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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HSINGCHING HSU, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

PUMA BIOTECHNOLOGY, INC., ALAN H. AUERBACH, and CHARLES R. EYLER,

Defendants.

CASE NO. 8:15-cv-00865-AG (SHKx)

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Date: September 24, 2018
Time: 10:00 a.m.
Courtroom: 10D
Judge: Hon. Andrew J. Guilford

Trial Date: November 6, 2018

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I. INTRODUCTION

Puma Biotechnology, Inc. and its CEO Alan Auerbach developed a life-saving breast-cancer drug—neratinib—that has now been approved by the U.S. Food & Drug Administration ("FDA"), and recommended for approval by a committee of the European Medicines Agency ("EMA"). Notwithstanding this remarkable success, Plaintiff attacks pre-approval statements made by Puma as being inaccurate and misleading. Plaintiff alleges that Puma received clinical trial results for neratinib in July 2014, but then supposedly misled investors about the positive top-line results of the trial, while withholding other negative pieces of data about the drug. After full development of the facts in discovery, though, Plaintiff's securities fraud allegations fail at every level. Most fundamentally, Puma's July 2014 disclosure of the successful top-line results of the trial was undisputedly true. The trial (called ExteNET) was a success, and the information Puma disclosed about the trial was accurate. The FDA approval and EMA recommendation were both based on the ExteNET data. Neratinib is now being prescribed to thousands of breast-cancer patients who would otherwise be without hope of treatment.

Plaintiff is left to quibble that Puma's July 2014 disclosures were materially incomplete when they were not. Puma accurately disclosed that the ExteNET trial met its primary endpoint by demonstrating a statistically significant 33% improvement in disease-free survival ("DFS") at two years. Plaintiff now admits that this statement was true—but argues that Puma should have also disclosed select other data from the trial, including the absolute difference in DFS rates between neratinib and placebo at a particular point in time, rates of diarrhea, patient drop-out rates, and a graphical depiction of data called Kaplan-Meier ("KM") curves. Plaintiff is wrong as a matter of law. These four pieces of data do not contradict the 33% top-line results or render them false, and thus do not constitute material omissions. Moreover, Puma plainly stated that it was presenting only the top-line results, and that clinical details would be presented at a

future medical conference—a common practice in the industry. Investors were not misled.

Further, Plaintiff has not developed any remotely sufficient evidence of scienter. To the contrary, Plaintiff's theory regarding insiders' motivation to commit securities fraud demonstrates the opposite. Mr. Auerbach had no incentive to inflate the stock price between the announcement of top-line results and the presentation of the data at a medical conference: he sold no stock during that period. In fact, he and other top executives were personally harmed by the increase in stock price given that most of their compensation in 2015 was in stock options, which are now worthless. Plaintiff's fallback argument—that Puma's routine capital raise was the motivation to lie—is unsupported by any fact, as Puma has consistently raised capital throughout its existence.

As Puma anticipated, the ExteNET trial was selected for presentation at the medical conference of the American Society of Clinical Oncology ("ASCO") on June 1, 2015. Prior to that presentation, on May 13, 2015, ASCO released an abstract containing most of the data Plaintiff claims Puma omitted—including the absolute difference in DFS at two years, and the diarrhea rate. When those clinical details were disclosed, there was no lasting market reaction. Puma's stock price initially dipped, but rebounded almost immediately.

As to the information presented at the ASCO conference on June 1, 2015, Plaintiff cannot demonstrate loss causation as a matter of law. An independent physician presented the full ExteNET data at ASCO, reporting the same results that had been published on May 13, plus the KM curves, the 16.8% discontinuation rate due to diarrhea, and a host of other analyses of the total patient population and patient subgroups. Some doctors and analysts reacted favorably to the ExteNET data, and some reacted negatively. What is clear, however, is that no one reacted to the *only* new supposedly corrective information—the KM curves and the discontinuation rate. No evidence ties the decline on June 1 to these two data

points. Instead, the June 1 drop was caused by something else: the new ExteNET data presented and criticisms by independent oncologists at ASCO—information that Plaintiff does not contend should have been disclosed earlier—and the market's resulting speculation that neratinib would not receive FDA approval, or would be approved only for a narrow population. These predictions were, as it turned out, wrong, given that the FDA approved neratinib for the entire population studied in ExteNET, based on the same (positive) data Puma received in July 2014. This is a case not of fraud, but rather of investors betting on FDA approval.

More tenuous still is Plaintiff's attempt to connect the stock price decline on June 2 to the information disclosed at ASCO. Plaintiff's own loss causation expert concedes that Puma's stock traded in an efficient market and therefore absorbed information rapidly. There is no conceivable support for the position that Plaintiff may rely on declines over two trading days.

Plaintiff's own investment advisor, who had unfettered discretion over the account and whose admissions are therefore binding on Plaintiff, testified that she did not believe Mr. Auerbach (who made the statements at issue) "ever misled me in any way." Plaintiff, along with other investors, simply made an educated gamble that had (as of yet) not paid off as hoped. But the federal securities laws are not a form of investment insurance. Summary judgment should be granted.

II. STATEMENT OF FACTS

A. Puma Develops Neratinib for Breast Cancer Patients

Breast cancer is the second-leading cause of cancer deaths in women, and approximately 230,000 new cases are reported each year in the United States. UF 1. The worst type of breast cancer is known as HER2+, meaning that the body makes too much of a protein called the human epidermal growth factor receptor-2 (HER2). UF 2. Approximately 20-25% of women with breast cancer are HER2+. UF 3. HER2+ cancers tend to be aggressive and difficult to treat. UF 4.

Puma is a biopharmaceutical company dedicated to developing innovative

drugs to cure breast cancer. UF 5. Alan Auerbach founded Puma in September 2010. UF 6. Mr. Auerbach is Puma's largest stockholder and serves as Puma's CEO, President, and Chairman. UF 7. Before founding Puma, Mr. Auerbach founded (and later sold) Cougar Biotechnology, Inc., which developed a drug called abiraterone, known as Zytiga®, now the leading treatment for metastatic prostate cancer. UF 8-10. Charles Eyler is Puma's Senior Vice President of Finance and Administration. UF 11.

In August 2011, Puma bought (via a license) the rights to neratinib, now known as Nerlynx®. UF 12. Neratinib works by blocking cancer cells' ability to receive growth signals through the HER2 protein. UF 13. The main side effect of neratinib (and other similar breast cancer drugs) is diarrhea, which can be reduced through treatment with loperamide, better known as Imodium. UF 14-15.

B. Puma's ExteNET Trial Successfully Meets Its Primary Endpoint

The ExteNET trial was a Phase III trial (meaning a large-scale trial in humans) designed to test neratinib's ability to prevent HER2+ breast cancer from coming back after surgery. UF 16, 18. Before ExteNET, there were no options for "extended adjuvant" treatment—that is, treatment after a patient has undergone surgery (the initial treatment) and one year of treatment with the drug trastuzumab, known as Herceptin (the adjuvant treatment). UF 17, 19. The ExteNET trial was designed to test whether neratinib could reduce the risk of cancer coming back, referred to as improving disease-free survival, for the HER2+ patients who were still at risk after using Herceptin. UF 18.

Like all clinical trials of its type, the ExteNET trial was subject to a clinical trial protocol, which is a set of rules approved by the FDA before the inception of a study on humans. UF 20-21. The trial protocol defined in advance a "primary endpoint"—or goal—of the trial. UF 22. For ExteNET, the pre-specified primary endpoint was to "compare disease free survival (DFS) of women . . . receiving neratinib against that of women receiving placebo." UF 23. The trial protocol

documents specified the statistics that would determine whether ExteNET was successful: the **hazard ratio**, which quantifies the difference in the risk of cancer recurrence between the treatment and placebo groups over time, and the **p-value**, which measures whether there is a statistically significant difference between the two groups. UF 24-26, 28-29. In order to achieve its primary endpoint, ExteNET had to show a hazard ratio of less than 1 (meaning that the risk of disease recurrence is lower in the treatment group than the control group) and a p-value of less than 0.025 (signifying a statistically significant result). UF 27, 30-31. The trial protocol also specified visual analyses of the results by means of Kaplan-Meier curves, which provide a graphical depiction of the estimate of patients in each group who remain disease free at particular points in time. UF 32-33.

On July 7, 2014, after months of preparation, Puma locked the clinical trial database in order to analyze "Part A": the results after patients had been treated for two years. UF 34-35. Puma's biostatistician, Dr. Claire Sherman, and Puma's outside clinical research organization, Rho, Inc., each received a database snapshot containing all patient data collected as of October 2013. UF 36-37. Dr. Sherman and Rho then analyzed the data. UF 38. Dr. Sherman prepared a document reflecting the ExteNET efficacy results entitled, "Topline Efficacy Analyses—Part A," that was distributed to Mr. Auerbach, certain other members of management (not including Mr. Eyler), and the ExteNET team on July 17, 2014. UF 39-40. These analyses showed that the trial was successful and had met its primary endpoint. UF 41-42. The very low p-value of 0.0046 showed a strongly statistically significant difference in DFS between patients taking neratinib versus placebo. UF 31, 43. The hazard ratio of 0.67 quantified that difference in risk over the two-year period and demonstrated that treatment with neratinib resulted in a 33% reduction in risk of disease recurrence, or, stated differently, a 33% improvement over placebo. UF 44-46. These results mean that one in three neratinib patients who would have otherwise had their cancer return within two

years will avoid recurrence. UF 47.

Also in July 2014, Puma received certain topline safety tables generated and validated by Rho. UF 48. These tables included information regarding patients' safety experience with the drug, including adverse events such as diarrhea. UF 49. Although these safety tables had been validated by Rho, they had not yet been validated by Puma. UF 50-51. Puma's validation process for the safety results began in late August 2014 and was not completed until January 30, 2015, after Puma had identified and corrected errors in Rho's tables. UF 52-54.

C. Puma Announces the Validated Topline Efficacy Results

On July 22, 2014, Puma issued a press release announcing "Positive Top Line Results" from the ExteNET trial, with the headline "Neratinib Achieves Statistically Significant Difference in Disease-Free Survival." UF 55 (Ex. 59). Puma's press release explained that ExteNET achieved its primary endpoint, as reflected by the p-value and hazard ratio:

> The primary endpoint of the trial was disease free survival (DFS). The results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo. The hazard ratio was determined to be 0.67 which was statistically significant with a p-value of 0.0046.

Ex. 59. While Puma possessed many additional details and results of the ExteNET trial at the time of the press release, those additional data were not laid out in the press release. Instead, as is customary across the industry, Puma told investors that these "full results" would be presented later "at a future scientific meeting." *Id.*

Like many biotechnology companies, Puma limited the information it disclosed in its press release to the primary endpoint in order to preserve its ability to present the full results at a future scientific meeting. UF 56-57. Such presentations are essential to the success of a new drug because they enable drug companies to educate doctors on the benefits and potential uses of a particular drug. UF 58. Many conferences, including the one most prestigious for cancer treatments—ASCO—have strict confidentiality policies. ASCO's Policy stated:

> For a study to be eligible for acceptance into an ASCO Annual Meeting, information contained in the abstract . . . must not be disclosed before the findings have been publicly released in conjunction with the ASCO Annual Meeting. If information from the abstract or additional study data are disclosed in advance . . . the abstract will be subject to rejection, removal, or downgrade, unless an official Confidentiality Policy Exception applies.

UF 59. For this reason, it is widely known in the industry that disclosing too many details about a study in advance of a medical conference can result in a submission being rejected for presentation (or, if already accepted, removed from being presented at the conference). UF 60-61.

Puma's July 22, 2014 press release also announced that Puma planned to submit an application for FDA approval of neratinib in the extended adjuvant indication. Ex. 59. Puma was careful to caution investors that "the results of clinical trials may not support the Company's drug candidate claims"; neratinib "may never receive regulatory approval"; and "even if approved, physicians or patients may not accept or use the Company's products." *Id*.

The same day Puma issued its press release, it held an investor call to discuss the ExteNET results. UF 62 (Ex. 106). Mr. Auerbach reiterated statements from the press release regarding the top-line efficacy results, informed investors that the safety results were "still being validated," and explained that the "main adverse event that's been seen with neratinib [was] diarrhea." Ex. 106 at 3. Mr. Auerbach cautioned investors that the ExteNET trial did not use "prophylaxis to prevent the neratinib-related diarrhea," and that Puma was now employing Imodium in "all of its current ongoing studies." *Id.* at 4.

Analysts pushed for further details. First, analyst Yaron Werber asked about the difference in raw percentage of patients who remained disease free at the end of the initial study period (two years) between the treatment group and placebo group. *Id*. at 5. Mr. Werber gave his own estimates of DFS rates: "mid-high 80s, around 86% or so on the control [group] or so" and "around 90% or 91%" in the treatment group. *Id*. Mr. Auerbach responded, "Yeah. I think you can do a 33%

improvement in DFS and come up with that calculation given the numbers we give." *Id*. at 6. Mr. Werber later published an analyst report with discussion acknowledging that Mr. Auerbach had not disclosed the difference in absolute DFS rates between the treatment and placebo groups, and speculating that the difference ***could be between 2 and 8%***. UF 70.

Second, another analyst asked Mr. Auerbach to give "a sense as to whether the separation [in Kaplan-Meier curves was] widening over time?" Ex. 106 at 7. A widening of Kaplan-Meier curves over time suggests that neratinib has an increasing benefit to patients. UF 65. Mr. Auerbach responded that because the trial had commenced in April of 2009, Puma had "a lot of patients who've been in for much more than the two-year cut-off. If we look at the curves going out beyond that, it looks like the curves are continuing to separate." Ex. 106 at 7. He was careful to describe this separation as a "preliminary trend." *Id*.

Third, several analysts asked about the safety results. Mr. Auerbach said that the safety data had not been validated, but Puma anticipated "the grade 3 diarrhea rate would be in line with the 29% to 30% that's been seen in the prior studies of neratinib." *Id.* at 5. When asked about the "dropout rate due to side effects," Mr. Auerbach again explained Puma anticipated it would be in "the same vein" as previous trials where "it was usually in the 5% to 10% range." *Id.* at 14. Mr. Auerbach made clear that he did not "want to comment too much on the data, [] because [he] didn't want to jeopardize it being presented." *Id.* at 8.

D. Puma Conducts a Routine Secondary Stock Offering

Before, during, and for some time after the Class Period, Puma, like all biotechnology companies without a product for sale in the market, periodically raised capital through public stock offerings to fund the business. UF 71-72. While the timing of a public stock offering can vary due to market conditions, it is not uncommon for biotechnology companies to conduct a stock offering after announcing positive top-line clinical trial results. UF 73.

Puma engaged in a securities offering in January 2015. UF 72. Puma hired two major investment banks to serve as co-lead underwriters—J.P. Morgan and Merrill Lynch, Pierce, Fenner & Smith. UF 74. Underwriters facilitate public stock offerings by purchasing stock from public companies and selling the shares, in turn, to the market. UF 75. Before acting in this role, investment banks conduct extensive background checks, or due diligence, to ensure that investors who purchase in the offering are provided with sufficient information to make an informed decision. UF 76. As part of the diligence process, Puma provided the confidential results of the ExteNET trial to William Hicks of Mintz Levin, counsel for the underwriters, and Mr. Hicks advised the underwriters regarding the offering disclosures. UF 77-82. Based on this information and other extensive diligence, Mintz Levin and the underwriters concluded that Puma's disclosures were adequate and signed off on the offering. UF 83-84. The offering closed on January 27, 2015, yielding $218.5 million. UF 72.

E. Puma Presents Additional Results at Investor Conferences

Once Puma's validation process for the safety results was completed on January 30, 2015, Puma was able to present the safety data with more specificity. At a Leerink healthcare conference on February 12, 2015, Mr. Auerbach said, "As I mentioned, the ExteNET trial, which is our Phase III, did not use the Imodium prophylaxis, so the grade 3 diarrhea rates are in line with what we've expected in the 30% to 40% range." UF 85 (Ex. 210 at 2). He repeated the same range at the RBC healthcare conference on February 25, 2015. UF 88 (Ex. 111 at 3). Also at RBC, he gave more insight into the potential absolute DFS range, while being careful to remain vague, suggesting to investors that, within the 1-6% range with which he had previously expressed comfort, the absolute DFS difference might be "2%, 3% at year two." Ex. 111 at 2. The stock price did not react negatively to these comments. UF 86-87, 90-91.

F. Puma Presents the Full Trial Results at a Medical Conference

The ExteNET trial's Academic Steering Committee ("ASC"), made up of a group of independent academics and oncologists (no Puma employees are part of the ASC), originally oversaw and developed the protocol for the ExteNET trial. UF 91-92. In December 2014, the ASC met at the San Antonio Breast Cancer Symposium and decided to submit the ExteNET trial data to ASCO, in the hopes of presenting the data at ASCO's medical conference in Chicago, Illinois. UF 93-95. Puma submitted the ExteNET data to ASCO in February 2015 and was selected for an oral presentation to be given in early June. UF 96-97, 99.

After market close on May 13, 2015, ASCO released summaries prepared by the presenters, called abstracts, of the clinical trial data that would be presented at the meeting. UF 101. Puma's abstract (#508) disclosed, among other data points, that 93.9% of patients in the ExteNET treatment arm experienced DFS, compared to 91.6% in the control arm, for an overall absolute difference in DFS rates (benefit) of 2.3% at two years. Ex. 40. Abstract #508 revealed even more robust improvement in DFS, reflected by lower hazard ratios, for two subgroups of patients: patients whose HER2+ status had been "centrally confirmed" with independent testing, and those with hormone sensitive breast cancer. *Id*. Abstract #508 also disclosed that 40% of patients treated with neratinib had reported grade 3 or higher diarrhea. *Id*.

Following the release of Abstract #508, many analysts reacted positively and opined that neratinib's commercial potential remained strong. UF 102. Analysts believed that they would get a better understanding of the ExteNET data at ASCO. UF 104. On May 14, Puma's stock price closed at $170.67 (down 18.6% from the previous day's $209.72). UF 105. Several analysts believed that the market had misread the data, and many—including Lead Plaintiff's investment advisor—recommended that their clients continue to buy Puma stock. UF 103. Within two weeks, Puma's stock had regained nearly all of its lost value, closing at $200.21 on

May 27, 2015. UF 106.

On June 1, 2015, the Chair of the ASC, independent oncologist Dr. Arlene Chan, presented the full ExteNET dataset at ASCO, beginning at 11:24 a.m. EST. UF 94, 98, 107-08. Trading in Puma's stock was halted at 11:23 a.m. EST. UF 109. Dr. Chan presented the same ExteNET trial results as in the July 2014 press release and Abstract #508, and presented much more data in over twenty slides describing protocol changes, demographic data, additional efficacy and subgroup results, and analyses of adverse events. UF 110-12. The presentation contained visual KM curves through year two, showing separation between the treatment and control arms for the full trial population and for subgroups. UF 113-14. For the centrally confirmed HER2+ subgroup, the absolute DFS difference at year one was 3.2%, and at year two, 4.1%. UF 116. For the node-negative subgroup (that is, patients who did not have cancer cells present in their lymph nodes), there was not a statistically significant difference in efficacy between neratinib and placebo. UF 117. Multiple slides were devoted to safety data, including that 16.8% of participants discontinued treatment because of diarrhea. UF 118.

Immediately following Dr. Chan's presentation, another independent oncologist, Dr. Shanu Modi, provided her views about Dr. Chan's presentation. UF 119. With respect to the ExteNET trial data, Dr. Modi was skeptical, noted a lack of overall survival data, and predicted that doctors would need longer-term follow-up data before determining "how/whether to offer neratinib extended therapy" as an option for certain patients. UF 120. In the Q&A session that followed (UF 121), oncologists in the audience questioned neratinib's commercial opportunity, the potential need to amass longer-term data, and the likelihood of FDA approval. Dr. Steven Vogl referred to neratinib as a "terrible drug." UF 122. Dr. Richard Gelber hypothesized that the short follow-up time in the ExteNET trial was a "fatal limitation" and stated that he "would consider the results non-actionable"—predicting that the FDA would not approve the drug. UF 123.

Analysts quoted these comments in their reports on Puma's performance at ASCO and reiterated the concern that the FDA might not approve the drug or would require more data if so. UF 124-25. Moreover, the efficacy results for node-negative patients led some analysts to expect a smaller market for neratinib. UF 126-27. Most analysts did not mention the KM curves or the 16.8% discontinuation rate in their reports on ASCO; the four analysts that mentioned one or both of these facts characterized them as neutral or positive. UF 128.

From the resumption of trading at 12:28 p.m. EST on June 1 to market close that day, Puma's stock declined from $195.45 to $169.97, or 13.07%. UF 129. On June 2, Puma's stock declined from $169.97 to $146.65, or 14.06%. UF 130. Plaintiff does not allege that any new corrective information was released between ASCO and the close of trading on June 2.

G. Lead Plaintiff Purchases Additional Puma Stock

Following both the May 13 and June 1 disclosures, Lead Plaintiff Norfolk Pension Fund (through its investment adviser, Capital International) continued to purchase additional shares of Puma stock because its investment adviser viewed it as a "strong buying opportunity." UF 131-33. The Capital analyst testified that she was not misled, lied to, or defrauded by Mr. Auerbach in any way. UF 134.

H. The FDA Approves Neratinib; the EMA Follows Suit

On July 21, 2016, Puma announced that it had submitted its New Drug Application for neratinib, based on the efficacy and safety data from the primary two-year analysis (Part A) of the ExteNET trial. UF 135-36. On July 17, 2017, following a favorable vote by the Oncologic Drugs Advisory Committee, the FDA approved neratinib for the extended adjuvant treatment of HER2+ breast cancer in all patient subgroups. UF 137-38. As of April 30, 2018, physicians had ordered more than 2,400 new patient prescriptions for neratinib in the United States. UF 139. On June 29, 2018, a key committee of the EMA recommended marketing authorization for neratinib in Europe based on the same ExteNET data. UF 140.

III. LEGAL STANDARD

The Court may grant summary judgment where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). To prevail under Section 10(b) and Rule 10b-5, Plaintiff must establish a materially false or misleading statement, made with scienter, that caused its alleged losses. *Provenz v. Miller*, 95 F.3d 1376, 1382 (9th Cir. 1996). To survive summary judgment, Plaintiff "must do more than simply show that there is some metaphysical doubt as to the material facts" supporting each element. *Giron v. Hong Kong*, 2017 WL 5495504, at *8 (C.D. Cal. Nov. 15, 2017) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). Plaintiff cannot meet this burden.

IV. ARGUMENT

A. Plaintiff Cannot Establish Any Materially False or Misleading Statement

"The issue [of falsity] is appropriately decided as a matter of law . . . if no reasonable investor could conclude public statements, taken together and in context, were misleading." *Silver v. H&R Block, Inc.*, 105 F.3d 394, 396 (8th Cir. 1997). Plaintiff must present evidence raising a genuine issue of fact that the challenged statements were "misleading or untrue, not simply [that] the statements were incomplete." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). Here, Plaintiff has failed to adduce evidence that any reasonable investor was misled by the challenged statements. *See* Appendix A (chart).

1. Puma's "33% Improvement" Statement Was True

Plaintiff originally challenged Puma's statement about the ExteNET trial results—that the trial demonstrated "a 33% improvement in disease free survival

versus placebo"—by alleging that the 2.3% absolute difference in DFS rates at two years did not represent a 33% improvement. AC ¶ 65. That allegation was wrong, and Plaintiff has abandoned it. UF 44-46, 63. There is no dispute that a 2.3% absolute difference in DFS rates at two years is a different statistic, and that this result is consistent with the 33% improvement in DFS across the study period as reflected by the hazard ratio of 0.67. *Id*.

Plaintiff also challenged the "33% improvement" statement by claiming the drug reduced risk, rather than improved DFS. AC ¶ 49. After discovery, there is no genuine dispute that those are the same thing, and that both are true. That is, 33% improvement in DFS is the same as 33% reduction in risk reflected by the 0.67 hazard ratio (1 – 0.67 = 0.33). UF 46. Plaintiff's own investment advisor, whose understanding of these statements is attributable to Plaintiff, admitted that she was not misled by the press release (or any other statements made by Mr. Auerbach). UF 134; *see In re Vivendi Universal, S.A. Sec. Litig.*, 183 F. Supp. 3d 458, 466 (S.D.N.Y. 2016) (attributing knowledge of investment advisor to plaintiff where advisor learned of and "was indifferent to" the alleged fraud).

Now, however, Plaintiff has apparently pivoted to a third argument—that it was necessary to see the absolute difference in DFS rates in order to understand the admittedly true 33% improvement results. Ex. 34 at 6. This claim fails as a matter of law. The federal securities laws "do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011); *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012) ("[S]ection 10(b) and Rule 10b-5 prohibit only misleading and untrue statements, not statements that are incomplete."). Instead, in order to render an otherwise true statement misleading, the omitted fact must "conflict with what a reasonable investor would take from the statement itself." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1329 (2016).

That is not the case here. Puma identified the information it was disclosing:

the fact that the ExteNET trial met its primary endpoint, as measured by the hazard ratio and p-value. It also plainly stated that the rest of the data would be presented at a later medical conference. Ex. 59. While Plaintiff's expert claims he would have wanted to see the 2.3% DFS rate difference, that figure does not contradict the 33% improvement statement and does nothing to change the settled law. *See Kleinman v. Elan Corp.*, 706 F.3d 145, 156 (2d Cir. 2013) (holding that defendants' statements regarding clinical trial results were not false or misleading simply because statements did not also disclose additional data urged by plaintiff).

2. Mr. Auerbach's Response to an Analyst's Estimate of Absolute DFS Rates Was Not Materially Misleading

Plaintiff also points to analyst Yaron Werber's statement guessing at absolute DFS rates, and claims that Mr. Auerbach's response gave investors the misleading impression that the absolute difference in DFS rates was 5%. AC ¶¶ 52-54. The evidence shows this is not the case. The press release issued prior to the July 22, 2014 analyst call stated that Puma was not disclosing the absolute DFS rates, and that it would do so at a later medical conference. Ex. 59. On the call, Mr. Auerbach reiterated the reason for this sequencing: so that Puma would not risk being precluded from presenting at a conference. Ex. 106 at 4, 8. Accordingly, Mr. Auerbach kept his response vague, acknowledging Mr. Werber's range rather than giving any particular hard number. Mr. Werber's range is plain from his comments: "mid to high 80s, around 86% or so [in the placebo arm]" and "around 90% or 91% [in the treatment arm]." *Id*. at 5. The small end of that range is 1% (difference between 89% and 90%); the large end of that range is 6% (difference between 85% and 91%). The 2.3% absolute DFS difference disclosed on May 13 fell squarely in the middle of the 1-6% range Mr. Auerbach agreed he would be "comfortable with." *Id*. Mr. Auerbach's comfort with Mr. Werber's range did not "'affirmatively create[] an impression of a state of affairs that differ[ed] in a material way from the one that actually exist[ed].'" *Pompano Beach*

Police & Firefighters' Ret. Sys. v. Las Vegas Sands Corp., 2018 WL 2015510, at *2 (9th Cir. May 1, 2018) (quoting *Brody*, 280 F.3d at 1006); *see also Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 679 F.3d 952, 956 (7th Cir. 2012) (noting that the law recognizes that "[o]ral exchanges are less precise than written ones").

Further, the market understood that Mr. Auerbach was not giving a precise number, much less 5%. On a call with investors, Mr. Werber and an independent breast-cancer oncologist provided their expectations for the absolute DFS rate in a range of 2-8%. UF 70. Many other analysts estimated a range of the DFS difference in their reports—some in the 2-3% range and some higher—but each analyst identified different ranges as estimates or predictions. UF 64. Analysts clearly understood that the absolute DFS benefit data would be released later. *Id*; *see Tongue v. Sanofi*, 816 F.3d 199, 211 (2d Cir. 2016) (dismissing claims based, in part, on knowledge of "sophisticated investors, well accustomed to the 'customs and practices of the relevant industry'").

And later, when Mr. Auerbach suggested at an investor conference in February 2015 that, within the 1-6% range, the absolute DFS difference could be "2, 3% at year two," the market did not react. UF 88-90; Ex. 111 at 2. This undisputed evidence demonstrates that the market was well aware that Puma would not disclose the specific rates until later, and that the analysts themselves had a wide range of expectations. *See In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1116 (9th Cir. 1989) (granting summary judgment where articles showed that market "could not have been made more aware of [the new product]'s risks"); *In re REMEC Inc. Sec. Litig.*, 702 F. Supp. 2d 1202, 1217 (S.D. Cal. 2010) ("Plaintiffs must demonstrate more than a 'difference between two permissible judgments, but rather [must present facts explaining that the statement is] the result of a falsehood.'"). In the words of Plaintiff's own investment advisor: "I do not believe [Mr. Auerbach] ever misled me in any way." UF 134.

3. Mr. Auerbach's Statement Regarding Kaplan-Meier Curve Separation Was Not Materially Misleading

Plaintiff further contends that Mr. Auerbach's statement about a trend of continuing separation of the KM curves was misleading because the two-year curves allegedly were narrowing, not widening. AC ¶ 52. Plaintiff has mischaracterized Mr. Auerbach's statement. He did not comment on the curves at two years. He said he saw in the data a preliminary trend of what might happen beyond two years. Ex. 106 at 7. No evidence contradicts this statement, which Mr. Auerbach qualified as preliminary and based on a small amount of data. *See McGonigle v. Combs*, 968 F.2d 810, 817-19 (9th Cir. 1992) (affirming grant of summary judgment where statements contained "specific disclaimers"). There is no dispute that Puma had these preliminary data in July 2014. UF 66. Plaintiff's statistical expert admitted that these data were available and showed an increased DFS rate on a year-over-year basis (UF 67), and Puma's own analysis of that data projected an increased absolute DFS difference of 3.5% at three years (UF 68).

4. Mr. Auerbach's Statements Regarding Safety Results Were Not Materially Misleading

Finally, Plaintiff asserts that Mr. Auerbach falsely stated that the grade 3+ diarrhea rate was 29%-30% when it was actually 39.9%, and that the dropout rate due to adverse events was 5%-10% when it was actually 16.8% for diarrhea alone. AC ¶¶ 53-54. But this is not what he said. He said the data were still being validated, and that once validated he expected the data to be in line with the ranges observed in past studies. Ex. 106 at 3, 10. There is no dispute that Puma had not yet validated the safety data as of July 2014, and that Puma's statisticians later identified errors in those data. UF 51-53. Puma had no obligation to disclose unvalidated data. *See Brody*, 280 F.3d at 1006. When Mr. Auerbach gave further guidance on the safety data in February 2015, after it had been validated—telling investors on two separate occasions that without Imodium prophylaxis, the grade 3

diarrhea rates were expected in the 30-40% range—the market did not react. UF 85-90; Exs. 111 at 2, 210 at 3. This fact suggests that the ranges based on past studies were in line with ExteNET such that the 39.9% rate did not "significantly alter[] the total mix of information." *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 38 (D. Mass. 1997) (granting summary judgment on statements that put a "positive spin" on trial results where omitted data did not change analyst's assessment).

B. Plaintiff Cannot Establish Scienter

Plaintiff cannot establish as a matter of law that Defendants acted with scienter—the "intent to deceive, manipulate, or defraud." *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 & n.12 (1976). Proving scienter requires evidence of actual knowledge or recklessness, which involves conduct amounting to conscious misconduct. *See Provenz*, 102 F.3d at 1388. Far from meeting this standard, Plaintiff offers speculation and conjecture that Mr. Auerbach deliberately misled the market, while ignoring the fact that he had no motive to do so.

1. Mr. Auerbach's Access to ExteNET Trial Data Does Not Establish Scienter

Plaintiff's scienter claim rests upon the unremarkable fact that Mr. Auerbach had access to certain data in July 2014 that Puma did not disclose until May and June 2015. *E.g.*, AC ¶¶ 48, 66, 71, 105. That is true. But it does not establish scienter. The reason Puma disclosed the data in this order is not in dispute: if a company that announces top-line study results discloses too much of the underlying data, it risks forfeiting the chance at a coveted presentation such as at ASCO. UF 60-61. Without being presented to doctors and key opinion leaders at a medical conference, the drug may never gain acceptance in the medical community or market share. UF 58. Even Plaintiff's own witnesses testified to this point. *Id*. And far from anticipating the criticism received at ASCO, in July 2014 Mr. Auerbach (along with everyone else at Puma) had every reason to view the full ExteNET trial data as strongly positive—optimism that proved well

founded, given the FDA's approval followed by the EMA's recommendation. UF 138, 140. "[C]ourts do not presume that corporate officers make false statements simply out of spite or to impress others." *Schuster v. Symmetricon, Inc.*, 2000 WL 33115909, at *7 (N.D. Cal. Aug. 1, 2000), *aff'd*, 35 F. App'x 705 (9th Cir. 2002).

Moreover, Mr. Eyler was not even aware of the additional ExteNET trial results (UF 141), and thus he cannot have acted with scienter as a matter of law. *See Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 748-49 (9th Cir. 2008) (affirming dismissal on scienter grounds where no alleged facts show defendant's personal knowledge of the omitted information); *In re PETCO Corp. Sec. Litig.*, 2008 WL 8876554, at *3-9 (S.D. Cal. Apr. 29, 2008) (granting summary judgment, in part, where certain defendants were not aware of the alleged omitted facts).

2. Defendants Had No Reason to Mislead Investors

Plaintiff offers three motive arguments: personal financial gain, Puma's stock offering, and a potential sale of the Company. Undisputed evidence contradicts each of these theories.

a. Neither Mr. Auerbach Nor Mr. Eyler Had Any Personal Financial Motive to Commit Fraud

Plaintiff argues that Mr. Auerbach and Mr. Eyler were motivated to commit fraud by personal financial gain. AC ¶¶ 81-84. This is wrong for three reasons. First, neither Mr. Auerbach nor Mr. Eyler sold a single share of Puma stock during the Class Period. UF 142-43. This fact negates any reasonable conclusion that they had a personal financial incentive to commit fraud. *See Schuster*, 2000 WL 33115909, at *8 (granting summary judgment for defendants where "key insiders–the highest ranking executives who actually made the allegedly false or misleading statements" sold no stock); *see also In re Acceptance Ins. Cos., Inc. Sec. Litig.*, 352 F. Supp. 2d 940, 961-62 (D. Neb. 2004) (similar).

Second, rather than gain from any fraud, Mr. Auerbach and Mr. Eyler were substantially harmed by the increase in Puma's stock price in July 2014. In 2014,

94.8% of Mr. Auerbach's annual compensation consisted of stock options granted in December 2014 at a strike price of $195.33 per share—a price that Plaintiff contends was artificially inflated at Mr. Auerbach's doing. UF 145-46. Mr. Eyler's options, representing 90.3% of his annual compensation, were likewise granted in November 2014 at a strike price of $223.32 per share. UF 148-49. The options would have value to Mr. Auerbach and Mr. Eyler only if Puma's stock price increased above the (allegedly already inflated) strike price after the options began to vest in late 2015. UF 147, 150. That has not occurred, and the options remain worthless to this day. UF 146, 149, 151. What kind of a fraud is it to inflate the stock price ahead of receiving almost 95% of one's compensation in options, knowing that the "truth" will come out before a single share vests? *See Schuster*, 2000 WL 33115909, at *7 (noting "undisputed evidence that defendants were actually harmed by their alleged fraud often negates an inference of scienter and supports entry of summary judgment for defendants") (citation omitted).

Third, Mr. Auerbach's and Mr. Eyler's compensation packages of base salary, bonus, and stock options were not tied to Puma's stock price or the results of the ExteNET trial, negating scienter. UF 152-53; *see also In re Fed. Nat'l Mortg. Ass'n Sec., Deriv., & ERISA Litig.*, 905 F. Supp. 2d 63, 78 (D.D.C. 2012) (granting summary judgment where "earnings-per-share performance was not the dominant incentive underlying [defendant's] performance").

b. Puma's Secondary Offering Did Not Motivate Fraud

Plaintiff contends that Puma's January 2015 secondary stock offering was motive to commit fraud, in order to raise $218.5 million that Puma would not have otherwise been able to raise. AC ¶¶ 11, 76-80. The evidence contradicts this allegation. Puma conducted capital raises through stock offerings both before and after the Class Period, each time raising significant sums and at much lower stock prices than the January 2015 offering. UF 72. Puma accordingly did not need its stock price to increase in order to raise money. There is no evidence that Puma

would not have been able to raise money during the Class Period, whether or not the stock had risen after the announcement of top-line results. At summary judgment, Plaintiff's mere say-so is not enough. *See Vaughn v. Teledyne, Inc.*, 628 F.2d 1214, 1220 (9th Cir. 1980) (affirming summary judgment as "mere conclusory allegations" about stock transactions did not establish fraud); *Steiner v. Tektronix, Inc.*, 817 F. Supp. 867, 884-85 (D. Or. 1992) (finding that defendants' "interest in protecting their positions" and need for bank financing were insufficient to establish scienter at summary judgment). Moreover, corporate stock offerings are just the type of routine activity insufficient to prove scienter. *See Steiner*, 817 F. Supp. at 884-85.

c. A Potential Sale of Puma Did Not Motivate Fraud

Finally, Plaintiff contends that Mr. Auerbach misrepresented the ExteNET results in order to drive M&A interest so that he could sell the company and cash out his shares. AC ¶¶ 11, 84. No facts support this allegation. Puma has received interest from potential acquirers before, during and after the Class Period. UF 154. Such routine discussions do not provide any motivation to increase the stock price, but rather the opposite. *Cf. Paramount Commc'ns, Inc. v. QVC Network Inc.*, 637 A.2d 34, 49 (Del. 1994) (directors did not satisfy fiduciary duties in merger transaction when, among other factors, they had achieved only a modest change in control premium over the pre-merger stock price). Any claims of a potential sales process are baseless to support scienter.

C. Plaintiff Cannot Establish Loss Causation

At trial, Plaintiff also bears "'the burden of proving' that the defendant's misrepresentations 'caused the loss for which the plaintiff seeks to recover.'" *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345-46 (2005) (quoting 15 U.S.C. § 78u–4(b)(4)). To satisfy this burden at summary judgment in the Ninth Circuit, Plaintiff must show that the revelation of the alleged misrepresentations and omissions was a "substantial factor" in Puma's stock price declines. *Mineworkers'*

Pension Scheme v. First Solar Inc., 881 F.3d 750, 753 (9th Cir. 2018) (per curiam). In other words, Plaintiff must trace the stock price declines back to the "very facts" about which Defendants purportedly lied. *Id.* at 753 (citing *Nuveen Mun. High Income Opp. v. City of Alameda*, 730 F.3d 1111, 1120 (9th Cir. 2013)).

Plaintiff claims losses based on stock price declines on three dates: May 14, 2015, attributed to the 2.3% absolute DFS benefit and 39.9% grade 3+ diarrhea rate disclosed in Abstract #508; and June 1 and 2, 2015, attributed to the KM curves and 16.8% diarrhea drop-out rate disclosed at ASCO. AC ¶¶ 66, 71-72. Plaintiff cannot establish loss causation with respect to losses on June 1 or 2.

1. Plaintiff Cannot Prove That the KM Curves or 16.8% Discontinuation Rate Caused Puma's Stock Drop on June 1

Plaintiff cannot prove that the revelation at ASCO of the KM curves or the 16.8% diarrhea discontinuation rate caused Puma's stock price to decline on June 1. As an initial matter, Mr. Auerbach's statement on the July 22, 2014 analyst call about the KM curves described a preliminary trend for data beyond two years that was accurate. *Supra* at §IV(A)(3). The ASCO presentation did not disclose any KM curves beyond two years (UF 113), and therefore did not correct an earlier statement. *See REMEC*, 702 F. Supp. 2d at 1266-67 (a "corrective disclosure" must "reveal[] the fraud, or at least some aspect of the fraud to the market").

But even accepting Plaintiff's theory that the two-year KM curves corrected a prior statement, there is no evidence that either the two-year KM curves or the 16.8% discontinuation rate was a substantial factor in Puma's stock price decline. The parties' experts agree that analyst commentary is a critical component of the causation analysis. UF 155. The vast majority of analysts commenting on Dr. Chan's ASCO presentation did not even mention the two-year KM curves or the 16.8% discontinuation rate; the four analysts that mentioned these facts referred to them briefly as neutral or positive. UF 128. In short, no one saw these pieces of information as bad news. These undisputed facts are fatal to Plaintiff's ability to

prove loss causation. *See, e.g.*, *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 393-94 (9th Cir. 2010) (granting summary judgment where the few analyst reports plaintiff identified "would not allow a jury reasonably to render a verdict in their favor in light of the agglomeration of evidence supporting a contrary conclusion").

Unable to cite to any negative analyst commentary or testimony regarding the KM curves or 16.8% discontinuation rate, Plaintiff's expert Dr. Feinstein instead simply speculated that *any* negative reaction to the safety or efficacy results disclosed at ASCO must have been due to the disclosure of the KM curves or 16.8% rate. Ex. 10. These conjectures of an economist with no training in oncology must be rejected as ungrounded in any scientifically accepted economic principles or methodology, for the reasons that will be set forth in Defendants' *Daubert* motion. Dr. Feinstein's speculation that analysts meant something other than what they actually said is unreliable and cannot defeat summary judgment.

2. Plaintiff Ignores the Impact of Confounding Information

In addition to the KM curves and the 16.8% discontinuation rate—to which no one reacted—a host of confounding information was released in Dr. Chan's presentation on June 1 at ASCO. Plaintiff's expert Dr. Feinstein does not account for that "tangle of [other] factors affecting a security's price," such as changed investor expectations or non-corrective, new information. *Nuveen*, 730 F.3d at 1123. Accordingly, Plaintiff cannot prove loss causation on June 1.

The new information released at ASCO—data that Plaintiff does not allege should have been disclosed earlier—included trial protocol changes, demographic characteristics, efficacy results for certain subgroups, analyses of all adverse events, and oncologists' reactions to the trial results. UF 112, 117, 122-23. Unlike the KM curves and the 16.8% discontinuation rate, which analysts uniformly ignored, many analysts reacted negatively to this new information. In particular:

- **At ASCO**: No statistically significant DFS benefit was observed for node-negative patients—a population comprising the majority of breast cancer patients and a large portion of neratinib's commercial opportunity. UF 117.

Analysts' reactions: multiple revised estimates for neratinib's commercial potential due to modest benefit in the node-negative subgroup. UF 126-27.

- **At ASCO**: Oncologists, including Dr. Modi and audience questioners, indicated a desire to see longer follow up data to determine if neratinib's benefit was retained over time. UF 120, 122-23. **Analysts' reactions**: many predictions that more data, including three-year follow up and overall survival data, would be necessary for FDA approval. UF 124-26.
- **At ASCO**: One oncologist speculated that the trial's "short follow up" was "fatal" to the prospect of FDA approvability; another doctor called neratinib a "terrible drug." UF 122-23. **Analysts' reactions:** many cites to the negative reactions from oncologists; indeed, one analyst attributed Puma's entire stock drop on June 1 to the "terrible drug" sound-bite. UF 124.

Applying Plaintiff's expert Dr. Feinstein's methodology—reliance on analyst commentary—the record thus shows that the June 1 stock drop was caused by (1) the new (non-fraud related) node-negative data, and correspondingly revised investor expectations about the anticipated market for neratinib, and (2) ASCO oncologists' negative reactions to old and new data in the presentation, and investors' resulting speculation that neratinib would not receive FDA approval or would be approved only for node-positive patients. UF 124-27. Plaintiff does not allege that Defendants wrongfully concealed these reactions. "A recharacterization of previously disclosed facts" is not "corrective" for purposes of establishing loss causation. *In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d 546, 552 (granting summary judgment where corrective disclosure was really an observation based on facts already in the market), *aff'd* 597 F.3d 501 (2d Cir. 2010). As ASCO was the first forum for these oncologists to react publicly to the data disclosed in May in Abstract #508, these facts cannot be the cause of losses on June 1. *See REMEC*, 702 F. Supp. 2d at 1267 (corrective information must be new).

Plaintiff's expert Dr. Feinstein does not account for the impact of these non-fraud related factors on Puma's stock price. This failure renders Dr. Feinstein's analysis, and therefore Plaintiff's sole "proof" of loss causation, deficient as a matter of law. *See, e.g.*, *Nuveen*, 730 F.3d at 1123 (affirming summary judgment and exclusion of loss causation expert because of his failure to distinguish among

other non-fraud related factors impacting the stock price); *REMEC*, 702 F. Supp. 2d at 1274-75 (granting summary judgment and excluding loss causation expert where he did not account for additional information disclosed on the same day); *Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse First Boston*, 853 F. Supp. 2d 181, 193-94 (D. Mass. 2012) (granting summary judgment where plaintiffs failed to "isolate the extent to which the decrease in stock price was caused by the [corrective] disclosure"), *aff'd* 752 F.3d 82 (1st Cir. 2014).

3. Plaintiff Cannot Recover Alleged Losses on June 2

Plaintiff's attempt to recover losses from Puma's stock price drop on June 2 based on disclosures made on June 1 fails as a matter of law. The circumstances under which a two-day window can be appropriate (*e.g.*, where the corrective information is released after market close), are absent from the record. Trading in Puma stock was halted when Dr. Chan's presentation began at 11:23 a.m. EST on June 1, and was reopened at 12:27 p.m. EST. UF 109. The only new data presented during that period that Plaintiff claims to be corrective was the KM curves and the 16.8% discontinuation rate. Investors had a full three-and-a-half hours before the close of the trading day to react to those two discrete pieces of data. Consistent with the efficient market principle embraced by Plaintiff's expert, Dr. Feinstein, "if investors already knew the truth [on June 1], the drop in stock price [on June 2] could not be attributed to" the earlier-disclosed facts. UF 156; *Bricklayers*, 853 F. Supp. 2d at 193; *see also In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 269 (3d Cir. 2005) (public information is absorbed into a stock price "in the period immediately following disclosure").

D. Plaintiff Cannot Establish Control Person Liability

Plaintiff's "control person" claims under Section 20(a) fail because Plaintiff cannot prove a primary violation of Section 10(b). *See* 15 U.S.C. § 78t(a).

V. CONCLUSION

For the reasons set forth above, summary judgment should be granted.

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