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11 UNITED STATES DISTRICT COURT  
 12 CENTRAL DISTRICT OF CALIFORNIA  
 13 SOUTHERN DIVISION

14 HSINGCHING HSU, Individually and )  
 15 on Behalf of All Others Similarly )  
 Situated, )

16 Plaintiff, )

17 vs. )

18 PUMA BIOTECHNOLOGY, INC., et )  
 19 al., )

20 Defendants. )

Case No. 8:15-cv-00865-AG-SHK

CLASS ACTION

PLAINTIFF'S OPPOSITION TO  
DEFENDANTS' MOTION FOR  
SUMMARY JUDGMENT

DATE: September 24, 2018

TIME: 10:00 a.m.

CTRM: 10D

JUDGE: Hon. Andrew J. Guilford

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Federal Rules of Civil Procedure

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**APPENDIX OF ACRONYMS AND DEFINED TERMS**

<b>Acronym/Defined Term</b>	<b>Meaning/Reference</b>
AE	Adverse event
ASCO	American Society of Clinical Oncology
DFS	Disease-free survival
ITT	Intent to treat
KM curves	Kaplan-Meier curves
DBr.	Memorandum in Support of Defendants’ Motion for Summary Judgment (ECF No. 372-1)
DSUF	Statement of Uncontroverted Facts and Conclusions of Law in Support of Defendants’ Motion for Summary Judgment (ECF No. 378-1)
DEx.	Defendants’ exhibits attached to the Declaration of Kristin N. Murphy in Support of Defendants’ Motion for Summary Judgment (ECF No. 376) or the Declaration of Alan H. Auerbach in Support of Defendants’ Motion for Summary Judgment (ECF No. 375)
RDSUF	Plaintiff’s Statement of Genuine Disputes of Material Fact to Defendants’ Statement of Uncontroverted Facts and Conclusions of Law (filed August 14, 2018)
PSUF	Plaintiff’s Statement of Uncontroverted Facts in Support of Plaintiff’s Opposition to Defendants’ Motion for Summary Judgment (filed August 14, 2018)
PEx.	Plaintiff’s exhibits attached to the Declaration of Trig R. Smith in Support of Plaintiff’s Opposition to Defendants’ Motion for Summary Judgment (filed August 14, 2018)

1 **1. INTRODUCTION AND OVERVIEW OF DEFENDANTS’**  
2 **SECURITIES FRAUD**

3 This is a straight-forward case of securities fraud. On July 22, 2014, Defendants  
4 announced the top-line results of the ExteNET trial, touting the positive efficacy and  
5 benign safety results of the drug neratinib. In response, Puma’s stock price  
6 skyrocketed from \$59 per share on July 22, 2014, to \$233 per share by the close of  
7 trading on July 23, 2014. The truth was that the ExteNET trial results showed  
8 neratinib’s marginal efficacy and alarming toxicity. Defendants misled investors.  
9 Specifically:

- 10 • Defendants led investors to believe that DFS, the primary endpoint of the  
11 trial, was 86% in the placebo arm and 90%-91% in the neratinib arm for  
12 an absolute difference in DFS of 4%-5%. In fact, the DFS rates in the  
13 placebo and neratinib arms were 91.6% and 93.9%, respectively, for an  
14 absolute difference of only 2.3%.
- 15 • Defendants stated that the KM curves for the trial, the visual  
16 representation of the DFS rates over time, were separating at and after  
17 two years of the trial. Those KM curves were actually narrowing at the  
18 end of two years.
- 19 • Defendants told investors that they had not seen the safety results from  
20 the ExteNET trial, but that they anticipated the rate of Grade 3+ diarrhea,  
21 the primary side effect with neratinib, would be 29%-30%. Defendants  
22 had the safety results from the trial and knew the Grade 3+ diarrhea rate  
23 was 39.9%.
- 24 • Defendants repeated that they had not seen the safety results from the  
25 ExteNET trial, and claimed the dropout rate in the neratinib arm due to  
26 AEs should be in the 5%-10% range. But the safety results identified  
27 that 16.8% of neratinib users discontinued the drug due to diarrhea AEs  
28 alone, and the total dropout rate due to AEs was 27.6%.

1 Throughout the Class Period, Defendants continued to tout the purported  
2 findings from the ExteNET trial while failing to disclose the true safety and efficacy  
3 results. As a result, Puma's shares continued to trade at inflated levels. Taking  
4 advantage of this artificial inflation, Defendants sold 1.15 million shares of Puma  
5 stock in a January 2015 stock offering, raising more than \$218 million, and rewarded  
6 themselves with \$22.3 million in compensation and bonuses.

7 Defendants' lies were revealed beginning on May 13, 2015, when ASCO  
8 released an abstract that disclosed the actual DFS rates in the ExteNET trial (including  
9 the marginal 2.3% absolute difference in DFS rates), and that 40% of neratinib users  
10 suffered Grade 3+ diarrhea. The market reacted sharply, and Puma's stock price  
11 immediately dropped \$40 per share. On June 1, 2015, during the ASCO conference,  
12 the results of the ExteNET trial were presented, including the actual KM curves and  
13 the discontinuation rate due to diarrhea AEs. In response, Puma's stock price  
14 plummeted another \$48 per share. All told, members of the Class lost up to \$87.20  
15 per share as a result Defendants' fraud.

16 Faced with these facts, Defendants spend nearly half of their summary  
17 judgment brief trying to rewrite them. DBr. at 3-13. But much of that revisionist  
18 history is untethered to any argument. Even more of it is inaccurate. And none of it  
19 supports summary judgment on the elements of falsity, scienter, or loss causation. On  
20 falsity and scienter, as this Court already recognized, "[t]he most direct way to show  
21 both that a statement was false when made and that the party making the statement  
22 knew it was false is via contemporaneous reports or data, available to the party, which  
23 contradict the statement.'" ECF No. 76 at 19 (quoting *Nursing Home Pension Fund,*  
24 *Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004)). Plaintiff has done  
25 just that. On loss causation, Defendants concede that there is no dispute about the loss  
26 caused by the May 13, 2015 disclosure of the true DFS and diarrhea rates. They then  
27 fail to meet their burden of establishing that the undisputed stock price decline on  
28 June 1-2, 2015 was caused by something other than the disclosure of the actual KM

1 curves and AE discontinuation rate. That stands in sharp contrast to Plaintiff's  
2 evidence that the fraud-related disclosures caused Puma's stock price decline.  
3 Defendants' motion should be denied.

## 4 **2. LEGAL STANDARD**

5 Summary judgment is only appropriate where the record, read in the light most  
6 favorable to the nonmoving party, shows that "there is no genuine dispute as to any  
7 material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ.  
8 P. 56(a). A factual issue is "genuine" when there is sufficient evidence such that the  
9 jury could resolve the issue in the nonmovant's favor, and an issue is "material" when  
10 its resolution might affect the outcome of this suit under the governing federal  
11 securities laws. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The  
12 moving party initially has the burden to show an absence of a genuine issue of  
13 material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Only if that  
14 showing is made does the burden shift to the nonmovant to identify evidence showing  
15 there is a genuine issue for trial. *Id.* at 324.

16 Because Plaintiff is the nonmoving party, its evidence must be taken as true,  
17 and the Court must view the facts and draw reasonable inferences in the light most  
18 favorable to Plaintiff. *See Scott v. Harris*, 550 U.S. 372, 378 (2007). Moreover, "[i]f  
19 [Plaintiff] produces direct evidence of a material fact, the court may not assess the  
20 credibility of this evidence nor weigh against it any conflicting evidence presented by  
21 [Defendants]." *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626,  
22 631 (9th Cir. 1987). "Thus, the court's ultimate inquiry is . . . whether the 'specific  
23 facts' set forth by the [Plaintiff], coupled with undisputed background or contextual  
24 facts, are such that a rational or reasonable jury *might* return a verdict in its favor  
25 based on that evidence." *Id.* "If so, the Court must deny the motion for summary  
26 judgment." *Lund v. Crane Co.*, 2016 WL 2742383, at \*2 (C.D. Cal. May 10, 2016).

27  
28

1 **3. DEFENDANTS’ STATEMENTS ABOUT THE EXTENET**  
2 **RESULTS WERE FALSE AND MISLEADING WHEN MADE**

3 A statement is misleading if it “‘affirmatively create[s] an impression of a state  
4 of affairs that differs in a material way from the one that actually exists.’” *Todd v.*  
5 *STAAR Surgical Co.*, 2016 WL 6699284, at \*5 (C.D. Cal. Apr. 12, 2016) (quoting  
6 *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)). “[O]nce  
7 defendants cho[o]se to tout’ positive information to the market, ‘they [are] bound to  
8 do so in a manner that wouldn’t mislead investors,’ including disclosing adverse  
9 information that cuts against the positive information.” *Schueneman v. Arena Pharm.,*  
10 *Inc.*, 840 F.3d 698, 705-06 (9th Cir. 2016). Moreover, “‘statements, although  
11 literally accurate, can become, through their context and manner of presentation,  
12 devices which mislead investors. For that reason, the disclosure required by the  
13 securities laws is measured not by literal truth, but by the ability of the material to  
14 accurately inform rather than mislead prospective buyers.’” *Miller v. Thane Int’l,*  
15 *Inc.*, 519 F.3d 879, 886 (9th Cir. 2008). Thus, the question of “‘whether a public  
16 statement is misleading . . . is a mixed question to be decided by the trier of fact.’”  
17 *SEC v. Todd*, 642 F.3d 1207, 1220 (9th Cir. 2011) (quoting *Fecht v. Price Co.*, 70  
18 F.3d 1078, 1081 (9th Cir. 1995)); *see also SEC v. Mozilo*, 2009 WL 3807124, at \*9  
19 (C.D. Cal. Nov. 3, 2009) (assertions that statements were not misleading are “rarely  
20 successful on a motion for summary judgment”).<sup>1</sup>

21 **3.1. Defendants’ Statements About the DFS Rates and 33%**  
22 **Improvement in DFS Were False and Misleading**

23 On July 22, 2014, in response to an analyst’s questions, Alan Auerbach agreed  
24 that the DFS rates in the ExteNET trial for the placebo and neratinib groups were  
25 “around 86% or so” and “90% or 91%,” respectively. PSUF 1-3. Auerbach also told  
26 investors that they could “do a 33% improvement in DFS and come up with that

27 <sup>1</sup> Defendants attach, as Appendix A to their memorandum, a purported chart of the  
28 alleged false and misleading statements. But that chart does not identify all of the  
alleged statements and inaccurately identifies the speaker for many of the statements.

1 calculation, given the numbers we gave,” which equated to an absolute DFS  
2 difference of 4%-5%. PSUF 3. In fact, the placebo DFS rate was 91.6%, the neratinib  
3 DFS rate was 93.9%, and the absolute difference in DFS rates was only 2.3%. PSUF  
4 6-8. Auerbach’s statements were unequivocally false.

5 Defendants say “Plaintiff now admits” that the statement about a 33%  
6 improvement in DFS “was true.” DBr. at 1. That’s not right. Plaintiff specifically  
7 denied Defendants’ requests for admissions on that very subject. PEx. 139 at RFA  
8 Nos. 16-22. Defendants also say that Plaintiff “abandoned” the claim that the 33%  
9 statement was false when made. DBr. at 14. That’s not right either. Plaintiff  
10 maintains and the facts have established that Defendants’ statements about the 33%  
11 relative DFS improvement in the ExteNET trial, as described by Auerbach on July 22,  
12 2014, were false. But, Defendants argue, the hazard ratio in the ExteNET trial was  
13 0.67, which equates to a 33% improvement in the relative risk of disease recurrence.  
14 DBr. at 14. That’s true. But, to have any meaning, it begs the question of “what is the  
15 recurrence rate?” See PEx. 21 at 10-14; PEx. 22, ¶¶11-13. And when Auerbach was  
16 asked that very question on July 22, 2014, he lied. He placed the 33% improvement  
17 in the context of the (false) 86% placebo DFS rate and 90%-91% neratinib DFS rate.  
18 PSUF 3. So, even if “literally true,” Defendants’ statements about the 33% relative  
19 improvement was still “misleading and thus actionable under the securities laws.”  
20 *Brody*, 280 F.3d at 1006.<sup>2</sup>

21 \_\_\_\_\_  
22 <sup>2</sup> Defendants repeatedly claim that “Plaintiff’s own investment advisor, who had  
23 unfettered discretion over the account and whose admissions are therefore binding on  
24 Plaintiff, testified that she did not believe Mr. Auerbach . . . ‘ever misled me in any  
25 way.’” DBr. at 3, 12, 14, 16. One, Defendants did not depose Philip May, who was  
26 actually Plaintiff’s investment advisor at Capital International Limited. PSUF 9.  
27 Instead, Defendants deposed Skye Drynan, one of multiple analysts at Capital who  
28 covered Puma. PSUF 10. Drynan did not have “unfettered discretion” over Plaintiff’s  
account. In fact, she has never communicated with any representative of Plaintiff and  
was not even aware of the fact that Plaintiff had acquired Puma stock before her  
deposition. PSUF 11-12. Her testimony could not bind Plaintiff. It couldn’t even  
bind Capital. And, while Defendants suggest that Drynan exonerated Defendants, she  
actually testified that she had never investigated whether Auerbach committed  
securities fraud, but would want to know if he did. PEx. 5 at 177:20-180:22.

1 Defendants next argue that just identifying the 33% relative improvement did  
2 not create an “affirmative duty” to disclose the absolute difference in DFS rates. DBr.  
3 at 14-15. But Defendants didn’t just identify the relative DFS improvement.  
4 Auerbach spoke about the DFS rates and placed the 33% relative improvement result  
5 in the context of those (false) rates. PSUF 3. “By voluntarily” speaking about the  
6 DFS rates, he “assume[d] a duty to speak fully and truthfully on those subjects.”  
7 *FindWhat Inv’r Grp. v. FindWhat.com*, 658 F.3d 1282, 1305 (11th Cir. 2011); *see also*  
8 *Meyer v. JinkoSolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014) (“once a  
9 company speaks on an issue or topic, there is a duty to tell the whole truth”).<sup>3</sup>

10 Defendants also try to rewrite the transcript of the July 22, 2014 conference  
11 call. DBr. 15-16. They argue that Auerbach “kept his response vague” about the DFS  
12 rates. That’s not true. He specifically said he would be “comfortable” with the  
13 estimated placebo DFS rate of 86% and agreed with the estimated neratinib DFS rate  
14 of 90% or 91%. PSUF 3. The audio recording of the call evidences no hesitation or  
15 attempt to hedge those statements. PEx. 67. Defendants claim Auerbach was  
16 implying an absolute DFS range of 1%-6%, encompassing the actual 2.3% rate. DBr.  
17 at 15. First, that would still make his statements about the individual DFS rates false.  
18 Second, it makes no sense: given a 33% relative improvement, it is impossible to  
19 arrive at a 2.3% absolute difference in DFS rates with a placebo DFS rate of 86% (or  
20 anywhere between 86%-89%) or a drug DFS rate of 90% or 91%. PSUF 4-5.

21 Auerbach’s statements undoubtedly “create[d] an impression of a state of  
22 affairs that differ[ed] [materially] from the one that actually exist[ed].” *In re Quality*  
23 *Sys.*, 865 F.3d 1130, 1144 (9th Cir. 2017). Following Defendants’ July 22, 2014

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24 <sup>3</sup> Defendants’ affirmative misstatements about the DFS rates render their cited  
25 authority distinguishable. *See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus.*  
26 *Pension Fund*, \_\_\_ U.S. \_\_\_, 135 S. Ct. 1318, 1322 (2015) (case concerned alleged  
27 omissions); *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 878 (9th Cir. 2012)  
28 (case concerned “disagreements with . . . statistical methodology” and not  
misrepresentations regarding results); *Kleinman v. Elan Corp.*, 706 F.3d 145, 152-53  
(2d Cir. 2013) (case “center[ed] on omissions” and statements were not alleged to be  
“literally false”); *see also* ECF No. 76 at 19 (distinguishing *Kleinman*).

1 statements, the estimated 4%-6% absolute difference in DFS rates in ExteNET was  
2 widely reported. PSUF 13-15. Defendants counter that “Mr. Werber [the analyst who  
3 had asked Auerbach about the DFS rates on July 22, 2014] and an independent breast-  
4 cancer oncologist provided their expectations for the absolute DFS rate in a range of  
5 2-8%.” DBr. at 16. Really? No. Defendants cite to the portion of the transcript  
6 where the doctor, who was not aware of the July 22, 2014 conference call, explained  
7 the importance of knowing “the actual magnitude of difference” in the DFS rates:  
8 “let’s assume though that it’s [the placebo DFS] like 85%. If you have a hazard ratio  
9 of 0.67 then in theory you reduce that risk by a third. So instead of 85%, you know,  
10 you should be something like 90% which is a 5% absolute difference and I think is a  
11 difference most people would think of as pretty robust and worthwhile.” DEx. 110 at  
12 CGMI000475; RDSUF No. 70. To which Werber responded: “so we’ve actually  
13 asked on the call” and Auerbach had confirmed the placebo DFS rate was 86%-87%  
14 (and the neratinib DFS rate was 90%-91%). *Id.* None of the reports issued by Werber  
15 (or anyone else) identified a potential absolute DFS difference range of 2%-8%.  
16 PSUF 14-15; RDSUF 70. To the contrary, Werber testified that in October 2014,  
17 Auerbach again assured him that the placebo DFS rate in the ExteNET trial was  
18 “~86%” and the neratinib DFS rate was “~90%.” PSUF 16.

19 Defendants also argue that in February 2015 Auerbach disclosed that the  
20 absolute DFS difference could be “2, 3% at year two” and there was no market  
21 reaction. DBr. at 16. That is, at best, a truth-on-the-market defense for which  
22 Defendants would “bear a heavy burden” of “prov[ing] that the information that was  
23 withheld or misrepresented was “transmitted to the public with a degree of intensity  
24 and credibility sufficient to effectively counterbalance any misleading impression  
25 created by insider’s one-sided representations.”” *Provenz v. Miller*, 102 F.3d 1478,  
26 1492-93 (9th Cir. 1996). Defendants haven’t done that – nor can they. On its face,  
27 the statement is just about what the result Auerbach thinks doctors would want to see.  
28 DEx. 111 at PUMA0001315 (discussing “the feedback we’ve got[ten]”). As



1 Auerbach testified, his comments had “nothing to do with the ExteNET [trial] data”  
2 and he was just providing “a hypothetical example.” PEx. 3 at 759:18-763:8.  
3 Tellingly, following the February 2015 conference, no analyst or media report  
4 estimated the absolute difference in DFS rates would be only 2%-3% (until the truth  
5 came out on May 13, 2015). PSUF 15.

### 6 **3.2. Defendants’ Statements About the KM Curves Were False 7 and Misleading**

8 During the July 22, 2014 call Auerbach was also asked about the KM curves.  
9 He responded: “the curves are continuing to separate” and “the curves appear to be  
10 continuing to separate as you go out year over year.” PSUF 17. But the primary KM  
11 curves that Auerbach had received on July 17, 2014 were clearly narrowing at the end  
12 of year two. PSUF 18-19. Unable to refute that fact, Defendants argue that Auerbach  
13 “did not comment on the curves at two years” and was only stating “what might  
14 happen beyond two years.” DBr. at 17. That’s neither credible nor dispositive. By  
15 assuring investors that the curves were “continuing” to separate, Auerbach created the  
16 false impression that they were separating at two years. Even if Auerbach only  
17 intended to disclose what the curves were doing after two years (not likely), once he  
18 elected to speak about the curves he was required to disclose all material information  
19 about them – namely that the curves were narrowing at the end of year two. PSUF 19;  
20 *Schueneman*, 840 F.3d at 706. As Auerbach acknowledged, “the duration of the  
21 treatment effect was very, very important to investors.” PEx. 3 at 367:9-10; *see also*  
22 *id.* at 366:18-24, 372:9-12, 402:11-18. And other than Defendants’ say-so and curves  
23 that they created solely for this litigation, there is no evidence that Auerbach saw KM  
24 curves for the period beyond two years prior to July 22, 2014. PSUF 20-21; RDSUF  
25 66-67. In fact, Auerbach had fake, “simulated” KM curves concocted during the  
26 Class Period and repeatedly tried to pass them off as the multi-year curves he claims  
27 to have seen before July 22, 2014. PSUF 22-31.  
28

1           **3.3. Defendants’ Statements About the Grade 3+ Diarrhea Rate**  
2                                   **and AE Discontinuation Rate Were False and Misleading**

3           On July 18, 2014 Auerbach was informed that the Grade 3+ diarrhea rate for  
4 neratinib users in the ExteNET trial was 39.9%, 27.6% of neratinib users discontinued  
5 treatment due to AEs, and 16.8% of neratinib users stopped taking the drug due to  
6 diarrhea AEs alone. PSUF 32-35. Four days later, on July 22, 2014, Auerbach told  
7 investors that Defendants “anticipate that the diarrhea rate, the grade 3 diarrhea rate,  
8 would be in line with the 29% to 30% that’s been seen in prior studies” and that the  
9 discontinuation rate due to AEs “should be somewhere in the 5% to 10% range.”  
10 PSUF 36-39. Now, Defendants argue that “this is not what he said.” DBr. at 17. But  
11 that is exactly what is in the transcript. PExs. 33, 66.

12           Defendants also argue that Auerbach “said the data were still being validated.”  
13 DBr. at 17. He said that too. It was also false. The July 18, 2014 email Auerbach  
14 received specifically reported that the top-line safety results “are now validated.”  
15 PEx. 25. When Auerbach asked for a copy of the “final validation safety data” in  
16 September 2014, he was sent the exact same results. PEx. 29. Puma also sent the  
17 exact same results to the FDA in September 2014. PEx. 30. And when the ExteNET  
18 safety results were disclosed on May 13 and June 1, 2015, they were the same results.  
19 PSUF 40-44. In any event, as this Court has already held, “[w]hether that data was  
20 still in preliminary form, or required further validation, isn’t really the point,” since  
21 “Auerbach knew that the current results weren’t in line with the historical information  
22 they provided.” ECF No. 154 at 6. There is no question about what results  
23 Defendants had as of July 22, 2014 and no evidence that those results were expected  
24 to change so dramatically as to render Auerbach’s statements accurate.

25           As with the DFS rates, Defendants also suggest that the true diarrhea rate (but  
26 not the AE discontinuation rate) was disclosed by Auerbach at Leerink and RBC  
27 conferences in February 2015. DBr. at 17-18. Again, this is a truth-on-the-market  
28 defense. And, again, Defendants cannot prove that Auerbach’s purported disclosures

1 corrected his prior misrepresentations. *See Provenz*, 102 F.3d at 1493; *see also*  
2 *Freeland v. Iridium World Commc'ns, Ltd.*, 545 F. Supp. 2d 59, 79 (D.D.C. 2008)  
3 (“Due to the fact-intensive nature of the truth-on-the-market defense . . . its resolution  
4 is best left to the jury.”). To the contrary, the slides that accompanied Auerbach’s  
5 February 2015 comments continued to represent that the neratinib Grade 3+ diarrhea  
6 rate was “~30%.” PEx. 140 at PUMA00176846; PEx. 141 at PUMA00170906.00006.  
7 And there is no evidence that, following those February 2015 conferences, the Leerink  
8 or RBC analysts (or anyone else) reported that the ExteNET Grade 3+ diarrhea rate  
9 was in the “30-40% range.” PSUF 45-46.

10 **4. THERE IS OVERWHELMING EVIDENCE OF**  
11 **DEFENDANTS’ SCIENTER**

12 Scienter is established with evidence that a defendant knowingly or recklessly  
13 made a false statement or material omission. It is a “‘fact-specific issue[] which  
14 should ordinarily be left to the trier of fact.’” *Alpha Grp. Consultants Ltd. v. Bear,*  
15 *Stearns & Co.*, 119 F.3d 5, 1997 WL 409531, at \*2 (9th Cir. 1997); *Provenz*, 102 F.3d  
16 at 1490 (same). “[O]nly ‘[where] there is no rational basis in the record for  
17 concluding that any of the challenged statements was made with the requisite  
18 scienter’” would summary judgment be proper. *In re Software Toolworks, Inc.*, 50  
19 F.3d 615, 626 (9th Cir. 1994). Moreover, the standard at summary judgment is  
20 actually lower than the PSLRA’s requirement that a plaintiff establish a “strong  
21 inference of scienter.” *See In re Novatel Wireless Sec. Litig.*, 830 F. Supp. 2d 996,  
22 1017-18 (S.D. Cal. 2011) (“As long as a reasonable jury could conclude that the  
23 danger of misleading investors was either ‘known’ or ‘so obvious’ that defendants  
24 ‘must have been aware of it,’ a triable issue of fact exists.”).

25 This Court has twice found that Plaintiff met the higher standard for pleading  
26 Defendants’ scienter on the basis of its allegations of Defendants’ knowledge or  
27 reckless disregard of the true ExteNET trial results. ECF No. 76 at 19; ECF No. 154  
28 at 7-8. Those allegations have now been fully borne out by the evidence amassed

1 through discovery, which more than suffices to establish scienter. *See Provenz*, 102  
2 F.3d at 1490 (“Plaintiffs can ‘establish scienter by proving either actual knowledge or  
3 recklessness.’”); *see also* Ninth Circuit Manual of Model Civil Jury Instructions, No.  
4 18.5 Securities – Knowingly (“A defendant acts knowingly when he makes an untrue  
5 statement with the knowledge that the statement was false or with reckless disregard  
6 for whether the statement was true.”).

#### 7 **4.1. Evidence of Auerbach’s Knowledge of the True ExteNET** 8 **Trial Results**

9 Where “[t]he evidence suggests that the individual defendants were aware” of  
10 the true facts, “yet knowingly failed to disclose [them] . . . and in fact, continued to  
11 report misleading positive news,” summary judgment on the issue of scienter is  
12 improper. *Huberman v. Tag-It Pac. Inc.*, 314 F. App’x 59, 61-62 (9th Cir. 2009).  
13 After all, “the ultimate question is whether the defendant knew his or her statements  
14 were false, or was consciously reckless as to their truth or falsity.” *In re VeriFone*  
15 *Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 702 (9th Cir. 2012).

16 The evidence of Auerbach’s knowledge of the very ExteNET trial results he  
17 lied about on July 22, 2014 is uncontroverted. On July 17, 2014, Alvin Wong, the  
18 leader of Puma’s ExteNET study team, sent Auerbach and other Puma executives an  
19 email with “the validated results of the 3004 [ExteNET] primary and secondary  
20 endpoints.” PSUF 18. The attached “Top-Line Efficacy Analyses” prominently  
21 featured the actual 93.9% (neratinib) and 91.6% (placebo) DFS rates, the 2.3% DFS  
22 “risk difference,” and the two year KM curves for the ITT population. PEx. 28 at  
23 PUMA00014632-36. Wong’s email also reported that “[w]e are still in the process of  
24 creating the slides and validating the safety data.” *Id.* at PUMA00014625. The next  
25 day, Wong sent Auerbach another email with “a slide deck of the safety results” and  
26 confirmed that “[t]hey are now validated.” PSUF 32-33. The slide deck, titled “Study  
27 3004: Summary of Safety,” reported that 39.9% of patients in the neratinib arm  
28 suffered Grade 3+ diarrhea and 16.8% of patients discontinued treatment due to

1 diarrhea AEs. PEx. 25 at PUMA00014834.00005, PUMA00014834.00007. And the  
2 attached safety tables identified that 27.6% of neratinib patients discontinued  
3 treatment due to AEs. *Id.* at PUMA00015081. Faced with this evidence (and much  
4 more), Auerbach has been forced to admit that he was aware of the actual ExteNET  
5 results prior to July 22, 2014 and throughout the Class Period. PSUF 47.<sup>4</sup>

6 Despite the Ninth Circuit’s clear guidance that knowledge establishes scienter,  
7 Defendants argue that “Auerbach’s access to ExteNET trial data does not establish  
8 scienter.” DBr. at 18. What does Defendants’ argument rest on? Not much. Legally,  
9 they cite only *Schuster v. Symmetricon, Inc.*, 2000 WL 33115909 (N.D. Cal. Aug. 1,  
10 2000). DBr. at 19. But *Schuster* doesn’t even suggest that scienter is not established  
11 by evidence a defendant knew the facts he is alleged to have misstated or omitted.  
12 There is, of course, a long list of cases holding that knowledge of misstated or omitted  
13 facts is key evidence of scienter, starting with this Court’s order denying Defendants’  
14 motion to dismiss. ECF No. 76 at 19; *see, e.g., S. Ferry LP, #2 v. Killinger*, 542 F.3d  
15 776, 785 (9th Cir. 2008) (“detailed and specific allegations about management’s  
16 exposure to [important] factual information within the company” evidence scienter);  
17 *SEC v. Platforms Wireless Int’l Corp.*, 617 F.3d 1072, 1094 (9th Cir. 2010) (“When  
18 the defendant is aware of the facts that made the statement misleading, ‘he cannot

19 \_\_\_\_\_  
20 <sup>4</sup> A sample of the “and much more” evidence of Auerbach’s scienter includes:

- 21 • Auerbach altered the date, time, and content of Wong’s July 17, 2014  
22 email to make it appear that he received the efficacy results at a later date  
(PSUF 48-61);
- 23 • Auerbach lied to Pfizer, the licensor of neratinib, about what safety and  
24 efficacy data he had as of July 22, 2014 (PSUF 62-90);
- 25 • Auerbach altered the Top-Line Efficacy Analyses report, including  
26 removing the DFS rates and KM curves, before sending the document to  
27 Pfizer (PSUF 71-78, 86-87);
- 28 • Auerbach had “simulated” KM curves prepared and represented to Pfizer  
(as well as to Plaintiff in this litigation) that they were the actual curves  
from the ExteNET trial results (PSUF 22-31, 91-93); and
- Auerbach altered official FDA Meeting Minutes, removing the actual  
DFS rates and changing the wording of the FDA record and represented  
to counsel for the underwriters of Puma’s January 2015 stock offering  
that the altered document was the actual FDA record (PSUF 94-100).

1 ignore the facts and plead ignorance of the risk.”); *Anderson v. Peregrine Pharm.,*  
2 *Inc.*, 2013 WL 4780059, at \*7 (C.D. Cal. Aug. 23, 2013) (“Courts addressing scienter  
3 in the context of statements regarding clinical trials of pharmaceutical products have  
4 focused on whether the defendants alleged to have made misleading statements had  
5 access to or actual knowledge of information contradicting the veracity of their  
6 statements when the statements were made.”); *In re Immune Response Sec. Litig.*, 375  
7 F. Supp. 2d 983, 1022 (S.D. Cal. 2005) (“[T]he fact that the defendants published  
8 statements when they knew facts suggesting the statements were inaccurate or  
9 misleadingly incomplete is classic evidence of scienter.”).

10 In a gambit that failed on motion to dismiss, Defendants argue they didn’t  
11 disclose the actual ExteNET results during the Class Period because it would “risk[]  
12 forfeiting the chance at a coveted presentation such as ASCO.” DBr. at 18. One, you  
13 can’t violate the federal securities laws to get into a conference. (This “ASCO  
14 defense” does, however, suggest a motive to mislead – yet more evidence of scienter.)  
15 Two, there is no statutory exception in the federal securities laws for misstating or  
16 omitting clinical trial results so that they can be presented at a later time. Three, there  
17 is an exception to ASCO’s confidentiality policy that recognizes companies may be  
18 “legally required to disclose certain data” and thus specifically allows for companies  
19 “to satisfy requirements of the U.S. Securities and Exchange Commission” without  
20 losing the ability to present at ASCO’s conference. PSUF 101-102. And four, most  
21 important, this isn’t a case about omissions. Auerbach *did* speak about ExteNET  
22 results – the DFS rates, KM curves, diarrhea rate, and AE discontinuation rate – on  
23 July 22, 2014. Indeed, when asked why he didn’t just refuse to answer questions  
24 about the ExteNET results, Auerbach testified “[w]ell, if you give that type of an  
25 indication, you are signaling that something is wrong; it’s negative.” PEx. 3 at  
26 324:18-20.<sup>5</sup>

27 \_\_\_\_\_  
28 <sup>5</sup> Because “a corporation ‘can only act through its employees and agents,’” *In re*  
*ChinaCast Educ. Corp. Sec. Litig.*, 809 F.3d 471, 475 (9th Cir. 2015), the individual

1           **4.2. Evidence of Eyler’s Knowledge or Reckless Disregard of the**  
2           **True ExteNET Trial Results**

3           Charles Eyler, unlike Auerbach, denies that he knew (or even had access to) the  
4 true ExteNET trial results prior to May 13, 2015. DBr. at 19; PSUF 103. But there is  
5 strong evidence that Eyler did know, and certainly had access to, those results by no  
6 later than January 20, 2015 (the date of the first false statement Eyler is alleged to  
7 have made). For example, during the Class Period Eyler requested a “list of  
8 individuals who may have had access to information related to 3004 [ExteNET] in the  
9 mid-2014 timeframe.” PSUF 104. The list he received *had Eyler’s name on it*. *Id.*  
10 And there is no evidence Eyler ever denied the accuracy of that list. PSUF 105. In  
11 the fall of 2014, Eyler also “help[ed] spearhead[ed]” Puma’s response to an insider-  
12 trading investigation by FINRA, including gathering documents for Puma’s counsel,  
13 Latham & Watkins. PSUF 106. On November 25, 2014, Puma’s counsel sent FINRA  
14 a letter and Puma documents regarding the ExteNET trial results, a copy of which was  
15 provided to Eyler. PSUF 107-108. Included in the Puma documents sent to FINRA –  
16 and Eyler – was the July 17, 2014 “Top-Line Efficacy Analyses” that identified the  
17 DFS rates and KM curves. PEx. 57 at FINRA0003018.

18           Eyler was also responsible for confirming that any employee who wished to sell  
19 their Puma securities was not in possession of material, non-public information.  
20 PSUF 109. To do so, Eyler would have to know what material, non-public  
21 information employees had in their possession. At least one employee specifically  
22 told Eyler “I don’t think there will be any time in the near future that I don’t see or  
23 have access to data that is not in the public domain, related to [ExteNET].” PSUF  
24 110. But Eyler still approved that employee’s sale of more than \$2.6 million in Puma  
25 stock. PSUF 111-112. In fact, during the Class Period, Eyler approved stock sales by

26 defendants’ scienter is imputed to Puma. *See Nordstrom, Inc. v. Chubb & Son, Inc.*,  
27 54 F.3d 1424, 1435-36 (9th Cir. 1995) (“corporate scienter relies heavily on the  
28 awareness of the directors and officers”), *as amended on denial of reh’g* (Aug. 1,  
1995); *In re Hienergy Techs., Inc.*, 2005 WL 3071250, at \*8 (C.D. Cal. Oct. 25, 2005)  
(collecting cases).

1 Puma insiders totaling over \$146 million, and the employees and officers identified on  
2 the “list of individuals who may have had access to information related to 3004  
3 [ExteNET] in the mid-2014 timeframe” sold over \$70 million in Puma stock. PSUF  
4 114-117. At a minimum, this is evidence of Eyler’s reckless disregard of the true  
5 facts about the ExteNET results. *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1064  
6 (9th Cir. 2000) (“an actor is reckless if he ‘had reasonable grounds to believe material  
7 facts existed that were misstated or omitted, but nonetheless failed to obtain and  
8 disclose such facts although [he] could have done so without extraordinary effort”).

9 While Eyler denies that he even had “access to the results of the ExteNET trial”  
10 (PEx. 118 at Interrogatory No. 19), his co-defendant has testified otherwise.  
11 According to Auerbach, Eyler “would need it [the unpublished ExteNET results] for  
12 his role as senior vice-president . . . of the company” and he “assumed [Eyler] knew  
13 what the data was.” PEx. 3 at 786:23-25, 709:8. After all, as Eyler acknowledged, he  
14 was responsible for ensuring that Puma’s “financial disclosures are full, fair, accurate,  
15 timely, and understandable.” PEx. 142 at PUMA00000905; *see also* PEx. 6 at 67:3-8.  
16 Eyler signed Puma’s annual SEC filing during the Class Period as well as the January  
17 2015 stock offering documents, and in doing so, attested to their accuracy. PSUF  
18 118-121. Accordingly, he had an affirmative duty to know what he was certifying.  
19 PEx. 3 at 709:8; 15 U.S.C. §7241(a)(4)(B) (mandating “signing officers” of annual  
20 and quarterly reports to certify that they have “designed such internal controls to  
21 ensure that material information relating to the issuer and its consolidated subsidiaries  
22 is made known to such officers”).

### 23 **4.3. Evidence of Defendants’ Motive to Defraud**

24 Unable to refute the evidence of their knowing misconduct, Defendants recycle  
25 an argument made in their motions to dismiss – “[we] had no reason to mislead  
26 investors.” *Compare* DBr. at 19-21, *with* ECF No. 60 at 20-23, *and* ECF No. 146 at  
27 18-24. But this Court has already found that the allegations regarding Puma’s \$218.5  
28 million stock offering and Defendants’ \$23.2 million in compensation supported a



1 strong inference of scienter. ECF No. 76 at 19. And Defendants do not dispute that  
2 those allegations have been borne out by the evidence. In January 2015, Defendants  
3 orchestrated the sale of 1.15 million shares of Puma stock at artificially-inflated  
4 prices. PSUF 122. As Plaintiff’s expert, Professor Brett Trueman, explains, but for  
5 that offering Puma would have run out of money by the end of 2015. PSUF 123. And  
6 Auerbach and Eyler also collected compensation of \$17.8 million and \$5.4 million,  
7 respectively, for 2014 based on Puma’s inflated stock price and the misstated  
8 ExteNET results. PSUF 127-133.

9 Defendants argue that they “did not need [Puma’s] stock price to increase in  
10 order to raise money.” DBr. at 20. But the facts are that they did need to raise money,  
11 they took advantage of the artificial inflation in Puma’s stock price caused by their  
12 false statements, and that enabled them to raise more money selling fewer shares.  
13 PSUF 122-126. Defendants can try to convince the jury otherwise, but those facts are  
14 evidence of motive.<sup>6</sup> Defendants also argue that their compensation was largely in  
15 Puma stock so they were “substantially harmed” when the truth about the ExteNET  
16 results was revealed. DBr. at 20-21. Perhaps the jury will be sympathetic to the  
17 plight of these executives who didn’t cash out before their fraud was exposed. But  
18 while that may be a story for the jury to consider, it is not grounds for summary  
19 judgment. *See SEC v. Seaboard Corp.*, 677 F.2d 1297, 1298-99 (9th Cir. 1982)  
20 (“Drawing inferences favorably to the nonmoving party, summary judgment [on the  
21 issue of intent] will be granted only if all reasonable inferences defeat the plaintiff’s  
22 claims.”); *In re Homestore.com, Inc. Sec. Litig.*, 347 F. Supp. 2d 769, 784 (C.D. Cal.  
23 2004) (“Conflicting inferences [of scienter] result in a case for the jury.”).

24 \_\_\_\_\_  
25 <sup>6</sup> Defendants cite to *Vaughn v. Teledyne, Inc.*, 628 F.2d 1214, 1220 (9th Cir. 1980),  
26 and *Steiner v. Tektronix, Inc.*, 817 F. Supp. 867, 884-85 (D. Or. 1992), for the  
27 proposition that a corporate stock offering is “insufficient to prove scienter.” DBr. at  
28 21. Problem one: the issue is not whether Puma’s offering, standing alone, proves  
scienter, but simply whether it is evidence of scienter. Problem two: neither case  
actually involves a stock offering or holds anything about offerings as evidence of  
scienter.

1 Defendants also say that the considerable evidence of their scienter is negated  
2 because they didn't sell their own Puma stock. DBr. at 19. That argument didn't  
3 work at motion to dismiss and doesn't work now. The Supreme Court has held that  
4 even the complete absence of any motive allegation "is not dispositive." *Matrixx*  
5 *Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 48 (2011). And the Ninth Circuit has held  
6 that "the lack of stock sales by a defendant is not dispositive as to scienter." *No. 84*  
7 *Employer-Teamster Joint Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320  
8 F.3d 920, 944 (9th Cir. 2003); *see also Hanon v. Dataproducts Corp.*, 976 F.2d 497,  
9 507 (9th Cir. 1992) (reversing summary judgment on issue of scienter despite lack of  
10 insider sales where evidence showed defendants' knowledge of product defect);  
11 *Commodity Futures Trading Comm'n v. JBW Capital*, 812 F.3d 98, 108 (1st Cir.  
12 2016) (lack of stock sales did not "rebut a finding of scienter").

13 **5. DEFENDANTS FAIL TO PROVIDE ANY BASIS FOR**  
14 **SUMMARY JUDGMENT ON LOSS CAUSATION**

15 Defendants also move for summary judgment on the basis that Plaintiff cannot  
16 prove that the June 1, 2015 disclosure of the true KM curves and AE discontinuation  
17 rate were causally connected to the 28.73% (\$46.24 per share) decline in Puma's stock  
18 price on June 1-2, 2015. DBr. at 21-25. Defendants do not challenge the evidence of  
19 loss causation for the disclosures on May 13, 2015 and the 20.60% (\$40.96 per share)  
20 stock price decline caused by those disclosures. PSUF 134-135.

21 To establish loss causation, "the plaintiff must prove that the alleged  
22 misrepresentations or omissions played a substantial part in causing the injury or loss  
23 the plaintiff suffered." Ninth Circuit Manual of Model Civil Jury Instructions, No.  
24 18.8 Securities – Causation. "Because loss causation is simply a variant of proximate  
25 cause, the ultimate issue is whether the defendant's misstatement, as opposed to some  
26 other fact, foreseeably caused the plaintiff's loss." *Lloyd v. CVB Fin. Corp.*, 811 F.3d  
27 1200, 1210 (9th Cir. 2016); *see also Mineworkers' Pension Scheme v. First Solar Inc.*,

28

1 881 F.3d 750, 753 (9th Cir. 2018) (“This inquiry requires no more than the familiar  
2 test for proximate cause.”).

3 **5.1. Defendants Have Not Met Their Burden of Demonstrating**  
4 **that Puma’s June 1-2, 2015 Stock Price Decline Was**  
5 **Unrelated to the Fraud**

6 In seeking summary judgment, the burden is initially on Defendants to establish  
7 the lack of any genuine issue of material fact. *Celotex*, 477 U.S. at 323. For loss  
8 causation, that means Defendants must “‘establish that, as a matter of undisputed fact,  
9 the depreciation in the value of [Puma’s stock] could not have resulted from the  
10 alleged false statement or omission of the defendant.’” *Novatel*, 830 F. Supp. 2d at  
11 1019; *see also Caremark, Inc. v. Coram Healthcare Corp.*, 113 F.3d 645, 649-50 (7th  
12 Cir. 1997) (defendant must “‘establish[] that the decline in the value of the security is  
13 attributable in total to some other factor”). Defendants’ cited authority is in accord.  
14 *In re REMEC Inc. Sec. Litig.*, 702 F. Supp. 2d 1202, 1266 (S.D. Cal. 2010) (citing  
15 *Caremark*, 113 F.3d at 649-50). This is a “heavy burden,” *Provenz*, 102 F.3d at 1492,  
16 that Defendants have failed to meet.

17 Based on the widely accepted regression analysis and event study methodology,  
18 Plaintiff’s economic expert, Dr. Steven Feinstein, established that Puma’s stock price  
19 suffered a company-specific, statistically significant decline of 28.73% on June 1-2,  
20 2015. PEx. 129, ¶¶65-67; PSUF137-138; *see also In re Vivendi, S.A. Sec. Litig.*, 838  
21 F.3d 223, 253-54 (2d Cir. 2016) (describing event study methodology). Feinstein also  
22 identified the company-specific stock price declines on June 1 (13.07%) and June 2,  
23 2015 (14.76%), and established that those declines were each statistically significant.  
24 PSUF 139-142. Defendants and their expert, Dr. Paul Gompers, do not dispute the  
25 price declines identified by Feinstein or their statistical significance. They also  
26 acknowledge that the June 1-2, 2015 price decline must have been due to a Puma-  
27 specific disclosure and cannot be explained by any macro-economic factors, industry-  
28 wide factors, or random chance. PSUF 138. And neither Defendants nor Gompers  
have identified any Puma disclosures, other than those during the June 1, 2015 ASCO

1 meeting regarding the ExteNET trial, that could account for the stock price decline.  
2 What's left is a dispute about which of the ExteNET trial results disclosed on June 1,  
3 2015 were a substantial cause of Class members to suffer the 28.73% loss.

4 Unable to refute the fact that the actual KM curves and diarrhea AE  
5 discontinuation rate were disclosed, for the first time, on June 1, 2015 (PSUF 143-  
6 145), Defendants argue that “the record . . . shows that the June 1 stock drop *was*  
7 *caused by* (1) the new (non-fraud related) node-negative data, and correspondingly  
8 revised investor expectations about the anticipated market for neratinib, and (2) ASCO  
9 oncologists' negative reactions to old and new data in the presentation.” DBr. at 24.  
10 But that's not what the record shows. In his report, Gompers could only suggest “the  
11 *potential* impact” of information about a node-negative subgroup or oncologist  
12 reactions to the ExteNET results, which he says “*may have* caused,” “*could have*  
13 affected,” or “*may have* contributed” to the June 1-2, 2015 price decline. PEx. 143,  
14 ¶7. He failed to quantify what, if any, impact any of these purported confounding  
15 factors actually had on Puma's stock price. And Gompers repeatedly testified “I was  
16 not asked to offer an affirmative opinion about what the cause of the stock price  
17 decline was on June 1st and June 2nd” and, specifically with respect to the node-  
18 negative subgroup disclosure and oncologist reaction, “I'm not offering an affirmative  
19 opinion that these are, in fact, the cause of the stock price decline.” PEx. 9 at 140:19-  
20 22, 181:10-16; *see also id.* at 276:16-21 (“Q. What is it that you think caused the  
21 statistically significant decline or negative residual return in Puma's stock price on  
22 June 2, 2015? A. I have no opinion nor have I been asked to investigate that.”).

23 Given their expert's limited and inconclusive opinions, Defendants have no  
24 evidence “establishing that the [June 1-2, 2015] decline in the value of the security is  
25 attributable in total to some other factor” unrelated to the KM curves and AE  
26 disclosures. *Caremark*, 113 F.3d at 649-50; *see also Nguyen v. Radiant Pharm. Corp.*,  
27 946 F. Supp. 2d 1025, 1040 (C.D. Cal. 2013) (denying summary judgment where  
28 defendants did not “show that depreciation of a stock was the result of factors other

1 than alleged false and misleading statements”); *In re Vivendi Universal, S.A. Sec.*  
2 *Litig.*, 2009 WL 10695884, at \*14 (S.D.N.Y. Apr. 6, 2009) (denying summary  
3 judgment where defendants failed to establish any “obvious competing cause” for  
4 plaintiffs’ loss). Accordingly, summary judgment on loss causation must be denied.

5 **5.2. The Disclosure of the KM Curves and AE Discontinuation**  
6 **Rate Caused Puma’s June 1-2, 2015 Stock Price Decline**

7 Defendants’ failure to meet their burden and establish that the June 1-2, 2015  
8 loss was due in total to some non-fraud factor means the Court need go no further.  
9 But even assuming the burden shifted to Plaintiff to identify evidence raising a  
10 genuine issue of material fact, Defendants’ motion would fare no better.

11 Starting again with facts that are not in dispute. On June 1, 2015, during the  
12 ASCO conference, Dr. Arlene Chan disclosed the actual ExteNET KM curves (which  
13 were narrowing at the end of two years), the discontinuation rate due to diarrhea AEs  
14 (16.8%), and that 39% of neratinib users failed to complete a year of treatment on the  
15 drug. PSUF 143-145. These facts directly contradicted the statements Defendants  
16 made on July 22, 2014. Defendants’ argument that Plaintiff cannot show that the  
17 decline in Puma’s stock price on June 1-2, 2015 was substantially caused by these  
18 disclosures (DBr. 22-23) simply ignores the evidence.

19 Feinstein’s rigorous event study analysis not only accounted for all potential  
20 macro-economic and industry factors that could have impacted Puma’s stock price,  
21 but also evaluated which company-specific disclosures could have caused the 28.73%  
22 stock price decline on June 1-2, 2015. PEx. 129, ¶¶43-61, 65-67; PEx. 145, ¶¶10-15.  
23 Based on that analysis, which included a review of contemporaneous statements (both  
24 at ASCO and in email communications), analyst reports, and news reports and a  
25 comparison to prior reports and disclosures about Puma, Feinstein concluded “that the  
26 residual decline of \$46.24 per share on 1-2 June 2015 was substantially caused by the  
27 corrective disclosures regarding the results of the ExteNET trial.” PEx. 129, ¶67.  
28 Defendants disagree.

1 First, Defendants argue that the “vast majority of analysts” did not comment on  
2 the KM curves or AE discontinuation rate or did not label it “bad news.” DBr. 22.<sup>7</sup>  
3 But Feinstein identifies numerous post-ASCO reports (analyst and news) that  
4 discussed the KM curves and discontinuation rate, as well as the concerns about  
5 neratinib’s efficacy (especially the long-term efficacy) and safety (especially with  
6 respect to diarrhea toxicity) that are directly related to the ASCO disclosures and  
7 Defendants’ false statements. PEx. 129, ¶37. In fact, four of the six analysts who  
8 issued reports between June 1 and June 3, 2015 specifically discussed the KM curves  
9 and/or the AE discontinuation rate. PSUF 146-147. That some analysts didn’t  
10 directly address the KM curves or AE discontinuation rate, or didn’t single them out  
11 as “bad news,” is hardly dispositive. *See Thorpe v. Walter Inv. Mgmt., Corp.*, 2016  
12 WL 4006661, at \*14 (S.D. Fla. Mar. 16, 2016) (“That market commentary did not  
13 mention the corrective disclosure does not by itself mean that the corrective disclosure  
14 had no price impact.”). As Feinstein noted, the discernable changes in how analysts  
15 described the efficacy and safety results as they tried to defend Puma was notable.  
16 PEx. 8 at 129:14-131:9. Accordingly, Plaintiff has “provided sufficient evidence to  
17 support their claims that the market learned of and reacted to” the alleged fraud.  
18 *Novatel*, 830 F. Supp. 2d at 1019.<sup>8</sup>

19 \_\_\_\_\_  
20 <sup>7</sup> Defendants claim “[t]he parties’ experts agree that analyst commentary is a critical  
21 component of the causation analysis.” DBr. at 22. That overstates it. Analyst reports  
22 are simply one of the sources of information that can be considered (and that Feinstein  
23 did consider) in an event study analysis. They are no more critical than news reports  
24 or other sources of information. Moreover, as Feinstein describes, analyst reports  
25 have to be considered in light of the substantial bias analysts and their employers often  
26 have towards defending a client company. PEx. 7 at 114:19-117:14; RDSUF 155;  
27 PSUF 148. Notably here, the majority of analyst firms that issued reports on Puma  
28 following the June 1, 2015 disclosures had been paid by Puma for investment banking  
services. PSUF 149-153.

<sup>8</sup> Defendants’ lone case, *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376 (9th Cir. 2010),  
is inapposite. In *Oracle*, there was no disclosure of facts contradicting earlier  
statements. The company simply announced an earnings miss due to customers  
delaying IT spending. The plaintiffs alleged that this announcement was related to  
undisclosed problems with Oracle software. *Id.* at 384. Thus, the question was  
whether investors and analysts understood from the generic disclosure of an earnings  
miss that prior statements about software had been misleading. In that context,

1 Second, Defendants claim that “Plaintiff ignores the impact of confounding  
2 information.” DBr. at 23-25. But the Ninth Circuit has repeatedly affirmed that “[a]  
3 plaintiff is not required to show ‘that a misrepresentation was the *sole* reason for the  
4 investment’s decline in value’ in order to establish loss causation.” *In re Daou Sys.,*  
5 *Inc.*, 411 F.3d 1006, 1025 (9th Cir. 2005) (emphasis in original); *see also Huberman,*  
6 *314 F. App’x* at 61-62 (same); Ninth Circuit Manual of Model Civil Jury Instructions,  
7 No. 18.8 Securities – Causation (“The plaintiff need not prove that the alleged  
8 misrepresentations or omissions were the sole cause of the economic injuries.”). It is  
9 Defendants who ignore the fact that their own expert could not conclude that any  
10 purported confounding factor caused any (let alone all) of the June 1-2, 2015 price  
11 decline.

12 Defendants also ignore that Plaintiff’s expert did assess each of the purported  
13 confounding factors and concluded that “other than the corrective disclosures, there  
14 was ‘no other Company-specific news that could have been a substantial cause of the  
15 1-2 June 2015 residual return.’” PEx. 145, ¶¶16-28; PEx. 129, ¶67. Defendants may  
16 disagree with Feinstein’s conclusion, but that’s not a basis for summary judgment.

17 For example, Feinstein has demonstrated that the June 1-2, 2015 price decline  
18 was not caused by a disclosure of the node-negative subgroup DFS results. After all,  
19 it was long known that the ExteNET trial was modified to exclude node-negative  
20 patients and there was no expectation of a statistically significant response in the  
21 node-negative subgroup after only two years of data. PEx. 145, ¶¶18-23. Defendants’  
22 expert opines that this subgroup result may have reduced investor expectations, citing  
23 to a June 1, 2015 analyst report that said “[n]eratinib showed modest iDFS benefit in  
24 node negative patients.” PEx. 143, ¶53. But as Feinstein showed, that same analyst  
25 had used nearly the exact same language ten days earlier, *before* the ASCO

26 \_\_\_\_\_  
27 analyst reports supported a finding that there was a lack of any connection between  
28 the disclosure and the alleged false statements. Here, however, there is no question  
that the true facts contradicting Defendants’ false statements – the actual KM curves  
and AE discontinuation rate – were disclosed on June 1, 2015.

1 presentation, reporting that the node-negative subgroup “is likely to only show a  
2 modest benefit.” PEx. 145, ¶20; PExs.144, 131.

3 Feinstein also shows that the “negative reactions” of certain oncologists at  
4 ASCO and their desire to see additional data from the ExteNET trial were fraud-  
5 related and not an independent cause of the June 1-2, 2015 stock price decline. PEx.  
6 145, ¶¶24-28; PEx. 129, ¶67 n.68. The oncologists’ commentary reflected the  
7 significant new disclosures regarding efficacy (KM curves – leading to commentary  
8 that the effectiveness of neratinib would diminish over time) and safety (AE  
9 discontinuations – leading to commentary about the tolerability of the drug), in  
10 conjunction with the previously disclosed DFS and diarrhea rates. Defendants’ expert  
11 suggests that the commentary was due to a desire for “additional data beyond two  
12 years.” PEx. 143, ¶55. But, as even he admits, it was known long before June 1, 2015  
13 that only two-year data would be presented at ASCO. PEx. 9 at 257:17-258:1; *see*  
14 *also* PEx. 33 at 6 (Auerbach stating that it would take “a couple of years” to get  
15 additional ExteNET data).

16 Defendants may not like Feinstein’s conclusions, but they’ll have the  
17 opportunity to cross-examine him at trial. At summary judgment, Defendants’ effort  
18 to raise “alternative explanations” for Puma’s June 1-2, 2015 stock price decline only  
19 serves to raise “a question of fact.” *See Novatel*, 830 F. Supp. 2d at 1019.<sup>9</sup>

20  
21 <sup>9</sup> Given Feinstein’s analysis of confounding factors here (as well as macro-economic  
22 and industry factors), Defendants’ cases are easily distinguishable. *See REMEC*, 702  
23 F. Supp. 2d at 1273 (expert “makes no attempt to account for other possible causes,  
24 *i.e.* industry-specific news . . . , market-specific news . . . , or other measurable  
25 macroeconomic variables”); *In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d  
26 546, 554 (S.D.N.Y. 2008) (expert’s event study “incorrectly identifies several  
27 corrective disclosures” and did not address “any potential effect” from other negative  
28 information), *aff’d*, 597 F.3d 501 (2d Cir. 2001); *Nuveen Mun. High Income  
Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1123 (9th Cir. 2013) (“expert  
assumed that almost the entire decline in price was the result of the truth gradually  
leaking into the market, despite . . . the overall decline in the telecommunications  
industry”); *Bricklayers & Trowel Trades Int’l Pension Fund v. Credit Suisse First  
Boston*, 853 F. Supp. 2d 181, 191 (D. Mass. 2012) (expert “fail[ed] to isolate the  
effect of defendants’ alleged fraud from other industry- and company-specific news  
reported on event days”), *aff’d*, 752 F.3d 82 (1st Cir. 2014).



1           **5.3. The Use of a Two-Day Event Window Is Appropriate and**  
2           **Accepted**

3           Defendants also argue that the use of a two-day event window (the period used  
4 to measure the stock price reaction to a disclosure) is only permitted “where the  
5 corrective information is released after market close.” DBr. 25. As an initial matter,  
6 Defendants’ argument cannot provide a basis for summary judgment on loss causation  
7 because there is no dispute that Puma’s stock price declined a statistically significant  
8 13.07% on June 1, 2015 alone. PSUF 139-140. So, even ignoring the June 2, 2015  
9 price decline, there is a material question of fact as to loss causation for the June 1,  
10 2015 disclosures.

11           Defendants’ purported rule that a two-day event window is only permitted  
12 “where the corrective information is released after market close” is also wrong. DBr.  
13 at 25. It is not even consistent with their expert, who argues (incorrectly) that a two-  
14 day event window is only acceptable when “the day of the announcement is known  
15 but not the exact time.” PEx. 143, ¶72. As Defendants and their expert have staked  
16 out supposedly sacrosanct rules about the length of an event window, one would  
17 expect that they could identify cases or academic texts that state those rules. They  
18 can’t. As Feinstein explains, there are numerous factors that must be taken into  
19 account when determining an appropriate event window. PEx. 128, ¶¶95-98; PEx.  
20 129, ¶¶50-53; PEx. 145, ¶¶29-46. Feinstein assessed those factors here – including  
21 the fact that the June 1, 2015 disclosure did not occur until the middle of the trading  
22 day – and justifiably concluded that a two-day event window was appropriate. *Id.*  
23 His conclusion is consistent with the use of multi-day event windows in academic  
24 literature. PEx. 145, ¶¶43-46. And courts throughout the country have routinely  
25 approved the use of multi-day trading windows in cases like this one. *See, e.g., SEC*  
26 *v. Jensen*, 2013 WL 12129377, at \*6 (C.D. Cal. Mar. 13, 2013) (permitting three-day  
27 window); *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 310 F.R.D. 69,  
28 96 & n.183 (S.D.N.Y. 2015) (permitting two-day window and noting that Gompers

1 himself had testified that “event studies often use a two-day window, the date of the  
2 announcement and the day after”); *United States v. Hatfield*, 2014 WL 7271616, at  
3 \*12 (E.D.N.Y. Dec. 18, 2014) (permitting two-day window); *In re Apollo Grp. Inc.*  
4 *Sec. Litig.*, 509 F. Supp. 2d 837, 846 (D. Ariz. 2007) (rejecting challenge to  
5 Feinstein’s use of a two-day window and denying defendants’ motion for summary  
6 judgment); *Am. W. Holding*, 320 F.3d at 934 (“As recognized by the Supreme  
7 Court . . . [market] distortions may not be corrected immediately. . . . Because of  
8 these distortions, adoption of a bright-line rule assuming that the stock price will  
9 instantly react would fail to address the realities of the market.”). Defendants’ cases  
10 do not hold otherwise. *See In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 269 (3d  
11 Cir. 2005) (considering stock price reaction over a five-day period); *Bricklayers*, 853  
12 F. Supp. 2d 181 (no discussion of event windows).

13 **6. DEFENDANTS ARE CONTROL PERSONS UNDER §20(A)**

14 Each defendant is a control persons under §20(a). 15 U.S.C. §78t(a); PSUF  
15 154-155. Defendants’ sole basis for summary judgment on this claim is that “Plaintiff  
16 cannot prove a primary violation of Section 10(b).” DBr. at 25. As set forth above,  
17 that is incorrect.

18 **7. CONCLUSION**

19 For the reasons set forth above, Defendants’ motion should be denied.

20 DATED: August 14, 2018

Respectfully submitted,

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