of "confirmation criteria." (*Id*.) This alone appears to undermine the Clovis Defendants' apparent suggestion that confirmation of responses was not possible until the end of a study, given that the "confirmation criteria" on the next page of the protocols states that confirmatory scans must be performed four to six or

Rather, the concept specifically takes into account that confirmation may be required, given that the EJC Article states that best overall response "tak[es] into account any requirement for confirmation." (*Id*.) In other words, when confirmation is required, confirmation goes hand-in-hand with reporting a best overall response. This is why RECIST contains a paragraph and a chart dedicated to best overall responses when confirmation is required. (*See id*. at 235.) In fact, this is where the language discussed *supra* comes from about claiming a CR or PR "only if the criteria for each are met at a subsequent time point as specified in the protocol (generally 4 weeks later)." (*See id*.)

Moreover, RECIST "assume[s] that at each protocol specified time point, a response assessment occurs." (*Id*. at 234.) In other words, RECIST assumes that initial responses are assessed at each subsequent time point, which necessarily includes the next one. As discussed *supra*, that is also precisely what the TIGER-X protocols provided for in establishing a schedule for tumor assessments. (*See* Ex. 1 at 64, 92.) These "time point" or "overall" responses, as RECIST describes them, are the vehicle through which confirmation is performed on an *ongoing* basis. That is, presumably, why the TIGER-X protocols described them as "Confirmatory Measurement[s]." (*See* Ex. 1 at 92.) Thus, rather than leaving open whether confirmation is required in ongoing studies, RECIST and TIGER-X were specifically designed to accommodate confirmation in ongoing trials. To the extent this was not clear enough, later in the EJC Article, it states that, "[i]n non-randomized trials where response is the primary endpoint, confirmation of PR and CR is required to ensure responses identified are not the result of measurement error." (ECF No. 104-10 at 236.)

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five to six weeks later. (*See id*. at 92.)

Put simply, although RECIST provides that the *best* overall response for an entire study is determinable only at the end of the study, confirmation of any of the individual responses that may become the best overall response is required "at a subsequent time point as specified in the protocol (generally 4 weeks later)." (*See id*. at 235.) While this language may not necessarily mandate a consecutive confirmatory response, it also certainly does not mean that confirmation can only be determined at the end of a study. Rather, confirmation will "generally" occur within four weeks of the initial response or as specified in the protocol, which, here, meant less than seven weeks later.

In summary, based upon the explanation of RESIST in the EJC Article, the Court does not find the Clovis Defendants' interpretation of RECIST (i.e., that responses could be confirmed so long as a patient demonstrates another PR at any time before disease progression) to be reasonable, especially when taken to the extreme that the Clovis Defendants attempt to take it by asserting that a response may never be confirmed. Such an interpretation is simply divorced from the language of RECIST. In addition, such an interpretation is divorced from the protocols governing confirmation for the TIGER-X trial, and, in that sense, the TIGER-X protocols appear to be entirely consistent with RECIST. As discussed *supra*, the TIGER-X protocols required confirmatory scans within seven days of the start of Cycles 3, 5, and 7, which meant that a scan was required within five to six weeks of the initial (screening) scan, and then every five to seven weeks for the next two scans. If a patient reached Cycle 7, then a scan was required every eight to ten weeks thereafter. If a CR or PR was first observed at or after Cycle 7, though, a confirmatory scan was required four to six weeks later. (Ex. 1 at 92.)

With this schedule of testing, assuming that Clovis complied with its own protocols during the TIGER-X trial, confirmatory scans should exist for every patient enrolled in the trial who did not

unenroll from the same before Cycle 3. Moreover, depending on how long a patient continued in the trial, multiple confirmatory scans should exist. In turn, those confirmatory scans should reflect a response; be it CR, PR, SD, PD, or NE, which means that the patient's initial response should be confirmable or not. To the extent that the next-in-time response was a borderline SD or a NE, then that too should be documented in the results. If this data exists, then it should be a question of matching dates of confirmatory scans with the cutoff dates for publicly disclosed objective response rates in order to determine whether those rates were no longer consistent with the results of the confirmatory scans. If confirmatory scans took place after the cutoff date for a publicly disclosed ORR, then the ORR may not be misleading. But, if confirmatory scans were performed before the cutoff date, and the disclosed ORR still only reflected the results of initial (unconfirmed) scans, then the ORR would likely be misleading. Equally, to the extent that a publicly disclosed ORR was based upon a blend of confirmed and unconfirmed responses, the data from Phase 2 of TIGER-X will help show to what extent the rate was truly a blend and on what basis unconfirmed responses were categorized as unconfirmed.[10]

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[10] For example, the publicly disclosed ORR with perhaps the most information at this point is the one disclosed in the NEJM Article. That Article stated that "[t]he response rate among 46 patients with centrally confirmed T790M-positive tumors was 59% …." (ECF No. 104-24 at 6.) A Chart in the NEJM Article reflected that responses for the 59% of patients were partial responses. (*Id.*) The NEJM Article further stated that "[a] total of 130 patients were enrolled between March 2012 and April 2014," and the cutoff date was June 18, 2014. (*Id.* at 4.) At this juncture it is not possible to assess whether (or how many of) the 46 patients received confirmatory scans. This would depend upon when those patients were enrolled in Phase 2 of TIGER-X and when an initial response was first observed. However, the Court finds it to be more than plausible that confirmatory scans had been performed by June 18, 2014, given that enrollment began in March 2012, Phase 1 of TIGER-X had been completed, and a confirmatory scan should have been performed, at most, just seven weeks after an initial response. (*See id.*; *see also* Ex. 1 at 92.). In a footnote in their reply, the Clovis Defendants assert that "the median patient" had not received a confirmatory scan because the NEJM Article noted that the median follow-up time for the 46 patients was 10.5 weeks. (ECF No. 124 at 40 n.22.) The Clovis Defendants are correct that the NEJM Article stated that the "median follow-up was 10.5 weeks (range, 0.1 to 53.9)." (ECF No. 104-24 at 6.) The Court, however, does not understand what this means. To the extent it means what the Clovis Defendants appear to suggest it does (that the median confirmatory scan took place within 10.5 weeks), the statement not only means that the

The Court acknowledges that this conclusion rests upon the Court's interpretation of RECIST and the TIGER-X protocols. The Court further acknowledges that, just because the Court has interpreted those matters in the way it has, does not mean that will remain true going forward. In other words, conceivably, the Clovis Defendants could present evidence at summary judgment indicating that their interpretation of RECIST was reasonable and that the FDA would accept their unconfirmed responses.[11] All that the Court is finding at this juncture is that the Clovis Defendants will not be able to make such a showing based purely upon the plain meaning of the language in the EJC Article.

On a related note, the Clovis Defendants argue that there are no well-pled allegations that objective response rates based upon confirmed responses tracked below objective response rates based upon blended responses at the time that the alleged public disclosures were made. (ECF No. 105 at 39.) The Court disagrees. As an initial matter, this issue brings up, and is connected to, another: whether a purported "[s]tatistical analysis" from a "preeminent mathematician" (David Madigan) should be considered in determining whether plaintiffs have plausibly alleged that the Clovis Defendants' statements were misleading. (*See* ECF No. 120 at 61-65.) On that issue, the Court agrees with the Clovis Defendants because, based upon the allegations in the Consolidated Complaint, the Court does not find the statistical analysis useful for its stated purpose.

TIGER-X protocols were not followed, but also appears to contradict two statements in the NEJM Article: (1) that the authors of the NEJM Article vouched "for the fidelity of the study to the protocol"; and (2) that the data described in the NEJM Article consisted of patients who had "follow-up data through at least the cycle 2 restaging scan or who discontinued treatment before the end of cycle 2." (*Id.* at 4.) In any event, this type of confusion is precisely why disclosure of the actual data may help resolve this case.

[11] Based upon the Court's understanding of their arguments, the Clovis Defendants would need to show that it was reasonable for them to believe that (1) an initial (unconfirmed) PR could be confirmed at any point thereafter even if, in between the initial and confirmed partial responses, multiple different responses were recorded, and (2) the FDA would accept the initial (unconfirmed) response despite the existence of multiple intervening and different responses.

The Consolidated Complaint alleges that Mr. Madigan used "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." (ECF No. 65 at ¶ 200.) Plaintiffs do not allege, however, what the disclosed "data" is. In their reply, plaintiffs appear to suggest that it is objective response rates disclosed at the end of the Class Period. (*See* ECF No. 120 at 62.) Although that statement is still not particularly enlightening, the Court assumes that plaintiffs are referring to the November 16, 2015 disclosure that the ORR for patients taking a 500mg dose of rociletnib was 28% and for patients taking a 625mg dose it was 34%. (*See* ECF No. 65 at ¶ 161.) If that is the case, the problem is that the only reasonable way to construe the allegations about the November 16, 2015 disclosures is that the objective response rates reported on that date reflected response rates as of November 16, or at least a cutoff date near to that time. To use those rates as an input to analyze the likely ORR for earlier dates (and in some cases, much earlier dates) simply does not make sense. Even for the latest alleged misleading disclosures in November 2015, those disclosures are allegedly based upon objective response rates reported in May 2015 (*see id*. at ¶¶ 206, 207), which seems too far removed from data disclosed months later. As such, without further information on how Mr. Madigan produced his statistics, and/or why he believed the inputs to be proper, the Court is unprepared to consider his analysis in determining whether the Clovis Defendants' statements were misleading.

Nonetheless, in assessing plaintiffs' allegations under the *Adams* factors, the Court believes that, in total, they are sufficient. Not all of the *Adams* factors weigh in favor of plaintiff however. The first—the level of detail provided by the facts in a complaint—does not support plaintiffs. The detail provided in the Consolidated Complaint is minimal; in sum, it amounts to the allegation that

the confirmed ORR was "significantly lower" than the unconfirmed ORR. (*See, e.g.*, ECF No. 65 at ¶ 255.) The fourth and fifth factors—whether the source of plaintiffs' knowledge about a stated fact is disclosed and the reliability of the sources from which the facts were obtained—do not support plaintiffs, largely because there is no source for plaintiffs' knowledge other than the large discrepancy between the ORR reported on November 16, 2015, and those reported before.

The Court, however, does not place great weight on the fourth and fifth factors in light of the alleged nature of the misleading statements here. Importantly, the misleading nature of the statements will not be difficult to verify. Instead, they will be "objectively verifiable" based upon the results of the TIGER-X trial: either those results support the alleged statements or they do not. *See Adams*, 340 F.3d at 1102. Moreover, contrary to the Clovis Defendants' apparent suggestion (*see* ECF No. 105 at 39), plaintiffs were not required to produce confidential sources to refute the publicly disclosed statements. *See Adams*, 340 F.3d at 1100-02. Taking a "common sense" approach to plaintiffs' allegations, *see id.* at 1102-03, the Court finds them to be coherent and plausible, and support the conclusion that a reasonable person would believe that the statements were misleading.

Notably, plaintiffs allege that: the TIGER-X protocols and RECIST required confirmatory scans, and TIGER-X required those scans take place within five to seven weeks of an initial response (ECF No. 65 at ¶¶ 78-80); the objective response rates disclosed during the Class Period for T790M positive patients were in excess of 50%, and frequently close to or in excess of 60% (*id*. at ¶¶ 95, 107, 128, 132, 148, 155); on November 16, 2015, the Clovis Defendants disclosed objective response rates of 28% and 34% for 500mg and 625mg dose patients, respectively, based upon confirmed responses (*id*. at ¶ 161); and, the objective response rates disclosed during the Class

Period had been "based primarily on unconfirmed responses" (*id*.). Applying "common sense" to these allegations, it is more than plausible that the Clovis Defendants disclosed objective response rates during the Class Period based upon unconfirmed responses, even though confirmatory scans were taken of patients enrolled in TIGER-X and the results of those scans tracked significantly lower than initial scans. If true, this was misleading.

It is of course also possible that the much lower objective response rates disclosed on November 16, 2015 merely reflected the clinical data at that time, and not lower rates throughout the Class Period. The Clovis Defendants go as far as to argue that the discrepancy in confirmed response rates and blended response rates only emerged "after" the alleged misleading statements were made. (ECF No. 124 at 38.) The Court's findings in this Opinion are not meant to suggest this may not be true, and, if it is, then this may be a very different case. The data from the TIGER-X trial may very well support such a contention. The only issue being resolved now is that, in light of the magnitude of the drop-off between confirmed and blended response rates on November 16, 2015, the Court finds it plausible that the discrepancy was not just a creature of the data at that time, but may have existed throughout the Class Period.[12] Put another way, the Court finds it less than

[12] The Clovis Defendants also argue that the difference in ORR on November 16, 2015 was attributable to two changes that the FDA required: using an "intent-to-treat" patient population, and obtaining independent review of responses. (ECF No. 105 at 43.) With respect to independent review, plaintiffs assert in response that the objective response rates disclosed on November 16, 2015 were not affected by this factor (ECF No. 120 at 52), and the Clovis Defendants do not contest this in reply (*see* ECF No. 124 at 39). As for the "intent-to-treat" factor, at present, the Court is unable to assess what affect, if any, this had on the November 16, 2015 objective response rates. Plaintiffs assert that it affected ORR by "approximately 2%" (ECF No. 120 at 53 & n.16), while the Clovis Defendants assert that it resulted in "an approximately 23% decrease in ORR on a percentage change basis in the 500mg patient group" (ECF No. 124 at 39). Based upon the evidence presented, the Court is unprepared to find whether either party is correct in their analysis, and, even if so, whether that analysis affects the overall finding that the statements are misleading. The Court, instead, will allow the parties, if they choose, to develop those issues at summary judgment.

plausible to believe that the confirmed and blended response rates reasonably tracked each other *prior* to all of the respective statements, and only *after* those statements were made did they diverge. At this stage, the Court does not find the latter to be a "common sense" construction of the alleged facts.

The Clovis Defendants also argue that the statements about objective response rates were not misleading because they never described the rates as being based upon confirmed responses. Instead, the Clovis Defendants assert that they disclosed that the results were "interim," "preliminary," "initial," and based upon "immature" data. (ECF No. 105 at 47.) The Clovis Defendants assert that only by ignoring these words could plaintiffs have believed that the disclosed objective response rates were based upon confirmed responses. (*Id*. at 47-48.) The Court disagrees.

First, with respect to data being "immature," as plaintiffs explain in their response, maturity has little or nothing to do with objective response rates or confirming responses. (*See* ECF No. 120 at 58-59 & n.19.) Instead, it concerns a different metric of a drug's efficacy—progression free survival. (*Id*. at 58.) The Clovis Defendants do not put up any meaningful opposition to plaintiffs' explanation of maturity. (*See* ECF No. 124 at 41 n.24.) Moreover, contrary to the Clovis Defendants' assertion, a confirmed response is not determinable only when a patient experiences tumor growth. (*See id*.) Otherwise, it would be impossible for a best overall response to be CR under RECIST, given that such a best response requires only a first-in-time CR and a subsequent CR. (*See* ECF No. 104-10 at 235 (Table 3)).

Second, in light of the Court's present interpretation of RECIST and the TRIAL-X protocols, using the words "interim," "preliminary," or "initial" does not magically change the misleading nature of the alleged statements. This is because, under RECIST and the TIGER-X protocols, even

an interim ORR should have been based upon confirmed responses. Put another way, provided that patients received confirmatory scans before a report's cutoff date and before a trial finished, the resulting ORR would be both interim (because the trial had not concluded) and based upon confirmed responses.[13] Merely because there might be patients in the trial with unconfirmed responses at that cutoff date does not mean that the Clovis Defendants needed to, or even could, include them in an ORR, at least not based upon the Court's interpretation of RECIST. Those unconfirmed patients could, instead, just be included in the next interim report, assuming that a confirmatory scan had been performed. As such, because designating an ORR as interim, preliminary, or initial could be construed by a reasonable investor as that ORR being based solely upon confirmed responses, the Court rejects this argument.

Plaintiffs also allege that statements pertaining to rociletnib's safety were misleading. Plaintiffs allege that it was misleading for the Clovis Defendants to make statements describing rociletnib as "well tolerated" and stating that the only "grade 3/4" adverse event from taking the drug was hyperglycemia. (ECF No. 65 at ¶¶ 301, 307.) Plaintiffs allege that these statements were misleading in light of data showing that, no later than January 2015, a "troubling cardiovascular safety signal" known as "QT prolongation" had emerged in rociletnib's safety data for patients taking the 625mg dose. (*Id*. at ¶ 223.) More specifically, plaintiffs allege that Clovis' data showed that

[13] For example, assume that the cutoff date for a report was May 31, 2015, and the underlying trial was ongoing. Provided that confirmed responses had been observed by the cutoff date, then any ORR reported could be based upon them. The Clovis Defendants acknowledge that confirmed responses could be reported like this, and even appear to suggest that some of their objective response rates included confirmed responses. (*See* ECF No. 124 at 42.) The Clovis Defendants assert, though, that it was "legitimate" to include a "blend[]" of confirmed and unconfirmed responses due to the "complications" of applying cutoff dates to responses. (*Id*. at 42-43.) The Court, though, does not understand the complication of applying a cutoff date to a response—either the response was confirmed or unconfirmed by that date. The only "complication[]" that the Court can discern is missing out on including favorable unconfirmed responses.

12% of 625mg dose patients "experienced QT prolongation of greater than 500ms," which allegedly is a "threshold of particular concern," and, by April 2015, this percentage had risen to 13% for 625mg dose patients and 12% for 500mg dose patients. (*Id*. at¶ ¶ 224, 226.) Plaintiffs further allege that Clovis' data showed that 72% of 625mg dose patients had "QT intervals increase more than 30ms," and, by April 2015, 76% of 500mg dose patients experienced the same increase. (*Id*. at ¶ 228.) Plaintiffs allege that a QT interval increase of more than 20ms means that a drug has "a substantially increased likelihood of being proarrhythmic." (*Id*. at ¶ 224.) Plaintiffs further allege that, no later than January 15, 2015, Clovis' data showed that 13% of 625mg dose patients experienced a "grade 3 or higher prolongation," which is considered "severe or life threatening," and, by April 2015, 8% of 500mg dose patients experienced the same event. (*Id*. at ¶¶ 224, 229.) Plaintiffs also allege that Clovis' data showed that 65% of all patients experienced adverse events leading to dose interruption or reduction, and 12% of patients discontinued treatment due to adverse side effects. (*Id*. at ¶ 233.)

With respect to the allegations about "grade 3 or higher prolongation," at this juncture, the Court finds that a reasonable person would believe the Clovis Defendants' alleged statements were misleading, but it is a close call. The Clovis Defendants argue that the statements were not misleading because those statements reported incidents of QT prolongation deemed to be related to rociletnib, while the data relied upon by plaintiffs is not based upon treatment-related adverse events. (ECF No. 105 at 61.) First, in supporting this argument, the Clovis Defendants cite to an earlier part of their motion to dismiss. In that section of the motion to dismiss, the Clovis Defendants assert that at major medical conferences they disclosed data deemed to be related to rociletnib. (*Id*. at 26.) However, the Clovis Defendants then only discuss one of those medical conferences. (*See id*.)

Plaintiffs allegations in this regard, though, pertain to seven different statements, thus, it will be necessary for the Clovis Defendants to show that each of those statements concerned treatment-related data.[14]

That being said, the one piece of data that the Clovis Defendants do rely upon (data disclosed at a May 31, 2015 conference) does indicate that Clovis disclosed some risk of QT prolongation from rociletnib. Notably, the data appears to disclose that 13% of 500mg dose patients experienced QT prolongation, while 23% of 625mg dose patients did so too. (*See id*.) At this point, though, it is not clear how those percentages compare to the ones alleged in the Consolidated Complaint. A main area of clear difference, though, appears to be in the reporting of grade 3 or higher QT prolongations. At the May 31, 2015 conference, the Clovis Defendants reported that the only grade 3 or higher adverse event in more than 10% of patients was hyperglycemia. (*Id*.) Plaintiffs allege, though, that 13% of 625mg dose patients experienced a grade 3 or higher QT prolongation. (ECF No. 65 at ¶ 229.) To what extent this discrepancy in disclosed and undisclosed data can be described as misleading is, perhaps, open to dispute, but, at this moment, the Court does not have material before it to say that a reasonable person would not find the failure to disclose the data upon which plaintiffs rely to be misleading, especially given that grade 3 or higher QT prolongations are

[14] The Court notes that plaintiffs argue that two of the statements do not concern treatment-related data. (ECF No. 120 at 81.)

considered severe or life threatening. (*See id*. at ¶ 224.)[15] As for plaintiffs' allegations about statements that described rociletnib as, *inter alia*, "well tolerated," the Court will address those *infra*.

Moving on, the Clovis Defendants challenge various specific statements alleged in the Consolidated Complaint. The Court will address each briefly. First is a statement allegedly made by defendant Allen during a May 31, 2015 investor call. (ECF No. 105 at 48 (citing ECF No. 65 at ¶ 335)). The Clovis Defendants assert that this statement concerned "timing: patients can be in the PFS [progression free survival] population from the moment they enter the study, whereas patients cannot 'respond' under RECIST until they have had a baseline scan (scan 1) and then a scan showing a 30% tumor reduction (scan 2)." (*Id*. at 48-49.) Based upon the Court's reading of the alleged statement, the Court disagrees with the Clovis Defendants. It is far from clear from the statement that Allen is referring to a timing discrepancy, rather, a plain reading of the statement suggests that Allen is confirming that a response, for purposes of RECIST, requires two scans. (*See* ECF No. 65 at ¶ 335.)

Second are statements allegedly made on November 5, 2015. (ECF No. 105 at 49.) The Clovis Defendants argue that they were under no obligation to disclose data that they had given to the FDA, and they disclosed that efficacy updates would not be provided while the FDA was reviewing their NDA. (*Id*. at 49-50.) Although the Court may agree with the Clovis Defendants that they were under no duty to disclose the data given to the FDA, the Court still finds the alleged

[15] To the extent the Clovis Defendants contend that comparing treatment-related adverse events, such as the ones they allegedly disclosed, to non treatment-related adverse events is like comparing apples to oranges, the Court is not persuaded at this juncture if the difference in the disclosed and undisclosed data is as allegedly misleading as plaintiffs contend. In other words, having stated that QT prolongation was not a grade 3 or higher adverse event in 10% or more of patients, it may have been misleading to not disclose less favorable data on that issue, even if that data was of a different variety. Resolution of that question would appear to require expert evidence.

statements misleading because the Clovis Defendants could not use the FDA review process as a vehicle to release misleading information when they were allegedly in possession of clarifying information *independent* of the information disclosed to the FDA. In other words, assuming that the FDA review process had not existed, the Clovis Defendants would still have been required to disclose information on objective response rates significantly lower than the rates they actually disclosed. The fact that the FDA process was in place did not absolve them of that requirement. To the extent that plaintiffs allege that the FDA information should have been disclosed (*see* ECF No. 65 at ¶ 367), the Court disagrees; it is the data from Clovis' TIGER-X trial that should have been disclosed (*see id*. at ¶ 366).

Third is a statement allegedly made by defendant Mahaffy during a November 5, 2015 analyst call. (ECF No. 105 at 50-51.) However, in their response, plaintiffs assert that this statement was not included in the Consolidated Complaint on the ground that it was false or misleading. (ECF No. 120 at 70 n.33.) As such, the Court considers any arguments with respect to the misleading nature of that statement to be unnecessary.

Fourth are statements made by defendant Mast at a November 10, 2015 conference. (ECF No. 105 at 51-52.) The Clovis Defendants argue that Mast's statements are not actionable because there are no allegations that they were "inconsistent with specific facts known to him at the time of the conference." (*Id*. at 52.) In light of the Court's findings *supra* about the meaning of RECIST and the TIGER-X protocols, the Court disagrees with the Clovis Defendants that Mast's statements were not inconsistent with facts known at the time.

The Clovis Defendants also challenge various statements that they assert concern expressions of "optimism and opinion" or are forward-looking statements, and thus, are not actionable. (ECF

No. 105 at 53-60, 62-63.) The Court will address these arguments briefly too. First, "optimism and opinion." The Securities Act requires misleading statements to be material, *In re Level 3 Commc'ns*, 667 F.3d at 1333, and statements of optimism are not considered material because they are, ordinarily, "incapable of objective verification," or are otherwise vague, *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1119-22 (10th Cir. 1997). In that light, the Court agrees with the Clovis Defendants in part.

Specifically, the Court agrees that statements characterizing rociletnib as "promising," "very active," "very compelling" or "compelling," "impressive," "striking," "surprising," "encouraging," and "not noise", are incapable of objective verification. Although, as plaintiffs assert (*see* ECF No. 120 at 71-73), many of these characterizations are made in the context of results from the TIGER-X trial (i.e., characterizing a 67% ORR as "very encouraging" (ECF No. 65 at ¶ 292)), based upon the totality of the allegations in the Consolidated Complaint, it is the result (67% ORR) that is material to a reasonable investor, not the Clovis Defendants' alleged gloss on those results. Nonetheless, the Court agrees with plaintiffs that characterizing rociletnib as "durable" is actionable because that term is allegedly a "term of art" with meaning to investors. (*See* ECF No. 120 at 71 n.34.)[16] Plaintiffs will be required to show that durability is a term of art and that it is capable of objective verification, but, at this stage, the Court will not dismiss claims to the extent they rest upon characterizing rociletnib as durable.[17]

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[16] Plaintiffs also assert that characterizing rociletnib as having a "sustained clinical benefit" is objectively verifiable. (ECF No. 120 at 71-73.) Given that "sustained clinical benefit" appears to be a derivative of durability, the Court will allow claims based upon this characterization to continue as well, with the proviso that plaintiffs will be required to show that the characterization is objectively verifiable and material to a reasonable investor.

[17] The Clovis Defendants argue that, to the extent any statements are considered more than optimism, they are still not actionable because the statements constitute opinions. (ECF No. 105 at 55-58.)

The Clovis Defendants raise the same argument with respect to their alleged statements about rociletnib's safety. (ECF No. 105 at 62.) Specifically, the Clovis Defendants focus upon statements describing rociletnib as "safe" and "well tolerated," its side effects as "very manageable," and comparing its safety profile to a rival drug. (*Id*.) This time, the Court disagrees with the Clovis Defendants because the statements are objectively verifiable at least to a certain extent. Notably, the Consolidated Complaint alleges that Clovis' data showed 65% of all patients experienced adverse events leading to dose interruption or reduction, 12% of patients discontinued treatment due to adverse side effects, and 13% of 625mg dose patients experienced a "grade 3 or higher prolongation," which is considered "severe or life threatening." (ECF No. 65 at ¶¶ 224, 229, 233.) At this stage, there is no way to assess, for example, whether 12% of patients discontinuing treatment due to adverse side effects can be considered safe, manageable, or tolerable, but the Court does not believe that those metrics (safety, manageability, and tolerance) are unquantifiable. Nor does the Court believe that a reasonable investor would not find material a statement that a drug was safe, manageable, or tolerable, when, in reality, it was not. Although plaintiff will need to show that those metrics are objectively verifiable, and that the alleged statements fell outside the verifiable meaning of the words used, at this juncture, the Court will allow the claims to continue.

Second, "forward looking statements." The Clovis Defendants argue that statements concerning rociletnib's market potential and future prospects are protected by the PSLRA's "safe

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As the Clovis Defendants assert in their reply, whether any of their characterizations of rociletnib can be considered opinions turns on the interpretation of RECIST and the TIGER-X protocols. (*See* ECF No. 124 at 47.) The Court agrees that whether the statements are opinions under *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. ___, 135 S.Ct. 1318 (2015), is to a large part dependent upon the interpretation of RECIST and the TRIAL-X protocols, as well as whether objective response rates based upon confirmed responses differed from the Clovis Defendants' blended rates. Because none of those issues can be conclusively determined at this time, the Court will not find the Clovis Defendants' statements to be opinions as a matter of law.

harbor" provision for forward looking statements. (ECF No. 105 at 35 & n.146, 58-60.) Specifically, the Clovis Defendants challenge statements in four paragraphs of the Consolidated Complaint. With respect to the latter two paragraphs (ECF No. 65 at ¶¶ 368, 373), the Court discerns not even a borderline-close forward looking statement, and, in their reply, the Clovis Defendants make no attempt to argue otherwise (*see* ECF No. 124 at 47-48). As for the first two paragraphs (ECF No. 65 at ¶¶ 284, 294),[18] although the words "could" and "potential," respectively, appear in the wider statements, the Court agrees with plaintiffs that the purpose of those statements was not to imagine some way to distinguish rociletnib from its rival in the future, but, rather, to emphasize that the point of differentiation had in fact been observed in rociletnib. (*See* ECF No. 120 at 76-77.) Moreover, other than asserting (1) that the statements concerned "the future commercial prospects of rociletnib," which the challenged statements did not, or, (2) without explanation, that they were "classic" examples of forward looking statements, the Clovis Defendants fail to explain why these statements should be considered forward looking. (*See* ECF No. 105 at 35 & n.146, 58-60; ECF No. 124 at 47-48.) Therefore, the Court rejects this argument.

b. Scienter

With the misleading nature of the statements resolved for present purposes, the Court now addresses the third element of a Section 10(b) claim: scienter. *See In re Level 3 Commc'ns*, 667 F.3d at 1333. To a large extent, the Court's analysis of whether the alleged statements were misleading begets whether the Clovis Defendants acted with scienter. The most important additional alleged fact is that data from the TRIAL-X study was "unblinded," and thus, available to the Clovis

[18] Essentially, the challenged statements are that results observed in T790M negative patients could differentiate rociletnib, or had the potential to do so. (*See* ECF No. 65 ¶¶ 284, 294.)

Defendants throughout the study's life. (*See* ECF No. 65 at ¶ 191.) If this is true, then, as discussed in more detail *infra*, this case largely turns upon (a) whether confirmed objective response rates tracked or failed to track unconfirmed rates (and to what extent), (b) the interpretation of RECIST and the TRIAL-X protocols, and (c) whether the Clovis Defendants could reasonably believe that the FDA would grant rociletnib accelerated approval.

The PSLRA requires a plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Supreme Court has held that courts must consider the complaint in its entirety in order to determine "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323, 127 S.Ct. 2499 (2007) (emphasis in original). In addition, to determine whether a complaint's scienter allegations are sufficient to state a claim, a court "must engage in a comparative evaluation; it must consider, not only inferences urged by the plaintiff, . . . but also competing inferences rationally drawn from the facts alleged." *Id*. at 314. As a result, a complaint may survive "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id*. at 324.

The Supreme Court has defined "scienter" as "'a mental state embracing intent to deceive, manipulate, or defraud.'" *City of Philadelphia v. Fleming Cos., Inc.*, 264 F.3d 1245, 1258 (10th Cir. 2001) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976)). The Supreme Court has held that "[t]he words 'manipulative or deceptive' used in conjunction with 'device or contrivance' strongly suggest that § 10(b) was intended to proscribe knowing or intentional

misconduct." *Ernst & Ernst*, 425 U.S. at 197. Section 10(b)'s scienter requirement can also be satisfied by "[r]ecklessness, defined as 'conduct that is an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Fleming*, 264 F.3d at 1258 (quoting *Anixter v. Home-Stake Prod. Co.*, 77 F.3d 1215, 1232 (10th Cir. 1996)). Thus, in order "to establish scienter in a securities fraud case alleging non-disclosure of potentially material facts, the plaintiff must demonstrate that: (1) the defendant knew of the potentially material fact, and (2) the defendant knew that failure to reveal the potentially material fact would likely mislead investors." *Fleming*, 264 F.3d at 1261.

The Court considers the following facts pertinent to its scienter analysis. First, the Consolidated Complaint alleges that the results from TRIAL-X were "unblinded," and thus, those results were "fully available" to the Clovis Defendants. (ECF No. 65 at ¶ 191.) The Consolidated Complaint further alleges that the Clovis Defendants "continuously reviewed and analyzed" the results. (*Id*. at ¶ 192.) In addition, the Consolidated Complaint alleges that Mahaffy told investors in August 2014 that data from TRIAL-X was "open to us," and that "[w]e have access to all that info." (*Id*. at ¶ 193.) The Clovis Defendants assert that plaintiffs fail to allege that they had access to data that contradicted their public statements, but this is inaccurate in light of the totality of plaintiffs' allegations, including, allegations that data related to confirmed responses was significantly lower than publicly disclosed data, and that the Clovis Defendants had access to all data related to TRIAL-X. In other words, if confirmed and unconfirmed responses were allegedly inconsistent and the Clovis Defendants allegedly had access to all data from TRIAL-X, then the Clovis Defendants must too have had access to the inconsistent data, given that it would have been

part of the whole. Whether or not this is true is another matter, but plaintiffs sufficiently allege it for current purposes. A similar situation exists with respect to the data related to rociletnib's safety. Plaintiffs allege repeatedly that data showing rociletnib's effect on QT prolongation and its general side effects was known to the Clovis Defendants from at least January 2015. (*See, e.g.*, ECF No. 65 at ¶¶ 176, 178.)

Second, the Consolidated Complaint alleges (throughout) that data for confirmed responses was significantly different compared to data for the publicly disclosed objective response rates. (*See, e.g.*, ECF No. 65 at ¶¶ 262, 280, 292, 310, 317, 339.) Although the Court does not place any reliance on Mr. Madigan's statistical conclusions, as discussed *supra*, based upon the totality of the allegations, the Court finds it plausible that confirmed responses were significantly lower than unconfirmed responses during the entire Class Period. Again, whether or not this is true is another matter, but plaintiffs' allegations are sufficient. With that in mind, if confirmed responses did track significantly lower than unconfirmed responses at the time that the Clovis Defendants made their public statements, and the Clovis Defendants knew of this information, then this could be a strong factor in favor of scienter, i.e. that the Clovis Defendants knowingly misled plaintiffs.

Third, the Consolidated Complaint alleges that the Clovis Defendants knowingly contravened the TRIAL-X protocols and industry practice in disclosing objective response rates based upon unconfirmed responses. (ECF No. 65 at ¶ 216.) The Clovis Defendants argue against this factor on the same basis that it was not misleading, i.e. based upon its interpretation of RECIST. (*See* ECF No. 105 at 66-67.) Given that the Court has rejected the Clovis Defendants' interpretation for now, the Court rejects the argument that plaintiffs have not sufficiently pled that the Clovis Defendants knowingly violated their own trial protocols. This is an important factor because, even if confirmed

and unconfirmed responses were significantly different, if the Clovis Defendants did not knowingly or recklessly violate their trial protocols or RECIST, then it would be much harder to prove that the Clovis Defendants acted with scienter (or, potentially, that their statements were misleading in the first place). The converse is also true however, i.e., if the Clovis Defendants did knowingly or recklessly violate their trial protocols and RECIST, then that could be a strong factor indicating an intent to mislead.

Fourth, in a similar vein, the Consolidated Complaint alleges that the Clovis Defendants contravened guidance from the FDA in disclosing objective response rates based upon unconfirmed responses. (ECF No. 65 at ¶ 216.) Plaintiffs' allegations with respect to this matter are much thinner. Specifically, in the Consolidated Complaint, plaintiffs appear to rely upon an excerpt from an April 2015 FDA presentation about "Breakthrough Therapy Designation: Exploring the Qualifying Criteria." (*Id*. at ¶ 90.) The slide appears to suggest that the FDA "[u]sed confirmed ORRs" in its analysis, presumably of whether to grant a Breakthrough Therapy Designation. (*See id*.) This, though, does not provide guidance that, for a different regulatory procedure (whether to grant accelerated approval), the FDA would *only* consider objective response rates based upon confirmed responses. Simply put, based solely upon the slide, the latter cannot be drawn from the former.

The question remains, though, whether the Clovis Defendants knew or should have known that the FDA would not grant accelerated approval based upon the data Clovis presented to the FDA. One of the Clovis Defendants' exhibits helps to shed light on this. Specifically, a document giving "Guidance to Industry: Expedited Programs for Serious Conditions – Drugs and Biologics." (ECF No. 104-5.) This document describes the "Accelerated Approval" process. (*Id*. at 20-29.) In the

document, the FDA noticeably states that it may grant accelerated approval to a product "that is reasonably likely to predict clinical benefit …." (*Id*. at 20.) In making that decision, the FDA states that it will consider "all relevant evidence," but refuses to address specific clinical evidence needed because "such evidence is case-specific and is not readily generalizable." (*Id*. at 25.) The important factor, though, remains the "predictive potential" of the evidence to produce a clinical benefit, such as tumor shrinkage in some cancer patients. (*See id*. at 25-26.) Thus, the question is whether, in light of the evidence presented to the FDA, the Clovis Defendants could reasonably believe that it had "predictive potential" of rociletnib's clinical benefits. Based upon the allegations in the Consolidated Complaint, including that the confirmed response rate was significantly lower than the unconfirmed response rate and that 13% of 625mg dose patients experienced a grade 3 or higher QT prolongation, the "predictive potential" of Clovis' data appears, at best, to have been on shaky ground.

In addition, the FDA also noticeably states that, even if accelerated approval is granted a drug, the FDA may withdraw the same if "[a] trial required to verify the predicted clinical benefit of the product fails to verify such benefit." (*Id*. at 28.) Here, arguably, the "predicted clinical benefit" of rociletnib was verified—through the confirmatory scans required by TRIAL-X, and those scans allegedly failed to verify the purported benefit of the unconfirmed scans. Thus, it may be hard to discern how a reasonable person could expect accelerated approval to be maintained, even if it was initially granted. In that regard, it is important to note that the possibility of being granted accelerated approval was not the alleged reason why Clovis' stock price soared and then plummeted; rather, it was the possibility of tapping into an alleged $3 billion market. (*See, e.g.*, ECF No. 65 at ¶¶ 54, 353.) Thus, even if rociletnib could have possibly been given accelerated approval based

solely upon unconfirmed responses, if such approval would have been withdrawn when "verif[ied]" data failed to verify a clinical benefit, the Clovis Defendants' statements may still have been misleading.[19]

Fifth, the Consolidated Complaint alleges that rociletnib was the single most important product for Clovis, and that it was one of only three Clovis had in development during the Class Period. (ECF No. 65 at ¶ 194.) If true, these allegations are a factor in support of scienter because the Clovis Defendants had knowledge of the company's most important product, and the Clovis Defendants' attention should not have been distracted by myriad other product trials. Although the Clovis Defendants assert that knowledge can not be presumed due to their positions in the company (ECF No. 105 at 64-65), this is not what is alleged here. In other words, the Consolidated Complaint does not merely allege the Clovis Defendants' knowledge due to their positions, it also alleges that Mahaffy, Mast, and Allen "gave detailed, data-laden responses to analyst questions on multiple occasions." (*See* ECF No. 65 at ¶ 196.) As such, their knowledge is not presumed, it is affirmatively alleged, which makes this case very different to *Wolfe v. Aspenbio Pharma, Inc.*, 587 F. App'x 493, 497-498 (10th Cir. 2014). Moreover, the Court notes that, in *Wolfe*, the Tenth Circuit stated that, "[a]lthough, standing alone, the fact that a defendant was a senior executive in a company cannot

[19] The Court also notes that the FDA guidance fails to support the Clovis Defendants' contention that they did not intend to deceive investors because they sought accelerated approval on the same basis that they were given a Breakthrough Therapy Designation. (*See* ECF No. 105 at 67-68.) In the document, the FDA also discusses criteria for achieving Breakthrough Therapy Designation. (ECF No. 104-5 at 15-19.) Noticeably, the FDA states that "[i]t is important to recognize that the standard for breakthrough therapy designation is not the same as the standard for drug approval." (*Id.* at 15.) The FDA then describes the evidence supporting breakthrough therapy designation as "preliminary," and states that, "in contrast," it will review the "full data" before approving a drug for marketing. (*Id.*)

give rise to a strong inference of scienter, " it can nonetheless be "a fact relevant in our weighing of the totality of the allegations." *Id*. (quotations omitted). That is precisely the case here.[20]

Sixth, the Consolidated Complaint alleges that Clovis was "heavily dependent" upon investor capital in order to fund its operating expenses. (ECF No. 65 at ¶¶ 52, 61.) More specifically, the Consolidated Complaint alleges that Clovis generated no sales revenue during the Class Period, but had operating expenses of more than $475 million during the same time. (*Id*. at ¶ 61.) This is a factor from which scienter may be inferred because, if true, the Clovis Defendants had a strong incentive to mislead potential investors about the efficacy and safety of rociletnib in order to attract the investors' capital.[21]

This leaves *Tellabs'* battle of the motives. Plaintiffs argue that they have alleged a cogent motive in that the Clovis Defendants were motivated to conceal negative trial data in order to maintain Clovis' ability to finance pipeline products, such as the other drugs it had under development. (ECF No. 120 at 98-99.) In light of the findings *supra*, the Court agrees. As noted, the Consolidated Complaint alleges that (1) Clovis was "heavily dependent" upon investor capital to fund its operating expenses because it had no sales revenue during the Class Period, (2) Clovis'

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[20] The Court also finds the Clovis Defendants' reliance upon *Weinstein v. McClendon*, 757 F.3d 1110 (10th Cir. 2014), to be misplaced. Contrary to the Clovis Defendants' contention, in that case, the Tenth Circuit did not refuse to draw an inference of scienter based upon the importance of a program to the defendants. (*See* ECF No. 105 at 65.) Instead, the Circuit found that the alleged statements did not give rise to a cogent theory of scienter because they were too "vague and subjective." *Weinstein*, 757 F.3d at 1114. The alleged importance of the program played no part in the Circuit's reasons for rejecting the plaintiffs' claims. *See id*.

[21] Because the Court finds that the factors listed *infra* allege with particularity facts giving rise to a strong inference that the Clovis Defendants acted with scienter, the Could will not dwell on plaintiffs' reliance upon alleged sales of shares held by two of the Clovis Defendants (ECF No. 65 at ¶¶ 235-238), or defendant Allen's allegedly "sudden[]" departure from Clovis (*id*. at ¶¶ 239-242). The Court notes that, to the extent plaintiffs wish to rely upon those facts later in this case, they will require further factual development to show why they give rise to a strong inference of scienter.

operating expenses were over $475 million during the same period, with expenses rising from $84 million in 2013, to $172 million in 2014, and to $230 million in the first nine months of 2015, (3) rociletnib was one of only three drugs Clovis had under development during the Class Period, and (4) Clovis' most important drug was rociletnib. With these facts in mind, the Clovis Defendants had a strong incentive to roll out encouraging news about the development of rociletnib whether or not that drug was, in fact, developing well in order to maintain investor interest in Clovis because without that interest, the company would not have been able to continue operating.

The Clovis Defendants argue that this is not a compelling motive because it is a generalized motive shared by all businesses, citing *Fleming*. The Court disagrees. The allegations of motive here are not generalized in any sense of the word. Rather, they are tied to specific needs and circumstances of Clovis' business: notably, the alleged facts that *Clovis* had no sales revenue, *Clovis* was heavily dependent upon investor capital, *Clovis* had only three drugs under development, and *Clovis'* most important drug was *rociletnib*. Those facts are not shared by *all* businesses. Thus, although the Tenth Circuit found *generalized* motives—of facilitating a notes offering and protecting the value of stock—to be insufficient, *see Fleming*, 264 F.3d at 1269-70, that is not the situation here.[22] Put another way, as the Circuit explained in *Fleming* with respect to a different, relevant motive, the motive alleged here "is specifically and directly related to the underlying facts" of

[22] The Clovis Defendants also cite *Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869 (S.D.N.Y. May 29, 2013). However, in that case, the court characterized the alleged motives as "the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation." *Id*. at *20. The appearance of profitability and increases in compensation are not the motives alleged here; rather, the motive is enabling Clovis to continue operating by hoodwinking investors into infusing capital into the company. Thus, although the company in *Abely* was allegedly on the brink of insolvency, the reason that the court in that case rejected the alleged motive is not at issue here. *See id*.

rociletnib and Clovis' financial dependency. *See id*. at 1268. As a result, the Court finds the motive to be sufficiently cogent.

The Clovis Defendants also assert that a competing inference can be drawn from the alleged facts. Specifically, the following: "Clovis genuinely believed it had designed and executed trials that would support approval of the drug [rociletnib]." (ECF No. 105 at 76.) For present purposes, the Court will assume that the Clovis Defendants' competing inference could be drawn from the alleged facts, and even that it is a cogent inference. However, in light of the Court's interpretations of RECIST and the TRIAL-X protocols *supra*, at best, the Court finds plaintiffs' inferences of motive to be at least as compelling as the Clovis Defendants'.

Notably, as discussed, based upon the allegations and the exhibits presently before the Court, the TRIAL-X protocols provided for scheduled confirmatory scans. This requirement was supported by RECIST, except in two limited circumstances that the alleged facts do not support as existing here. Despite requiring confirmatory scans from the outset of TRIAL-X, throughout the course of the Class Period, the Clovis Defendants disclosed publicly only objective response rates based upon an unknown blend of unconfirmed and confirmed responses, even though the Clovis Defendants knew of the results of the confirmatory scans. Why did the Clovis Defendants do this? Either, because the Clovis Defendants did not think it would mislead investors and rociletnib would still be approved, or, alternatively, because the Clovis Defendants needed investors' capital to continue Clovis' operations, and thus, could not allow investors to know that initially promising unconfirmed responses had not been confirmed by follow-up responses. The Court finds the latter motive and inferences to be at least as compelling as the former.

The Clovis Defendants assert that so finding defies logic because it would not make sense for them to disclose data to the FDA knowing that, that data would doom their bid for accelerated approval. (*See* ECF No. 105 at 75-76.) This argument, though, ignores a critical point in this case; a point that is revealed in the Clovis Defendants' own pleadings. According to the Clovis Defendants, as long as an unconfirmed PR is confirmed before a patient suffers disease progression, then it is a confirmed PR. (ECF No. 105 at 66.) Thus, as long as the Clovis Defendants held on long enough until another PR could be registered, then there was no reason to accept that a response was not a confirmed PR. That, however, is simply not accurate based upon the explanation of RECIST in the EJC Article. Therein, in Table 3, it states that, if PR is followed by SD (which is neither a partial response or *progressive disease*), then the best overall response is SD. (ECF No. 104-10 at 233, 235.) The same is true if PR is followed by NE, provided that minimum criteria for SD is met, and, if not, the best overall response is NE. (*Id*. at 235.)

In this light, it is more than logical for plaintiffs to assert that the Clovis Defendants acted in the hope that positive results would overtake negative ones (*see* ECF No. 120 at 100, 104) because, based upon the Clovis Defendants' own contentions, this is precisely what they did. The problem is that their interpretation of RECIST is simply wrong. Whether the Clovis Defendants knew this or acted recklessly will be a matter for later resolution, but as of now, either level of scienter has been sufficiently pled, and that plaintiffs' alleged motive satisfies *Tellabs*.

c. Ivers-Read

The Clovis Defendants next argue that, irrespective of all of the foregoing, defendant Ivers-Read should be dismissed from this action because the Consolidated Complaint does not allege that she made any of the challenged statements, and thus, under *Janus Capital Group, Inc. v. First*

Derivative Traders, 564 U.S. 135, 131 S.Ct. 2296 (2011), she is not liable for any of the same. (ECF No. 105 at 77.) In response, plaintiffs do not appear to contest that Ivers-Read did not make any of the challenged statements, but argue she is still liable because she had or shared "ultimate authority" over them. (ECF No. 120 at 104-105.) Plaintiffs assert that this is particularly the case here, given that Ivers-Read was Clovis' Chief Regulatory Officer, and the data disclosed in Clovis' regulatory submission contradicted statements made at conferences. (*Id*. at 105.)

The Court agrees with the Clovis Defendants that the Consolidated Complaint fails to allege that Ivers-Read had authority over the challenged statements. If one thing is evident from the Consolidated Complaint in this regard, it is the noticeable lack of allegations directed toward Ivers-Read. As far as the Court can discern, Ivers-Read is mentioned when the Consolidated Complaint introduces the parties (ECF No. 65 at ¶¶ 1, 41, 424), again when the Consolidated Complaint discusses Ivers-Read's sales of Clovis shares (*id* at ¶¶ 235-236), and that is about it. Contrary to plaintiffs' contention, nowhere in the Consolidated Complaint is it mentioned, or even suggested, that, due to Ivers-Read's position as Chief Regulatory Officer, she shared ultimate authority over all or any of the challenged statements. Moreover, the paragraphs to which plaintiffs cite to support that proposition (ECF No. 120 at 105 (citing ECF No. 65 at ¶¶ 135, 152-153)), do not mention Ivers-Read, and, more importantly, do not even pertain to any of the challenged statements.

As a result, the Court GRANTS the Clovis Defendants' motion to dismiss to the extent that Ivers-Read is DISMISSED from this case. However, except for certain statements that the Court has

found to not be material, the Clovis Defendants' motion to dismiss is DENIED with respect to plaintiffs' Section 10(b) claims under the Exchange Act.[23]

2. Section 20(a) of the Exchange Act

The Clovis Defendants argue that plaintiffs' Section 20(a) claims should be dismissed because plaintiffs have failed to establish a "primary violation" of the securities laws. (ECF No. 105 at 77.) The Clovis Defendants premise this argument on "all of the reasons stated above." (*Id*.) Because the Court has found that plaintiffs have sufficiently alleged a primary violation of the Exchange Act, though, this argument is rejected. As a result, the Clovis Defendants' motion to dismiss is DENIED with respect to plaintiffs' Section 20(a) claims under the Exchange Act.

3. Sections 11 and 12(a) of the Securities Act

The Clovis Defendants argue that plaintiffs' claims under the Securities Act should be dismissed because they "suffer from even more substantial hindsight bias" in that the sources of the allegedly misleading statements (two documents filed with the SEC in connection with the July 2015 secondary offering) "predate by several months the maturation of the rociletnib efficacy data and the FDA's rejection of Clovis' blended response rate." (ECF No. 105 at 78.) This argument, like the last one, is premised upon "the same reasons discussed above." (*Id* at 80.) Because the Court has rejected those "same reasons," except with respect to certain statements found not to be material, the Court rejects them again. Thus, to the exact same degree that the Clovis Defendants' motion to

[23] In a footnote, the Clovis Defendants assert that plaintiffs have failed to plead loss causation. (ECF No. 105 at 63 n.214.) However, that argument is premised upon (a) plaintiffs' failure to plead a material misrepresentation, and (b) the Clovis Defendants' "corrective disclosures" not correcting prior misrepresentations, but merely "disclos[ing] new facts about rociletnib from new data cuts." (*Id*.) Because the Court has rejected both of those arguments *supra*, the Court finds that there is no legitimate argument opposing the sufficiency of plaintiffs' loss causation allegations at this stage of proceedings.

dismiss was denied and granted with respect to plaintiffs' Section 10(b) claims under the Exchange Act, it is also DENIED and GRANTED with respect to plaintiffs' Section 11 and 12(a) claims against the Clovis Defendants.[24]

4. Section 15 of the Securities Act

Similar to their arguments against plaintiffs' Section 20(a) claims under the Exchange Act, the Clovis Defendants challenge plaintiffs' Section 15 claims under the Securities Act because plaintiffs failed to plead a primary violation of the Securities Act. (ECF No. 105 at 80.) Because the Court just rejected that argument, though, it again rejects the same with respect to the Section 15 claims. As a result, the Clovis Defendants' motion to dismiss is DENIED with respect to plaintiffs' Section 15 claims.

B. The Venture Capital Defendants' Motion to Dismiss

Plaintiffs bring one claim against the Venture Capital Defendants pursuant to Section 15 of the Securities Act. To state a prima facie claim under Section 15, a plaintiff must plausibly allege (1) a primary violation of the securities laws, and (2) control over the primary violator by the alleged controlling person. *Maher v. Durango Metals, Inc.*, 144 F.3d 1302, 1305 (10th Cir. 1998). Here, plaintiffs allege that the Venture Capital Defendants controlled Clovis in connection with its

[24] This also means that the Court need not resolve the parties' dispute as to the proper pleading standard for claims under the Securities Act. The Clovis Defendants assert the claims should be required to satisfy Rule 9(b)'s pleading standards because they "sound in fraud." (ECF No. 105 at 79.) Plaintiffs contend that their claims need only satisfy Rule 8's notice pleading standard. (ECF No. 120 at 106-107.) Because the Court has found that plaintiffs' Section 10(b) claims satisfy the PSLRA's heightened pleading standards, given that plaintiffs' Securities Act claims are purportedly premised upon the same allegations, they necessarily satisfy Rule 9(b) too. *See Fleming*, 264 F.3d at 1258. The only additional note that the Court makes in this regard is that it is far from certain in this Circuit whether the logic behind the Clovis Defendants' point of view applies. *See Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1252 (10th Cir. 1997) ("[a]ssuming without deciding" that, if a complaint is devoid of allegations that the defendant acted negligently and is instead premised upon fraud, Rule 9(b) would apply).

secondary public offering of common stock in July 2015. (ECF No. 65 at ¶¶ 49-50.) Plaintiffs allege that the Venture Capital Defendants obtained this control through their "significant stake in Clovis," and their representation on Clovis' board of directors. (*Id*.)

To recall, the Venture Capital Defendants are made up of two distinct party groupings: (1) the NEA Defendants, and (2) Aberdare. With respect to the NEA Defendants, plaintiffs allege the following in terms of share ownership and board representation. New Enterprise Associates, which is not a party to this case, owned 6.7% of Clovis' shares at the time of the July 2015 offering. (*Id*. at ¶ 49.) At the same time, New Enterprise Associates 13, L.P., which is also not a party to this case, held the shares owned by New Enterprise Associates. NEA Partners, 13 L.P., which is a defendant in this case, was the sole general partner of New Enterprise Associates 13, L.P. In turn, NEA 13 GP, LTD, another defendant in this case, is the sole general partner of NEA Partners, 13 L.P. Finally, defendants Sandell and Baskett, along with non-party M. James Barrett ("Barrett"), are members of NEA 13 GP, LTD. Plaintiffs allege that the NEA Defendants (i.e., NEA Partners, 13 L.P.; NEA 13 GP, LTD; Sandell; and Baskett) and Barrett "held all dispositive and voting power with respect to all Clovis shares held by New Enterprise Associates 13, L.P." Plaintiffs further allege that Barrett represented the NEA Defendants on Clovis' board. (*Id*.)

Somewhat less complicated, Aberdare, the actual defendant in this case, is alleged to have owned 2.5% of Clovis' shares at the time of the July 2015 offering. (*Id*. at ¶ 50.) Plaintiffs allege that Aberdare and Paul Klingenstein ("Klingenstein"), a non-party to this case, held all dispositive and voting power for the shares held by Aberdare. Plaintiffs further allege that Klingenstein represented Aberdare on Clovis' board. In addition, plaintiffs allege Aberdare's control due to it

being a party to a 2009 investor rights agreement, which entitled Aberdare to "registration right and access to Company information." (*Id*. at ¶ 50.)

Apart from joining the Clovis Defendants' arguments concerning a primary violation of the securities laws (ECF No. 98 at 2 & n.2), which the Court has rejected *supra*, the Venture Capital Defendants argue that plaintiffs have failed to plausibly plead their control over Clovis in connection with the July 2015 offering (*id*. at 2-12). More specifically, the Venture Capital Defendants assert that holding a minority stake in a company and serving on a board of directors are insufficient to provide control, and there are no allegations otherwise indicating control, such as influence over day-to-day operations or control over the July 2015 offering. (*Id*. at 7-10.) As to Aberdare's investor rights agreement with Clovis, the Venture Capital Defendants assert that there is no allegation that Aberdare attempted to exercise any of its rights under the same. (*Id*. at 10-11.) The Venture Capital Defendants request that the Consolidated Complaint be dismissed with prejudice. (*Id*. at 3, 11-12.)

The two most pertinent cases from the Tenth Circuit are *Maher* and *Adams*. In *Maher*, the Circuit applied the following definition of control: "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." *Maher*, 144 F.3d at 1305 (quotation omitted). The Tenth Circuit concluded that the alleged facts that the defendant had (1) access to a company's non-public information, (2) acquired stock in the company, and (3) the option to acquire a controlling interest in the company, were insufficient to plead control, especially when there was no allegation that the defendant had threatened to exercise its right to acquire a controlling interest. *Id*. at 1305-06. In *Adams*, the Tenth Circuit, applying the same definition of control, concluded that the plaintiffs had failed to allege sufficient facts that one of the defendants was a control person

because it was alleged that the defendant was "simply a member of the board of directors," without any allegation that he exerted control or influence over the day-to-day running of the company. *Adams*, 340 F.3d at 1108.

In light of the Tenth Circuit's definition of control in *Maher* and *Adams*, this Court agrees with the Venture Capital Defendants that neither the NEA Defendants nor Aberdare are control persons for purposes of Section 15 of the Securities Act. Importantly, plaintiffs allegations fail to show that the Venture Capital Defendants had the power to direct or cause the direction of management and policies of Clovis. Plaintiffs rely upon the Venture Capital Defendants' "significant stakes" and "concomitantly significant voting power" in Clovis. (ECF No. 120 at 109.) However, those characterizations are simply not accurate in light of plaintiffs' allegations that (1) the NEA Defendants held only 6.7% and Aberdare even less at 2.5% of Clovis' shares, and (2) at most, the NEA Defendants and Aberdare were each connected to just one member of Clovis' board of directors. (*See* ECF No. 65 at ¶¶ 49-50.) Those numbers simply do not add up to "significant" stock holdings or voting power, and, more importantly, do not amount to the power to control or direct.[25]

Plaintiffs also rely upon the investor rights agreement between Aberdare and Clovis (ECF No. 120 at 109-110), but the Court does not discern how the ability to access company information and "registration right" somehow resulted in Aberdare being able to cause the direction of management and policies. This is especially the case given that, in *Maher*, the Tenth Circuit

[25] The Court further notes that it is not just the Venture Capital Defendants who allegedly held all power with respect to their respective share holdings. Notably, the Consolidated Complaint alleges that Barrett, with respect to the NEA Defendants, and Klingenstein, with respect to Aberdare, held power over the respective share holdings. (*See* ECF No. 65 at ¶¶ 49-50.) Neither Barrett nor Klingenstein are defendants in this case, and thus, it is very hard to say that the Venture Capital Defendants alone held power over the respective share holdings, even if those holdings did amount to sufficient control over Clovis.

concluded that access to company information and the ability to acquire a *controlling interest* in a company were insufficient. *See Maher*, 144 F.3d at 1306.

Finally, plaintiffs rely upon the Venture Capital Defendants' alleged representation on Clovis' board of directors, and the representatives alleged power to "sign or withhold their signature to the registration statement at issue in this case." (ECF No. 120 at 110.) First, there is no allegation in the Consolidated Complaint that the alleged representatives (Barrett and Klingenstein) had the power to sign or withhold their signature from the relevant registration statement. Second, there is no allegation in the Consolidated Complaint that either Barrett or Klingenstein did sign the relevant registration statement. The allegations to which plaintiffs cite to support these contentions (ECF No. 120 at 110 (citing ECF No. 65 at ¶¶ 431-33, 479-80)) do not come close, as they merely recite the background information regarding share ownership, board representation, and the investor rights agreement that the Court summarized *supra*.[26]

Third, the case from this District to which plaintiffs cite for support, *In re Oppenheimer Rochester Funds Group Sec. Litig.*, 838 F. Supp. 2d 1148, 1181-82 (D. Colo. 2012), is distinguishable because, in that case, the defendants "personally sign[ed]" the relevant registration statements. *Id*. Here, there is no such allegation. Fourth, to the extent that the findings in *Oppenheimer* can be construed as supporting plaintiffs' argument, this Court disagrees with those findings. In *Adams*, the Tenth Circuit stated that "simply [being] a member of the board of directors" was insufficient, "without any allegation that the person individually exerted control or

[26] The Court also finds plaintiffs' allegations regarding the NEA Defendants' and Aberdare's representation on Clovis' board to be tenuous at best. Respectively, the only allegations supporting this are the following conclusory statements: "By virtue of … their representation, though Barrett, on Clovis' board of directors"; and "By virtue of … its representation, through Klingenstein, on Clovis' board of directors". (*See* ECF No. 65 at ¶¶ 49-50.) Why the Court should construe Klingenstein and Barrett's position on the board as representing the NEA Defendants and Aberdare, respectively, is not alleged.

influence over the day-to-day operations of the company." *Adams*, 340 F.3d at 1108. Here, plaintiffs do not allege any control over the day-to-day operations of Clovis; instead, they rely upon Barrett and Klingenstein's alleged power to sign or not sign the relevant registration statement. Those two things are not the same. Any finding otherwise would contravene the interpretation of 'control' applied in *Maher* and *Adams*, which involves the direction of *management and policy*, not the signing of registration statements. Thus, even if the Consolidated Complaint had alleged that Barrett and Klingenstein had the power to sign or withdraw their signatures from the registration statement, this still would not have been sufficient under *Adams*.[27]

As a result, the Court GRANTS the Venture Capitalist Defendants' motion to dismiss. In addition, because it does not appear that amendment can cure the deficiencies in the Consolidated Complaint, the Court DISMISSES the same WITH PREJUDICE as to the Venture Capitalist Defendants.

C. The Underwriter Defendants' Motion to Dismiss

Plaintiffs bring claims against the Underwriter Defendants pursuant to Section 11 and 12(a) of the Securities Act.

1. Section 12(a) of the Securities Act

Section 12(a)(2) makes any person liable who offers or sells a security in a prospectus or oral communication that includes an untrue statement of material fact or omits to state a material fact. 15 U.S.C. § 77l(a)(2). Such a seller is liable "to the person purchasing such security from him." *Id.*

[27] Plaintiffs' assertion that *Adams* is inapplicable because it concerned Section 20(a) of the Exchange Act, rather than Section 15 of the Securities Act (ECF No. 120 at 110 n.60), is misplaced, given that one of the cases upon which *Adams* relies is *Dennis v. Gen. Imaging, Inc.*, 918 F.2d 496 (5th Cir. 1990), *see Adams*, 340 F.3d at 1108, which involved control person violations of both Section 15 of the Securities Act and Section 20 of the Exchange Act. *Dennis*, 918 F.2d at 508-10.

The Underwriter Defendants argue that plaintiffs' Section 12(a)(2) claim should be dismissed because plaintiffs fail to allege that the Underwriter Defendants are "sellers" for purposes of the statute. (ECF No. 103 at 3.) The Underwriter Defendants assert that, to plead they are "sellers," the Consolidated Complaint needed to allege that they either (1) directly passed title of the alleged security to plaintiffs, or (2) directly solicited the sale of the security and were motivated in part to serve their own financial interests or the financial interests of the securities owner. (*Id*. at 9.) In their response to the Underwriter Defendants' motion to dismiss, plaintiffs do not appear to contest that the Underwriter Defendants did not directly solicit the sale of securities. (*See* ECF No. 120 at 108-109 (containing one page of response dedicated to whether the Underwriter Defendants' "passed title" of the Clovis securities to plaintiffs)). As a result, the Court will focus solely upon the parties' dispute as to the Underwriter Defendants' first argument.

Plaintiffs assert that their allegations are sufficient because all that is required are allegations that a plaintiff "purchased directly in the offering." (ECF No. 120 at 108.) In contrast, the Underwriter Defendants assert that the Consolidated Complaint is deficient because it does not allege a "buyer-seller relationship" in that there are no allegations that plaintiffs directly purchased securities from any one of the Underwriter Defendants. (ECF No. 103 at 10.)

A person is liable to a purchaser of securities if that person "pass[es] title, or other interest in the security, to the buyer for value." *Pinter v. Dahl*, 486 U.S. 622, 642, 108 S.Ct. 2063 (1988).[28] What does it mean then to pass title for value? The Supreme Court stated that it "contemplates a buyer-seller relationship not unlike traditional contractual privity." *Id*. The Tenth Circuit, in dicta,

[28] Although *Pinter* involved analysis of the term "seller" as used in Section 12(a)(1) of the Securities Act, the Tenth Circuit interprets "seller" in Section 12(a)(2) in the same way. *See Maher*, 144 F.3d at 1307 & n.10.

has explained that Section 12(a)(2) has "an express privity requirement, giving a cause of action only to individuals who purchase securities directly from a person who sells the securities by means of a prospectus." *See Joseph v. Wiles*, 223 F.3d 1155, 1161 (10th Cir. 2000) (distinguishing Section 12(a)(2) from Section 11 of the Securities Act). The need for privity and a direct relationship between buyer and seller then appears fairly clear.

The next question is what does a plaintiff need to allege in order to get a Section 12(a)(2) claim past a motion to dismiss? On that issue, the Tenth Circuit has not spoken, but, both parties offer cases which they claim are persuasive. As an initial matter, it is important to reiterate what Section 12(a)(2) requires. As just mentioned, the Supreme Court and the Tenth Circuit have described Section 12(a)(2) as requiring "a buyer-seller relationship not unlike traditional contractual privity," *Pinter*, 486 U.S. at 642, and "an *express privity requirement*, giving a cause of action only to individuals who purchase securities *directly from* a person who sells the securities by means of a prospectus," *Joseph*, 223 F.3d at 1161 (emphasis added). It would be odd then for Section 12(a)(2) to require a direct purchase from a seller or a buyer and seller relationship, only to allow a Section 12(a)(2) claim to survive dismissal based upon allegations that do not suggest such a relationship exists.

The lack of such a relationship (or, in fact, *any* relationship), though, is precisely what plaintiffs contend should be allowed; i.e., all that is needed is an allegation that plaintiffs "purchased directly in the offering." (ECF No. 120 at 108.) But purchased from whom? Plaintiffs apparently do not believe that 'from whom' is a necessary allegation, whether it be from the Underwriter Defendants collectively or individually. For all that the bare-boned allegations in the Consolidated Complaint provide is that "*Defendants named in this Count*, through one or more public offerings,

solicited and sold Clovis common stock to members of the Class." (ECF No. 65 at ¶ 469) (emphasis added). The remainder of plaintiffs' allegations are no more helpful, and are damaging for the survival of this claim.

Notably, the Consolidated Complaint states that the Section 12(a)(2) claim is asserted by "Named Plaintiff St. Petersburg," and, at the end of the pleading, in a Schedule, sets forth the number of shares bought by St. Petersburg, the price they were bought at, and the date they were bought on. (*See id*. at 159, ¶ 466.) The dates are particularly important. To recall, the July 2015 offering took place on July 14, 2015. (*Id*. at ¶ 436.) None of St. Petersburg's alleged purchases, however, took place on that date; instead, the only purchases occurring in July 2015 took place on July 9 and July 20, 2015. (*Id*. at 159.) Thus, although the Consolidated Complaint attempts to obfuscate the issue, it does not appear that St. Petersburg bought shares directly from any of the Underwriter Defendants, at least not on the day of the July 2015 offering. Instead, St. Petersburg bought shares "traceable to[] the Company's July 2015 Offering" and/or "pursuant to the Registration Statement." (*Id* at ¶¶ 419, 474.)

Both of these allegations very easily could place St. Petersburg's purchases outside of the July 2015 offering and away from any of the Underwriter Defendants. For example, what does "pursuant to the Registration Statement" mean? Does it mean that St. Petersburg relied upon the representations in the Registration Statement when it purchased its shares? If so, St. Petersburg could have relied upon the Registration Statement while still purchasing shares from a third party. As such, it is far from plausible that plaintiffs' have alleged *any* relationship between St. Petersburg and the Underwriter Defendants, let alone a buyer-seller relationship (whatever that may mean for purposes of a motion to dismiss). Equally confusing, as noted, the Consolidated Complaint alleges

that "Defendants named in this Count, *through one or more public offerings*, solicited and sold Clovis common stock to members of the Class." (*Id*. at ¶ 469) (emphasis added). The problem with this is that the Consolidated Complaint, when discussing the Underwriter Defendants, alleges that they only sold shares as part of the July 2015 offering; not through *multiple* public offerings. (*See id*. at ¶¶ 426-429.)

In these respects, this case is far different to the cases cited by plaintiffs where, for example, the plaintiffs alleged that they purchased stock *on the day of* the offering. *See In re BioScrip, Inc. Sec. Litig.*, 95 F. Supp. 3d 711, 745 (S.D.N.Y. 2015); *see also In re Westinghouse Sec. Litig.*, 90 F.3d 696, 718 (3d Cir. 1996) (concluding that, "[t]aken in the light most favorable to plaintiffs, the first amended complaint alleges that each of the underwriter defendants sold Westinghouse securities directly to plaintiffs and that each plaintiff purchased Westinghouse securities directly from an underwriter defendant."); *In re Washington Mutual, Inc. Sec., Derivative & ERISA Litig.*, 259 F.R.D. 490, 508 (W.D. Wash. 2009) (alleging that the plaintiffs purchased securities "on the October 2007 Offering.") (alteration omitted); *Northumberland Cnty. Ret. Sys. v. Kenworthy*, 2013 WL 5230000, at *8 (W.D. Okla. Sep. 16, 2013) (explaining that it was undisputed that "the offerings in question were firm commitment offerings," whereby "the underwriters purchase shares from the issuing company and then sell them to the public"); *In re Scottish Re Grp. Sec. Litig.*, 524 F. Supp. 2d 370, 400 (S.D.N.Y. 2007) (same).

As a result, the Court finds that plaintiffs have failed to allege a plausible claim that the Underwriter Defendants are sellers for purposes of Section 12(a)(2). The Consolidated Complaint does not allege that St. Petersburg bought directly from the Underwriter Defendants, the Consolidated Complaint does not allege that the July 2015 offering was a type of offering (like a firm

commitment offering) whereby the Underwriter Defendants sold directly to the public, and the Consolidated Complaint does not even allege that St. Petersburg bought on the day of the July 2015 offering (in fact, it alleges the opposite). Thus, even if the Court was prepared to find that plaintiffs were not required to allege from which specific Underwriter Defendant St. Petersburg bought its shares, plaintiffs' allegations are still way short of what would be necessary.

Nonetheless, unlike the claims brought against the Venture Capital Defendants, the deficiencies in plaintiffs' pleadings against the Underwriter Defendants can, arguably, be remedied by providing additional detail in an amended pleading Therefore, although the Court GRANTS the Underwriter Defendants' motion to dismiss with respect to plaintiffs' Section 12(a)(2) claim, the Court does so WITHOUT PREJUDICE. Plaintiffs shall have 14 days from entry of this Order to file an amended pleading directed *solely* as to their Section 12(a)(2) claim against the Underwriter Defendants. Should plaintiffs fail to file an amended pleading by that deadline, then the Section 12(a)(2) claim against the Underwriter Defendants will be deemed dismissed *with prejudice*.

2. Section 11 of the Securities Act

The Underwriter Defendants rely upon the Clovis Defendants' motion to dismiss with respect to the claim brought under Section 11 of the Securities Act. (ECF No. 103 at 2.) Because the Court has granted the Clovis Defendants' motion to dismiss with respect to the Section 11 claim only as to certain statements that the Court has found to be immaterial, and denied the motion to dismiss in all other respects, the Court likewise DENIES and GRANTS the Underwriter Defendants' motion to dismiss with respect to the Section 11 claim in the exact same manner.

IV. Conclusion

For the reasons discussed herein, the Court:

(1) GRANTS the Venture Capitalist Defendants' Motion to Dismiss (ECF No. 98), and DISMISSES the Consolidated Complaint WITH PREJUDICE as to the Venture Capitalist Defendants;

(2) GRANTS in part and DENIES in part the Underwriter Defendants' Motion to Dismiss (ECF No. 103) as follows:

(a) GRANTS the Motion to Dismiss with respect to plaintiff's claim under Section 12(a) of the Securities Act WITHOUT PREJUDICE;

(b) GRANTS the Motion to Dismiss with respect to plaintiff's claim under Section 11 of the Securities Act to the extent that it relies upon statements characterizing rociletnib as "promising," "very active," "very compelling" or "compelling," "impressive," "striking," "surprising," "encouraging," and "not noise"; and

(b) DENIES the Motion to Dismiss with respect to plaintiff's claim under Section 11 of the Securities Act in all other respects;

(3) GRANTS in part and DENIES in part the Clovis Defendants' Motion to Dismiss (ECF No. 105) as follows:

(a) GRANTS the Motion to Dismiss with respect to any claims that rely upon statements characterizing rociletnib as "promising," "very active," "very compelling" or "compelling," "impressive," "striking," "surprising," "encouraging," and "not noise";

(b) GRANTS the Motion to Dismiss with respect to all claims against defendant Ivers-Read, and DISMISSES the Consolidated Complaint WITH PREJUDICE as to Ivers-Read; and

(b) DENIES the Motion to Dismiss in all other respects; and

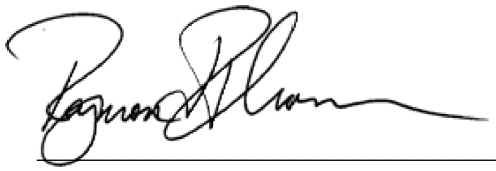
(4) GRANTS in part and DENIES in part the Clovis Defendants' Motion Requesting Judicial Notice in Support of Motion to Dismiss Consolidated Class Action Complaint (ECF No. 104).

Plaintiffs shall have 14 days from entry of this Order to file an amended pleading directed *solely* as to their Section 12(a) claim against the Underwriter Defendants. Should plaintiffs fail to file an amended pleading by that deadline, then the Section 12(a) claim against the Underwriter Defendants will be deemed dismissed *with prejudice*.

SO ORDERED.

DATED this 9th day of February, 2017.

BY THE COURT:



RAYMOND P. MOORE
United States District Judge