ROBBINS GELLER RUDMAN
& DOWD LLP
TOR GRONBORG (179109)
TRIG R. SMITH (237399)
SUSANNAH R. CONN (205085)
J. MARCO JANOSKI GRAY (306547)
DEBASHISH BAKSHI (311115)
655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)
torg@rgrdlaw.com
trigs@rgrdlaw.com
sconn@rgrdlaw.com
mjanoski@rgrdlaw.com
dbakshi@rgrdlaw.com

Lead Counsel for Plaintiff

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

HSINGCHING HSU, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. PUMA BIOTECHNOLOGY, INC., et al., Defendants.	Case No. 8:15-cv-00865-AG-JCG CLASS ACTION FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

JURISDICTION AND VENUE

1. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") (15 U.S.C. §§78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder by the U.S. Securities and Exchange Commission ("SEC") (17 C.F.R. §240.10b-5).

2. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

3. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b) because a significant portion of Defendants' actions, and the subsequent damages, took place within this District.

4. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications and the facilities of national securities exchanges.

INTRODUCTION AND OVERVIEW

5. Lead Plaintiff Norfolk County Council, as Administering Authority of the Norfolk Pension Fund ("Norfolk Pension Fund" or "Plaintiff"), hereby brings this action on behalf of itself and all persons or entities who purchased or otherwise acquired the common stock of Puma Biotechnology, Inc. ("Puma" or the "Company") between July 22, 2014 (after 6:00 p.m., EDT) and May 29, 2015, inclusive (the "Class Period"), and were damaged thereby. Excluded from the Class, as defined below, are Defendants, present or former executive officers of Puma and their immediate family members (as defined in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)). Plaintiff seeks to recover damages caused by Defendants' violations of §§10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

6. Plaintiff alleges the following based upon personal knowledge as to itself and its own acts and upon information and belief as to all other matters. Plaintiff's information and belief is based on, *inter alia*, the independent investigation of its

counsel, Robbins Geller Rudman & Dowd LLP. This investigation included, but was not limited to, a review and analysis of: (i) the results of Puma's clinical trials of the drug known as neratinib; (ii) Puma's public filings with the SEC; (iii) transcripts of Puma's public conference calls; (iv) Puma's press releases; (v) independent media reports regarding Puma; (vi) economic analyses of Puma's stock price movement and pricing and volume data; (vii) consultations with relevant experts; (viii) other publicly available material and data identified herein; and (ix) documents produced by Defendants and relevant third parties.

7. Counsel's investigation of the facts underlying this action continues, and counsel further believes that relevant facts are known only by Defendants or are exclusively within their custody or control. Plaintiff believes that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for additional discovery.

8. Puma is a development-stage pharmaceutical company formed in September 2010 with a primary focus on acquiring and developing drug products. Since its formation, the Company has not received marketing approval for any drug product and has not produced any revenue. Puma's primary focus has been on the development of the drug PB272 ("neratinib"). Neratinib was initially developed by Wyeth and Pfizer, and Puma acquired the rights to license the drug in 2011. As of 2015, neratinib was in various phases of clinical trials for the treatment of early- and late-stage human epidermal growth factor receptor 2 ("HER2") breast cancer in the adjuvant, metastatic, neoadjuvant and HER2 mutation settings.

9. Puma's Phase III clinical trial for neratinib as an extended adjuvant treatment for HER2-positive breast cancer, known as the ExteNET trial, was completed in October 2013. The primary endpoint for the ExteNET trial was improved disease-free survival ("DFS") of patients taking the drug versus placebo at two years. During the Class Period, Defendants made false and misleading statements regarding the results of the ExteNET trial and the efficacy and safety of neratinib.

Specifically, beginning on July 22, 2014, Defendants publicly claimed that the ExteNET trial demonstrated that the absolute difference in DFS rates between neratinib patients versus placebo patients was 5% – approximately 91% compared to 86% – and, as a result, "treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo." Defendants further claimed that the drug and placebo DFS rates were "in line" with prior Herceptin Adjuvant Studies and that the DFS Kaplan-Meier curves widened year-over-year, meaning that the absolute difference between neratinib and placebo was actually improving over the course of the trial. Defendants also told investors that they "ha[d] not seen the safety results from the ExteNET trial," but that the rate of diarrhea for neratinib patients was expected to be approximately 30%, and the dropout rate due to adverse events was only 5% to 10%.

10. At the same time Defendants were making their statements about neratinib and the ExteNET trial, they reassured investors about the basis for their positive claims. Defendant Auerbach, Puma's Chief Executive Officer ("CEO"), not only provided the summary of ExteNET DFS data, but also told investors that with regard to the trial, he and the Company had the "***full safety results***" and "***full DFS data . . . the Kaplan-Meier curves, all endpoints, the DFS rates, the whole nine yards***."

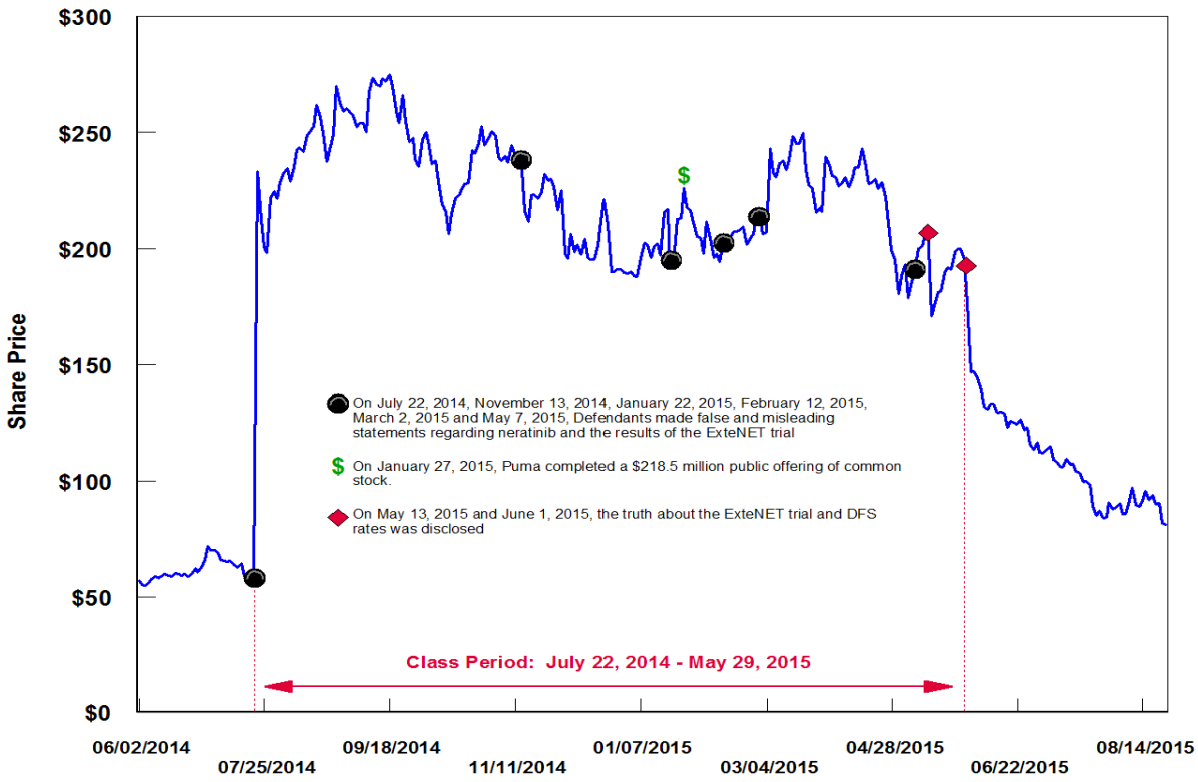
11. Defendants' statements had their intended effect. On July 23, 2014 alone, Puma's stock price more than quadrupled. Indeed, between July 22 and 23, 2014, the Company's stock price increased $174.40 per share, from $59.03 to $233.43, as more than 8 million shares changed hands. Over the following months, as Defendants repeated their statements about the purportedly positive ExteNET trial results, Puma's shares continued to trade at inflated levels up to and exceeding $250.00 per share. Taking advantage of this artificial inflation, in January 2015 Defendants sold 1.15 million shares of Puma stock for proceeds of $218.5 million in a secondary offering – money desperately needed to cover the Company's escalating

overhead costs. The Individual Defendants also lined their own pockets, collecting more than $22.3 million in salary and bonuses that were predicated on the supposedly positive ExteNET trial results and resulting stock price increase, and actively tried to sell Puma so they could cash out of their stock and option holdings.

12. After Puma's secondary offering and after the Individual Defendants had collected their bonuses, the true facts about neratinib and the ExteNET trial began to be revealed. Following the close of the New York Stock Exchange ("NYSE") on May 13, 2015, it was announced that Abstract #508 for the ExteNET trial had been posted on the American Society of Clinical Oncology ("ASCO") website. Abstract #508 revealed, for the first time, that the difference in DFS rates between ExteNET trial patients on neratinib versus placebo was not 5%, but ***only 2.3%,*** and, therefore, there was not a 33% improvement in DFS over placebo. Abstract #508 also revealed that ***39.9%*** of the neratinib patients in the ExteNET trial suffered from grade 3 or 4 diarrhea. As *Reuters* reported on the evening of May 13, 2015, Abstract #508 disclosed that "***93.9 percent of neratinib patients were alive without their disease progressing, compared with 91.6 percent of patents with a placebo***," and "***Puma had previously disclosed that treatment with neratinib had resulted in a significant 33 percent improvement in disease-free survival***." The *Reuters* report continued: "***The updated trial results also explained that 40 percent of patients in the trial experienced diarrhea***." Another article headlined that the disclosure left "Investors Growling in Disbelief." The response of those investors was swift and severe. On May 14, 2015 alone, Puma's stock price fell 18.6%, or $39.05 per share, on extremely heavy trading volume.

13. Two weeks later, at the ASCO conference, the false and misleading nature of Defendants' statements was further revealed. In a June 1, 2015 presentation, Dr. Arlene Chan disclosed that the Kaplan-Meier curves for the actual DFS rates from the ExteNET trial did not widen year-over-year and that the DFS rates for ExteNET were not close to being "in-line" with the Herceptin Adjuvant Studies. Dr. Chan's

presentation also revealed that the study discontinuation rate of neratinib patients due to grade 3 or 4 diarrhea alone was 16.8%, significantly higher than the total dropout rate of 5% to 10% Defendants had previously claimed. These disclosures were met with more investor disbelief and further declines in Puma's stock price. Over June 1 and 2, 2015, Puma's stock price plummeted an additional $48.80 per share, or over 24%, on heavy trading volume. All told, Plaintiff and investors who purchased or acquired Puma stock during the Class Period suffered damages of up to $87.85 per share and collectively suffered hundreds of millions of dollars in damages.



PARTIES

Plaintiff

14. **Norfolk Pension Fund**: Norfolk Pension Fund purchased Puma common stock during the Class Period on the NYSE and was damaged thereby. *See* Dkt. No. 106-1.

15. Norfolk Pension Fund is headquartered in Norwich, England. The employees of more than 200 organizations, including colleges and town councils, participate in the Fund. The Fund's primary objective is to provide for the pensions and benefits of members and their families following retirement or disability. Norfolk Pension Fund is administered by the Norfolk County Council, which established the Norfolk Pensions Committee. The Pensions Committee is responsible for the strategic management of the assets of the Fund and the administration of benefits. Norfolk County Council is empowered to act in the interests of all members and their dependents within the Fund.

Defendants

16. **Puma**: Puma is a Delaware corporation that describes itself as a development-stage pharmaceutical company that focuses on the acquisition, development and marketing of drugs for the treatment of certain cancers. The Company's principal offices are located at 10880 Wilshire Boulevard, Suite 2150, Los Angeles, California 90024. During the Class Period, the Company's stock traded on the NYSE under the symbol "PBYI."

17. **Alan H. Auerbach**: Defendant Alan H. Auerbach ("Auerbach") served as the Company's CEO, President and Chairman of the Board at all relevant times. Prior to founding Puma, Auerbach served as the founder and CEO of Cougar Biotechnology, Inc. ("Cougar") – a pharmaceutical company he sold to Johnson & Johnson in 2009. Puma's April 30, 2015 Proxy Statement emphasized Auerbach's "significant experience as an executive and research analyst in the biotechnology industry." In 2014, as a result of the fraudulent scheme alleged herein, Auerbach received $17.8 million in executive bonuses and compensation. During the Class Period, Auerbach had knowledge of the actual results of the ExteNET trial, as set forth in ¶48.

18. Prior to the Class Period, Auerbach was responsible for the content and approval of Puma's Code of Business Conduct and Ethics ("Code of Ethics"). The

Code of Ethics required that the Company's officers and employees ensure "the disclosure of accurate and complete information regarding the Company's business, financial condition and results of operations" and further warned that "[i]naccurate, incomplete or untimely reporting will not be tolerated and can severely damage the Company and result in legal liability." In addition, in accordance with Puma's Media Relations Policies and Procedures, Auerbach was required to review and approve all press releases, speeches, presentations and other communications to investors prior to release.

19. Auerbach made or had authority over the content and dissemination of the false statements and omissions set forth herein at ¶¶49-50, 52-54, 57, 59-63, and is liable for those false statements and omissions. Auerbach is also a control person of Puma within the meaning of §20(a) of the Exchange Act.

20. **Charles R. Eyler**: Defendant Charles R. Eyler ("Eyler") served as the Company's Senior Vice President of Finance and Administration and Treasurer (Principal Financial and Accounting Officer) at all relevant times. Prior to joining Puma, Eyler served as Chief Financial Officer ("CFO") and Chief Operating Officer ("COO") of Hayes Medical, Inc. In 2014, as a result of the fraudulent scheme alleged herein, Eyler received $4.5 million in executive bonuses and compensation. During the Class Period, Eyler had or had access to the actual results of the ExteNET trial, as set forth in ¶48.

21. Prior to the Class Period, Eyler was also responsible for the content and approval of Puma's Code of Ethics. The Code of Ethics required that the Company's officers and employees ensure "the disclosure of accurate and complete information regarding the Company's business, financial condition and results of operations" and further warned that "[i]naccurate, incomplete or untimely reporting will not be tolerated and can severely damage the Company and result in legal liability." In accordance with Puma's Code of Ethics, Eyler was responsible for ensuring that the Company's financial reports were full, fair, accurate, timely and understandable.

22. Eyler made or had authority over the content and dissemination of the false statements and omissions set forth herein at ¶¶49, 59, 61, and is liable for those false statements and omissions. Eyler is also a control person of Puma within the meaning of §20(a) of the Exchange Act.

23. Defendants Auerbach and Eyler are referred to herein, collectively, as the "Individual Defendants."

24. Defendants Puma, Auerbach and Eyler are referred to herein, collectively, as "Defendants."

BACKGROUND AND PRE-CLASS PERIOD EVENTS

Puma and Neratinib

25. Defendant Auerbach started Puma in 2010 with the intent to acquire, develop and market pharmaceutical products for use in treating cancer. As of October 2015, the Company has no products for sale and only one drug – neratinib – which it had acquired from Pfizer and was developing to sell as a treatment option for patients with breast cancer and solid tumors.

26. Neratinib is intended to be an irreversible inhibitor of the HER2 receptor tyrosine kinase with potential antineoplastic activity. The drug binds to the HER2 receptor irreversibly, thereby reducing what is known as "autophosphoylation" in cells, apparently by targeting a cysteine residue in the ATP-binding pocket of the receptor. Treatment of cells with neratinib is intended to result in inhibition of downstream signal transduction events and cell cycle regulatory pathways, arrest of the cell division cycle and, ultimately, decreased cellular proliferation.

27. At all relevant times, Puma was attempting to obtain regulatory approval for the use and marketing of neratinib (in oral and intravenous form) for the treatment of HER2-positive breast cancer and other forms of advanced cancer.

The Market for Neratinib as a Cancer Treatment

28. Breast cancer is the second leading cause of cancer deaths among women, with approximately 230,000 new cases reported each year in the United

States. Between 20% and 25% of breast cancer tumors show "over-expression" of the HER2 protein and women with these tumors are at a greater risk for disease progression and death than women with tumors that do not over-express HER2. Most patients with HER2-positive breast cancer develop resistance to the drugs currently approved by the U.S. Food and Drug Administration ("FDA") – *e.g.*, trastuzumab (Herceptin), pertuzumab and T-DM1 – thereby limiting treatment options. As a result, there is a recognized need for alternative treatments to block HER2 signaling pathways.

29. According to the Company's 2014 Form 10-K, neratinib has a large potential market with approximately 36,000 patients in the United States and 34,000 patients in the European Union diagnosed with HER2-positive breast cancer per year. Given the size of the potential market and the drug's potential to replace FDA-approved drugs on the market when a resistance develops, neratinib was expected to be a blockbuster drug if it could demonstrate a meaningful clinical benefit and ultimately be approved for use and marketing. Based on conversations with Defendants, analysts expected Puma would charge patients $6,500 a month, or $78,000 a year, for neratinib, a premium of over 40% over the cost of Herceptin. Defendant Auerbach, in a January 12, 2015 conference call with JP Morgan Chase analysts, touted that "neratinib will basically have the extended adjuvant setting all to itself with no competitive threats" and "[c]urrently Herceptin in year one of the adjuvant setting does approximately $4.3 billion, and all of those patients would be eligible for neratinib in year two." As *Bloomberg* reported, at the prices Puma intended to charge, neratinib could reap $2.5 billion in annual sales by 2020. The investment banking firm Cowen and Company also estimated that neratinib could generate total global sales for Puma of up to $6.0 billion by 2028.

Relevant Results and Statistics Discussed by Defendants and Market Participants During the Class Period

30. **Survival Rates**: In the context of studying cancer treatments, one of the most important endpoints to demonstrate is the improved chance of survival and recovery. Survival statistics describe the percentage of people with a certain type of cancer who are alive and whose cancer remains in remission after a cancer treatment is commenced. DFS is a specific survival statistic used in evaluating cancer treatments and refers to the percentage of people who survive and show no sign of the disease after finishing a treatment regimen.

31. The key metric in evaluating DFS rates across studies is the absolute benefit or absolute difference between the treatment arm and placebo arm in each study – the difference between the DFS rates for those on the drug and those on placebo. As a Leerink Partners equity analyst explained following Defendants' July 22, 2014 statements: "the magnitude of benefit (HR=0.63-0.67 depending on how disease-free survival [DFS] is measured, likely 4% absolute improvement in DFS on top of 1-year Herceptin) is among best-case scenarios that could be envisioned." Echoing Auerbach's statements, the analyst reported that "DFS for the control arm was in line with historical Herceptin adjuvant studies, likely in the range of 86-87%, which suggests a ~91% DFS in the drug arm, or absolute difference of ~4%." Leerink Partners also reported that in a conference call with key opinion leaders discussing Defendants' statements regarding the ExteNET trial results, the medical consultants "were enthusiastic about the magnitude of benefit seen for neratinib, and commented that the study could be practice-changing."

32. Following the disclosure of the actual ExteNET trial results, analysts again focused on the difference between DFS rates for patients on neratinib versus those on placebo. A Cowen and Company pharmaceutical analyst, for example, explained why the difference in absolute DFS benefit was so meaningful:

> Given prior comments from PBYI, investors had expectation of at least a 3% absolute benefit, and perhaps a benefit as high as 4-5%. In addition, some physicians are focused on absolute benefits as much as relative risk reductions. Given neratinib is associated with significant tolerability issues, some consultants have commented that they would like to see at least 3-4 women cured per 100 treated. Hence the 2.3% figure could lead to lower penetration in the marketplace.

A later Cowen and Company analyst report reiterated the importance of the DFS absolute benefit and why the truth about neratinib and the ExteNET trial was negative:

> Neither of our consultants were enthusiastic about the ExteNET dataset. They noted that the prognosis for HER2+ early stage patients is already very good with currently available therapies, therefore even though the hazard ratio targets were met, ***the absolute magnitude of difference in DFS was "trivial." Neratinib's use is likely to be limited to a small subset, most likely in ER/PR+ node positive disease***.
>
> * * *
>
> ***Both consultants believe that the market share for this drug is likely to be "very small" in the extended adjuvant setting*** because (1) patients do very well on existing therapies, (2) neratinib has significant tolerability issues, even with imodium prophylaxis, [and] (3) the vast majority [of patients] (~80%) are node negative, where the drug is likely to only show a modest benefit . . . .

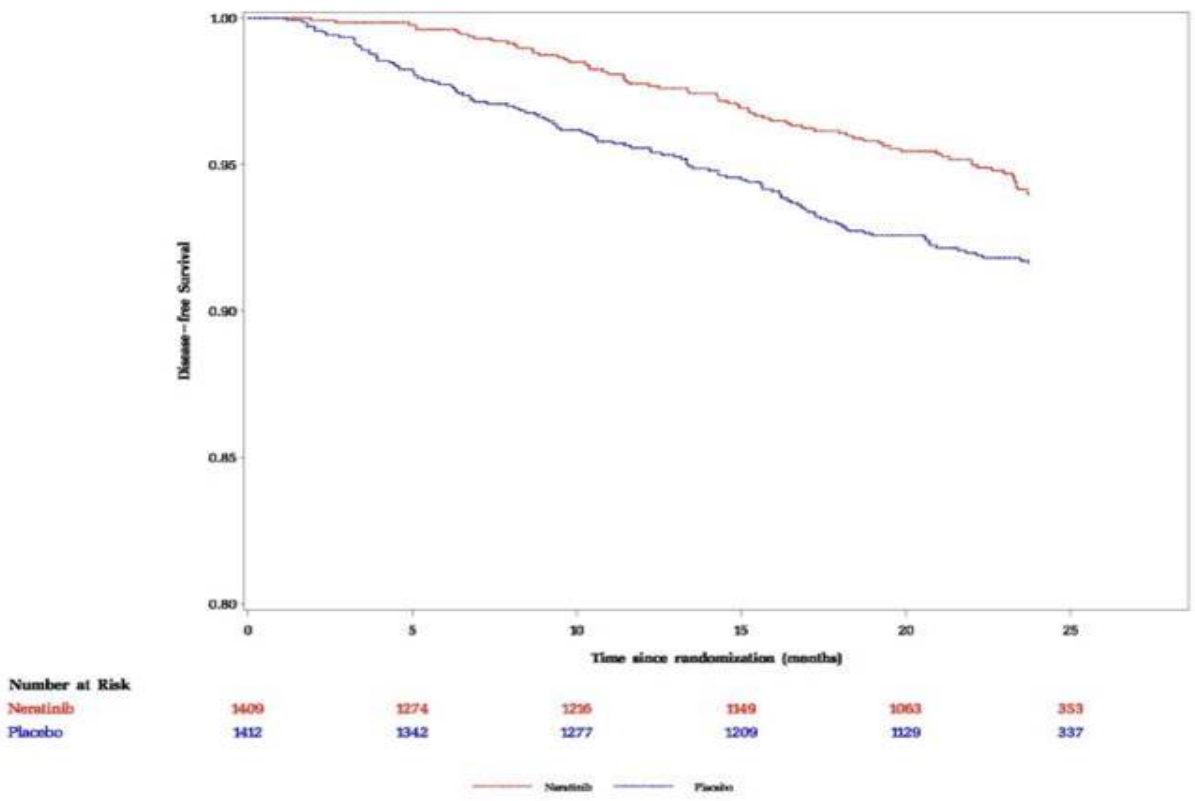
33. **Kaplan-Meier Curves**: In 1958, Edward L. Kaplan and Paul Meier published a seminal paper describing how "Kaplan-Meier curves" deal with differing survival times ("times-to-event") when not all study participants continue to the end of a clinical study. *See* E.L. Kaplan & P. Meier, *Nonparametric Estimation from Incomplete Observations*, J. Amer. Stat. Assoc. (1958, vol. 53:457-81). Kaplan and

Meier's academic research provided important examples of when survival times are key to certain studies, such as in cancer treatment trials.

34. In order to graph Kaplan-Meier curves, it is necessary to have the study data concerning the number of patients in the treatment arm that have and have not relapsed over pre-defined time intervals. The same holds true for the placebo arm. The DFS rate is calculated from this data. For example, if at the end of the first period, 0 out of 10 individuals that received the medication have relapsed, while 1 out of 10 individuals that received placebo have relapsed, the DFS rates at the end of the first period would be 100% for those patients receiving the drug and 90% for placebo. If, at the end of the second period, 1 out of 10 patients receiving the medication relapsed, while 2 out of 9 remaining placebo patients relapsed, the DFS rate would then be 90% for treatment and 78% for placebo. Under this hypothetical set of facts, it appears that it is more probable that patients who take the cancer drug will not experience an "event" or relapse.

35. Further, the distance between the Kaplan-Meier curves in the above-noted hypothetical can be said to be increasing or "widening" over time because at the end of the first period, the DFS rate for treatment versus placebo was 100% and 90% (an absolute difference of 10%), respectively, and at the end of the second period, the DFS rate for treatment versus placebo was 90% and 78% (an absolute difference of 12%). A widening of the Kaplan-Meier curves would be seen as a key, positive result in a trial like ExteNET. A pharmaceutical analyst at UBS Securities explained following Defendants' July 22, 2015 statements: "[C]ommentary on the call adds to our confidence: the DFS curves apparently widen over time, and neratinib appears active in all subgroups examined, suggesting broad utilization."

36. Below is a graphical depiction of the Kaplan-Meier curves for the ExteNET study provided to Auerbach and Puma executives on July 17, 2014:



37. **Adverse Events: Grade 3 or 4 Diarrhea**: In clinical trials, the analysis of safety is generally done by reporting and tracking incidences of adverse events of interest. An adverse event is any unfavorable change in health that occurs in trial participants during the clinical trial or within a specified period following the trial. Adverse events are generally characterized as "serious adverse events" or "other adverse events." Diarrhea adverse events are measured on a scale from grade 1 (minor change in bowel movements) to grade 5 (death). A patient is deemed to have grade 3 diarrhea when they suffer from an increase of greater than seven bowel movements a day over baseline and/or hospitalization as a result of diarrhea. A patient suffering from grade 4 diarrhea has life-threatening consequences, including extremely low blood pressure as a result of severe dehydration.

The ExteNET Trial and License Agreement with Pfizer

38. Neratinib, like other pharmaceutical products, is subject to a series of clinical trials to evaluate its effectiveness and safety for particular treatments prior to

obtaining marketing approval. Clinical trials progress through distinct phases, and Phase III trials are the most significant for testing the efficacy and safety of a drug. The Phase III clinical trial of neratinib for the extended adjuvant treatment of HER2-positive breast cancer, the ExteNET trial, was conducted between April 2009 and October 2013.

39. Originally initiated by Wyeth before its merger with Pfizer, the ExteNET trial was transferred to Puma as an ongoing "legacy trial" when Puma agreed to license neratinib from Pfizer in 2011. Under the terms of the agreement, Puma assumed sole responsibility for global development and commercialization of neratinib, while Pfizer remained entitled to receive royalties and other payments upon Puma's achievement of certain development milestones for neratinib. The original agreement also transferred financial responsibility for ExteNET and the legacy trials to Puma, but required Pfizer to reimburse the Company for all expenses above a pre-determined limit.

40. The ExteNET trial enrolled 2,821 patients with HER2-positive breast cancer. All of the patients had undergone surgery and one year of adjuvant treatment with Herceptin. After Herceptin treatment, patients were randomized to receive either extended adjuvant treatment with neratinib or placebo for one year. Patients were then followed for a period of two years after randomization. Other than the HERA trial – which failed to show that two years of Herceptin is better than one – the ExteNET trial was the only trial that tested the efficacy of a HER2 cancer drug in the extended adjuvant setting.

41. The primary endpoint for the ExteNET trial was the DFS of patients taking the drug versus placebo. On July 22, 2014, Defendants announced that the ExteNET trial had hit its primary endpoint. Specifically, Defendants claimed that treatment with neratinib demonstrated a 33% improvement in DFS over placebo – based on DFS rates of roughly 91% and 86% and an absolute difference of 5% – and

that the Kaplan-Meier curves continued to widen year after year. These purported results were enthusiastically greeted by investors and practitioners.

42. On July 22, 2014, the same day that Defendants made their announcement about the ExteNET DFS results, Puma also disclosed that it had reached an agreement with Pfizer to amend the licensing agreement. According to Puma, under the new terms, Pfizer would no longer be obligated to fund the legacy clinical trials – including post-trial expenses with ExteNET – in consideration for lowering its royalties from "10-20%" to a fixed rate of in the "low- to mid-teens." The terms of the amendment were agreed to before Pfizer and Defendants were aware of the ExteNET trial results announced on July 22, 2014.

The Herceptin Adjuvant Studies – HERA, NSABP, NCCTG and BCIRG

43. Several key breast cancer treatment studies had been conducted prior to the completion of the ExteNET trial in 2013. The current standard of care drug – Herceptin – underwent four major clinical trials in the adjuvant setting: Herceptin Adjuvant ("HERA"); National Surgical Adjuvant Breast and Bowel Project ("NSABP") B-31; North Central Cancer Treatment Group ("NCCTG") N9831; and Breast Cancer International Research Group ("BCIRG") 006 (collectively, the "Herceptin Adjuvant Studies"). The primary efficacy endpoint for each of the Herceptin Adjuvant Studies was DFS. In all four studies, the DFS rates from one year of Herceptin treatment ranged from 85.8% to 88.0%, with a median absolute difference between treatment and control groups of ***6.65%***.

44. The HERA study was designed to compare one and two years of Herceptin treatment following surgery and chemotherapy in patients with HER2-positive early breast cancer ("EBC"). At two years follow-up, HERA demonstrated that one year of Herceptin resulted in an absolute benefit of ***7.6%*** over placebo. Long-term follow-up established that two years of Herceptin was no more effective than one year of the drug.

45. The NSABP B-31 and NCCTG N9831 studies were designed primarily to investigate the clinical efficacy of combining Herceptin with the drug paclitaxel following AC chemotherapy. Because of the similar design of the two studies, both sets of data from the studies were analyzed jointly after discussion with the FDA. At three and a half years follow-up, the joint analysis found that one year of Herceptin resulted in an absolute benefit of ***15.3%*** over AC chemotherapy followed by just paclitaxel.

46. The BCIRG 006 study was designed to investigate the clinical utility of Herceptin treatment in post-surgery patients with HER2-positive EBC in two different settings: (i) following AC chemotherapy in combination with the drug docetaxel; or (ii) in combination with the drugs docetaxel and carboplatin. At three years follow-up, both settings demonstrated that Herceptin had an absolute benefit of ***5.7%*** and ***4.0%***, respectively, over AC chemotherapy followed by just docetaxel.

47. Combined, the Herceptin Adjuvant Studies were considered the gold standard of breast cancer research and development. Due to the magnitude of absolute benefit demonstrated in these studies, one year of Herceptin treatment has become the standard of care for early stage breast cancer patients. However, because two years of Herceptin provides no added benefit from one year of treatment and is often not a viable treatment due to developing resistance, a drug that could demonstrate a similar magnitude of benefit in year two (*i.e.*, extended adjuvant) would have the potential to profit enormously from the Herceptin patient market. Thus, during the Class Period, Defendants compared the results of the ExteNET against the results of completed Herceptin studies in order to stoke investor interest in the effectiveness and marketability of neratinib.

Defendants' Knowledge and Access to Material, Undisclosed Facts Concerning ExteNET Trial Results

48. On July 17, 2014, Puma's Senior Director of Clinical Science, Alvin Wong ("Wong"), emailed Auerbach and Puma executives a document entitled

"Neratinib Protocol 3144A2-3004-WW Top-Line Efficacy Analysis Part A (2 years + 28 days)" (the "ExteNET Top-Line Efficacy Analysis"). The ExteNET Top-Line Efficacy Analysis identified that: (a) the DFS rates for the primary endpoint in the ExteNET trial were 93.9% in the treatment arm and 91.6% in the placebo arm for an absolute difference of 2.3%; and (b) the Kaplan-Meier curves were essentially flat with no trend of separation between the treatment and placebo arms from one year after randomization to two years after randomization and were narrowing at the end of the two-year period. The next day, on July 18, 2014, Wong emailed Auerbach and other Puma executives a PowerPoint presentation entitled "3004 Executive Summary of Safety 18JUL2014" and the ExteNET top-line safety tables, which identified that: (a) 39.9% of patients in the treatment arm experienced grade 3 or 4 diarrhea; and (b) the discontinuation rate for neratinib patients due to grade 3 or 4 diarrhea was 16.8%, and the overall dropout rate for neratinib patients due to adverse events was 27.6%.

DEFENDANTS' MISLEADING STATEMENTS AND MATERIAL OMISSIONS

49. After the market closed on July 22, 2014, Puma issued a press release and thereafter filed a Form 8-K, signed by defendant Auerbach and attaching the press release, with the SEC. The press release, reviewed and approved for publication by Auerbach and Eyler, was entitled "Puma Biotechnology Announces Positive Top-line Results from Phase III PB272 Trial in Adjuvant Breast Cancer (ExteNET Trial): Neratinib Achieves Statistically Significant Improvement in Disease Free Survival Company Plans to File for Regulatory Approval in First Half of 2015." The press release reported: "***The results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo***."

50. Immediately after the Company issued its July 22, 2014 press release, Puma held a conference call with analysts and investors to further discuss the top-line results of the ExteNET trial. Auerbach participated in the conference call. During the

call, Auerbach engaged in the following exchange with Yaron Werber, a Citi Research equity analyst:

> [WERBER:] Congrats on this fantastically and, in many ways, unexpected data. So I have a ton of questions. Maybe I'll just take two, if you don't mind. One is, give us a little bit of a sense, what was the DFS on the control arm, first. And then second, help us understand, what do you know about the safety profile?
>
> [AUERBACH:] Okay. ***So in terms of the DFS of the placebo arm of the trial, it was in line with other reported trials. So it's inline with the Herceptin adjuvant studies***. ***And then in terms of the safety profile, we haven't yet fully validated the safety database***.
>
> * * *
>
> [WERBER:] ***You're thinking that, if I'm correct, the DFS is probably around mid to high 80s, around 86% or so in the control arm***?
>
> [AUERBACH:] ***I would be comfortable with that number***.
>
> [WERBER:] ***And one would imagine you probably had to show around 90% or 91% [in the treatment arm]? Is that reasonable***?
>
> [AUERBACH:] ***Yes. I think you can do a 33% improvement in DFS and come up with that calculation, given the numbers we gave***.

51. With these statements, Auerbach asserted that the DFS of the placebo arm was "in line" with the Herceptin Adjuvant Studies at roughly 86%. Auerbach also confirmed that the treatment arm demonstrated a DFS of 90%-91%. As a result, analysts and investors understood the 33% improvement claim was based on an absolute DFS benefit of approximately 5% – a magnitude of benefit that would support widespread clinical use of neratinib.

52. During the July 22, 2014 conference call, Auerbach also made the following statements during an exchange with Leerink Partners equity analyst Howard Liang regarding the Kaplan-Meier curves for the ExteNET trial:

> [LIANG:] Congratulations, Alan, and your team. So can you – ***I assume you have seen the curves for the two arms***. Can you give us a sense as to whether the separation is widening over time? Or how would you describe the curve separation?
>
> [AUERBACH:] ***Yes***, Thanks for that question, Howard. Okay, so the [ExteNET] trial started in April of 2009, and this data cut is as of October 2013. So that's essentially the last patient was followed for 2 years. So from those numbers, you can see we have a lot of patients who have been in for much more than that 2-year cutoff. ***If we look at the curves going out beyond that, it looks like the curves are continuing to separate***.
>
> ***And to give a little more detail on that, if you look at the curves in the Herceptin adjuvant trials – so the HERA study, the BCIRG study, et cetera – the absolute difference in disease-free survival increases as you go out year over year. So, for instance, in the BCIRG trial, the DFS difference was 6% at 2 years and 7% at 3 years, then 8% at 4 years*** . . . .
>
> ***We're seeing the same preliminary trend in the ExteNET trial, where the curves appear to be continuing to separate as you go out year over year, and the absolute DFS difference is increasing year over year as well***.

53. Also at the July 22, 2014 conference call, Auerbach made the following statement in his opening remarks:

> ***From a safety perspective, the Company has not yet seen the safety results from the ExteNET trial for neratinib, as the data is still being validated***.
>
> * * *
>
> Prior to Puma licensing the drug, neratinib monotherapy was previously tested in two Phase II trials in patients with HER2-positive metastatic breast cancer, the results of which were published in European Journal of Cancer in December 2013 and the Journal of Clinical Oncology in 2010. ***In those studies, grade 3 or higher diarrhea was seen in 29% and 30% of the patients, respectively***.
>
> The ExteNET trial was started in April of 2009, prior to Puma licensing the drug in 2011. Neratinib was given as a monotherapy, and no prophylaxis to prevent neratinib-related diarrhea was used. ***Therefore, the Company anticipates that the grade 3 diarrhea rates in the ExteNET trial are likely to be in line with what was previously published in the prior Phase II trials that were published in the European Journal of Cancer and the Journal of Clinical Oncology***.

54. At the same July 22, 2014 conference call, Auerbach had the following exchanges with analysts Yaron Werber of Citi Research, Eric Schmidt of Cowen & Co. and Matt Roden of UBS Securities regarding the diarrhea and dropout rates in the ExteNET trial:

> [WERBER:] Congrats on this fantastically and, in many ways, unexpected data. So I have a ton of questions. Maybe I'll just take two, if you don't mind. One is, give us a little bit of a sense, what was the DFS on the control arm, first. And then second, help us understand, what do you know about the safety profile?
>
> [AUERBACH:] Okay. So in terms of the DFS of the placebo arm of the trial, it was in line with other reported trials. So it's inline with the

Herceptin adjuvant studies. And then in terms of the safety profile, we haven't yet fully validated the safety database. Our anticipation is the main AE we're going to see is what we've historically seen with neratinib, which is the diarrhea. ***And again, we would anticipate that the diarrhea rate, the grade 3 diarrhea rate, would be in line with the 29% to 30% that's been seen in the prior studies of neratinib as a monotherapy.***

* * *

[SCHMIDT:] Thanks. And lastly, I think you probably do know the dropout rate from the trial. Could you remind us of that?

[AUERBACH:] Dropout rates due to side effects?

[SCHMIDT:] Sure, or anything, if you have it.

[AUERBACH:] ***I don't have that. I apologize. That's part of the stuff being validated, but we anticipate, typically in the neratinib studies – the legacy ones that were done before, when Pfizer was running it without any prophylaxis – it was usually in the 5% to 10% range was the dropout rate due to AEs. So we'd anticipate it's in that same vein***.

* * *

[RODEN:] I just wanted to clarify an earlier answer to a question. So you were asked about the dropout rate, and I think you wanted to defer to dropouts due to – discontinuations due to adverse events. But can you just mention, or maybe I missed it, how many patients actually completed the year of therapy? Or another way of saying it is how much missing data is there from the DFS analysis?

[AUERBACH:] ***Yes, so in terms of patients who dropped out due to AEs, like I said, historically with neratinib, that should be somewhere in the 5% to 10% range***.

[RODEN:] Okay, but do you have a sense for dropouts for any reason across the study?

[AUERBACH:] ***No***, the main one we would expect is due to AEs. And obviously, if they progressed or died.

55. In response to the Company's press release and conference call concerning the results in the ExteNET trial, Puma's stock price skyrocketed, increasing $174.37 per share by the close of the market on July 23, 2014, a one day increase of over 295%.

56. Media reports flagged Puma's stock price increase and tied it to Defendants' statements regarding the ExteNET trial results. For example, on July 23, 2014, an *MTNewswires* article entitled "Puma Biotechnology Up More Than 220% in Early Pre-Market on Results of Cancer Drug Trial," reported "[t]he results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival, the primary endpoint, versus placebo." Similarly, a *MarketWatch* article entitled "Puma Biotech's blast-off is not a typical short squeeze," reported the Company's stock "soared $170.83, or 289%, to $229.86 in midday trading [on July 23, 2014] . . . . The blast-off follows the company's announcement late Tuesday of positive results from a Phase 3 trial of its breast cancer treatment."

57. Approximately four months later, following the close of trading on November 13, 2014, Puma held a conference call with analysts and investors to discuss the top-line results of a different Phase III trial of neratinib for the treatment of metastatic breast cancer. During the call, Auerbach also spoke about the ExteNET trial and reiterated that: "***The primary endpoint of this trial was disease-free survival and neratinib demonstrated a 33% improvement in disease-free survival***."

58. Following the close of trading on December 2, 2014, Puma held a conference call with analysts and investors for the purpose of updating the market regarding the filing of the New Drug Application ("NDA") for neratinib as an extended adjuvant treatment for breast cancer. During the call, Auerbach confirmed

that the FDA had requested Puma to submit the results of the two-year DFS data from the ExteNET trial and again acknowledged that the Company maintained and had direct knowledge of the DFS rates for the treatment and placebo arms: In response to a question about the efficacy data discussed with the FDA, Auerbach stated: "***That's correct. The data that was provided [to the FDA] was the full DFS data – so the Kaplan-Meier curves, [all the] endpoints, the DFS rates, the whole nine yards***." In response to a separate question, "did you share with the [a]gency the full safety results" from the ExteNET trial, Auerbach confirmed "Yes."

59. On January 20, 2015, Defendants filed a Form S-3ASR Registration Statement with the SEC for a follow-on offering of securities, including common stock, debt securities and warrants. On January 22, 2015, Defendants filed a Form 424B2 Prospectus with the SEC for the sale of 1.15 million shares of Puma stock. Defendants Auerbach and Eyler signed the Form S-3ASR Registration Statement and wrote, adopted and approved of the contents of the Form 424B2 Prospectus. With regard to the ExteNET trial, the Form 424B2 Prospectus stated that "***[t]he results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo***." The January 2015 Registration Statement, moreover, incorporated by reference the Company's July 22, 2014 press release announcing the top-line results of the ExteNET trial.

60. On February 12, 2015, Puma held a conference call with analysts and investors for the purpose of updating the market regarding the Company's product pipeline. Auerbach led the call and again claimed that the top-line results of the ExteNET trial demonstrated that "***[t]here was a 33% improvement in disease-free survival***" for patients on neratinib.

61. On March 2, 2015, the Company filed its 2014 Form 10-K with the SEC. Defendants Auerbach and Eyler signed the Form 10-K and, pursuant to §302 of the Sarbanes-Oxley Act of 2002, certified that the Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make

the statements made, in light of the circumstances under which such statements were made, not misleading." With regard to the ExteNET trial, Defendants stated in the Form 10-K that "***[t]he results of the trial demonstrated that treatment with neratinib resulted in a 33% improvement in disease free survival versus placebo***."

62. On March 3, 2015, Puma held another conference call with analysts and investors for the purpose of updating the market regarding the status and results of the Company's clinical trial programs. During the call, Auerbach stated: "***So we announced the results in July of 2014, where we announced that the trial hit the primary endpoint. So, 33% improvement in disease free survival*** . . . ."

63. On May 7, 2015, Puma held another conference call with analysts and investors for the purpose of updating the market regarding the regulatory and clinical status of neratinib. During the call, Auerbach reiterated: "***In July last year, we announced the trial hit its primary endpoint. We saw a 33% improvement in invasive disease-free survival*** . . . ."

64. As a result of Defendants' false and misleading statements between November 2014 and May 2015, Puma stock continued to trade at artificially inflated levels, reaching more than $250 a share, and Defendants completed the sale of $218.5 million in stock.

65. Defendants' Class Period statements, set forth in ¶¶49-50, 52-54, 57, 59-63, which succeeded in artificially inflating Puma' stock price, were false and misleading when made. With regard to the efficacy results of the ExteNET trial, Defendants falsely informed investors that the absolute difference in DFS rates between neratinib and placebo was approximately 5%, purportedly demonstrating a 33% improvement in disease-free survival, and that the Kaplan-Meier curves (the difference between drug and placebo DFS rates) were separating. The true facts, that Defendants knew but failed to disclose during the Class Period, were that the actual absolute difference in DFS rates was only 2.3%, which did not represent a 33% improvement and was not in line with the Herceptin Adjuvant Studies, and that at the

end of the two-year ExteNET trial the Kaplan-Meier curves were not separating and were actually narrowing. With regard to the safety results of the ExteNET trial, Defendants falsely informed investors that approximately 29% to 30% of patients treated with neratinib suffered grade 3 or 4 diarrhea, and that the dropout rate due to adverse events would be 5% to 10%. The true facts, that Defendants knew but failed to disclose during the Class Period, were that 39.9% of patients treated with neratinib experienced grade 3 or 4 diarrhea, 27.6% of neratinib patients dropped out of the ExteNET trial due to adverse events, and that 16.8% of patients taking the drug discontinued treatment as a result of experiencing grade 3 or 4 diarrhea.

DISCLOSURE OF THE TRUTH ABOUT THE EXTENET TRIAL

66. After the market closed on May 13, 2015, it was announced that Puma had released Abstract #508, the summary of a journal reprint regarding the ExteNET trial, on the ASCO website, www.abstract.asco.org. Abstract #508 revealed that the DFS for patients in the treatment arm of ExteNET was 93.9%, while the DFS for patients receiving placebo was 91.6%. This difference in DFS – ***only 2.3%*** – was materially lower than what the market had been led to believe by Defendants' false and misleading statements. Abstract #508 also revealed that ***40%*** of patients in the treatment arm of ExteNET experienced grade 3 or grade 4 diarrhea, materially higher than what the market had been led to believe by Defendants' false and misleading statements.

67. As *Reuters* reported in a May 13, 2015 article entitled "Puma Biotech breast cancer trial detailed, shares fall 25 pct":

> Puma shares slid 25 percent after hours following release of the findings on Wednesday by the American Society of Clinical Oncology ahead of its annual meeting later this month.

* * *

> It found that after two years, 93.9 percent of neratinib patients were alive without their disease progressing, compared with 91.6 percent of patients treated with a placebo.
>
> Puma had previously disclosed that treatment with neratinib had resulted in a significant 33 percent improvement in disease-free survival.
>
> The updated trial results also explained that 40 percent of patients in the trial experienced diarrhea.

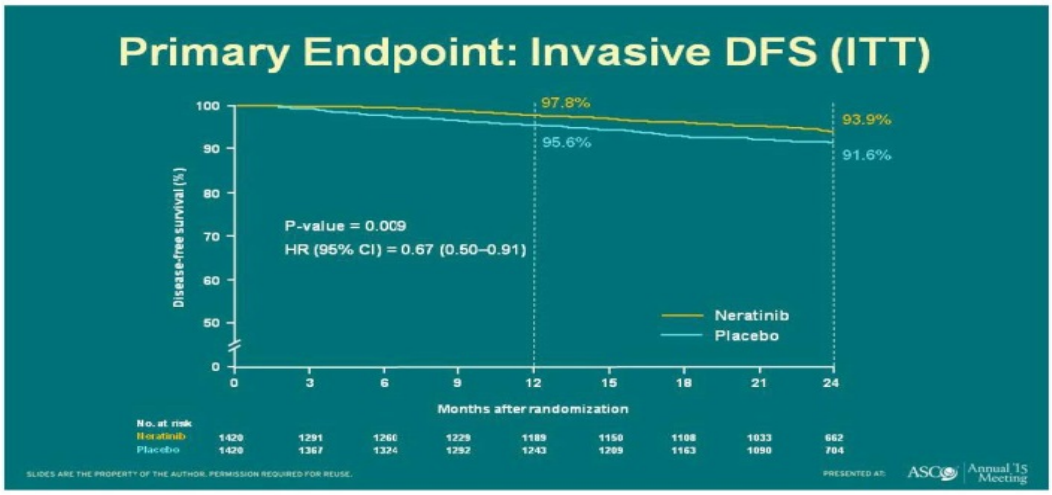
68. On May 14, 2015, *FierceBiotech* published an article entitled "The ASCO roundup: Thumbs down for Puma, up for Roche, mixed for Bristol-Meyers." The article referenced the ASCO abstract, noting it scored "the percentage of women who were free of invasive disease [and] the neratinib group hit 93.9% compared to 91.6% in the placebo arm. ***Analysts did a double take on the meager 2.3% difference and quickly turned thumbs down on the data***." The article continued, "***[a]bout four of 10 patients in the drug arm experienced severe diarrhea, which will likely have physicians looking to think twice before prescribing it*** . . . ."

69. As a result of investors learning the truth about the results of the ExteNET trial, Puma's stock priced dropped by $39.05 per share on May 14, 2015. This 18.6% decline came on massive volume, as the number of shares traded increased to 3.1 million, a 948% increase over Puma's average daily trading volume for the prior 90 days.

70. On May 28, 2015, in an article entitled "Puma Bio Restricting Access to Breast Cancer Event at ASCO Chicago," *TheStreet.com* reported that certain securities analysts with bearish positions on Puma stock were being excluded by the Company from attending the ASCO event. *TheStreet.com* noted "***[r]estricting access to a corporate event might not be such a big deal if not for Puma's penchant for selectively disclosing important information***" to investors concerning the ExteNET trial.

71. On June 1, 2015, the full data from the ExteNET trial was revealed in an oral presentation by Dr. Arlene Chan at ASCO. As previously disclosed in Abstract #508, the results showed that the absolute difference in DFS rates at two years was only 2.3%. The data presented also revealed, for the first time, the Kaplan-Meier curves for the ExteNET trial. This newly disclosed data showed essentially flat curves between the neratinib and placebo arms, with no trend of separation. In fact, one-year follow-up from randomization showed an absolute DFS difference of only ***2.2%*** (97.8% vs. 95.6%). Thus, between years one and two of observation, the absolute benefit experienced by study participants increased by only ***0.1%***, and the curves were actually narrowing by the end of year two – inconsistent with Auerbach's prior claims that "the curves are continuing to separate" and "the absolute DFS difference is increasing year over year." The actual trajectory of the DFS curves, as presented at ASCO, is set forth below:[1]

[1] The difference in appearance between the chart of Kaplan-Meier curves presented at the ASCO conference and the chart internally circulated at Puma on July 17, 2014, as set forth in ¶36, is the result of a change to the scale of the y-axis. While the Kaplan-Meier curves chart from July 2014 used a scale of 0.80 to 1.00 for the y-axis, for the ASCO presentation the scale was changed at the instruction of Auerbach to 0.50 to 1.00, minimizing the visual representation of the narrowing curves.



Presented By Arlene Chan at 2015 ASCO Annual Meeting

72. Dr. Chan's June 1, 2015 presentation at ASCO also confirmed that 39.9% of ExteNET patients treated with neratinib experienced grade 3 or 4 diarrhea and disclosed that 16.8% of patients taking the drug discontinued treatment as a result of experiencing grade 3 or higher diarrhea. This disclosure revealed that the percentage of patients taking neratinib in the ExteNET trial who dropped out and/or discontinued treatment was far in excess of the 5% to 10% Auerbach claimed during the Class Period.

73. On June 1, 2015, *TheStreet* published an article entitled "Puma Bio Breast Cancer Drug Given Rough Treatment at ASCO '15." Quoting Dr. Harold Burnstein, a breast cancer expert from the Dana-Farber Cancer Institute, the article noted that "[t]he benefit for breast cancer patients treated with Puma's neratinib was 'awfully small' for a drug that causes 'a lot of diarrhea.'" The article also reported that as a result of the ExteNET presentation "Puma shares are down more than 9% to $177.04 in Monday trading."

74. On June 4, 2015, *TheStreet* published an article entitled "Top-Performing Biotech and Drug Stocks During ASCO '15." The article stated that "Puma Biotech

(PBYI) was the worst-performing biotech and drug stock during the ASCO period, falling 28% due to the underwhelming efficacy and high rate of side effects seen with the company's breast cancer drug neratinib."

75. In response to the disclosures about neratinib and the ExteNET trial at the ASCO meeting, Puma's stock price dropped $21.98 per share on June 1, 2015, from an opening price of $191.95 down to $169.97. The following day, on June 2, 2015, Puma's stock price continued falling and dropped an additional $23.32 during trading hours, closing at $146.65. This two-day 23.6% decline came on massive volume, as the number of shares traded increased to 2.9 million and 3.6 million over June 1 and 2, 2015, respectively – representing increases of 647% and 818% over Puma's average trading volume for the prior 90 days. The stock price continued falling after disclosure of the truth about neratinib and the ExteNET trial and currently trades for less than $85 per share.

DEFENDANTS' MOTIVE AND OPPORTUNITY TO DEFRAUD INVESTORS

Puma's $218.5 Million in Stock Sales

76. After going public in February 2012, Puma repeatedly informed investors that the Company would need to continue to raise capital because it was a development-stage organization, produced no revenues and would incur significant expenses while pursuing clinical testing. Puma's 2013 Form 10-K revealed the Company's expenses for drug development and various clinical trials for neratinib resulted in net losses of $74.5 and $54.7 million in 2012 and 2013, respectively. While Puma had completed a follow-on offering of common stock in February 2014, raising approximately $138 million, the Company continued to spend heavily on research, development and overhead, including executive compensation.

77. In addition, as a result of the licensing amendment with Pfizer signed July 2014 – which obligated Puma to accept full financial responsibility for all ongoing legacy trials with neratinib – Puma began realizing even greater net losses.

Puma incurred losses of $19.8 million, $38.8 million and $35.8 million through the first three fiscal quarters of 2014, respectively. At year's end, Puma had burned through $142 million, and only had $149.4 million remaining in total current assets. At the rate Puma was burning through its cash and liquid assets, the Company's operations could barely last another year without an injection of capital.

78. With no revenue for the foreseeable future and increased R&D expenses from the licensing renegotiation, Puma's very existence as a company was (and continues to be) contingent on the amount of working capital it can raise through public and private offerings – a measure wholly dependent on the Company's stock price. As Puma admitted in its Form 10-Q filed November 10, 2014, "[t]he Company's continued operations will depend on its ability to raise funds through various potential sources such as equity and debt financing." The ultimate success of the Company thus "depends not only on the safety and efficacy of [its] product candidates, but also on [its] ability to finance product development."

79. As a result, following their July 22, 2014 false statements, Defendants launched an additional follow-on offering of Puma common stock to continue funding the Company's operations. This offering took place in January 2015. As stated in Puma's Prospectus Supplement Form 424B5, Defendants had to raise the funds to pay "for the overall development of our drug candidates, including, but not limited to, research and development and clinical trial expenditures, and for general corporate and working capital purposes."

80. According to the Company's 2014 Form 10-K, Defendants sold 1.15 million shares of Puma common stock – at an artificially inflated price of $190 per share – for total proceeds of $218.5 million in the January 2015 offering. This funding was vital for Puma to continue its operations, as the Company continued to report increased losses in 2015 – more than $117 million in net losses in the first two quarters alone. But for Defendants' deliberate decision to misstate and withhold the actual efficacy and safety results associated with the ExteNET trial, Puma's Class

Period stock price would have been substantially lower, and Puma would have been unable to obtain the $218.5 million in funds.

Defendants' Class Period Compensation

81. The Individual Defendants were also highly motivated to materially misstate the efficacy and safety results of neratinib in the ExteNET trial by the terms of their employment agreements with Puma. The Individual Defendants' compensation was directly tied to Puma's "performance on both a short-term and long-term basis," including "results intended to create value for stockholders" such as share price and clinical results – the very measures that were improperly manipulated by the Individual Defendants during the Class Period. The personal wealth of each of the Individual Defendants was enhanced by the repeated dissemination of materially misleading statements regarding the ExteNET study results.

82. According to the Company's April 30, 2015 DEF 14A Proxy Statement, Puma's executive compensation package consisted of: (a) base salary; (b) cash bonus awards; and (c) stock option awards. Puma's Compensation Committee determined each of the Individual Defendants' compensation package based on the "achievement of near-term corporate targets and longer term business objectives and strategies." Specifically, Puma highlighted the following factors as the bases for the increases in Auerbach and Eyler's executive compensation during 2014: (a) "[T]he price of our common stock increased approximately 82.8%," from $103.53 on December 31, 2013 to $189.27 on December 31, 2014; and (b) "In July 2014, we announced positive topline results" for the ExteNET trial. Yet, these factors were manipulated by the Individual Defendants' Class Period misrepresentations.

83. As a result of their false and misleading statements, the Individual Defendants personally profited. For 2014, Auerbach received $17.8 million in executive compensation – an increase of more than 229% from the $5.4 million he earned in 2013. Similarly, Eyler pocketed $4.5 million in 2014, an increase of 246% over the $1.3 million he received in 2013. In total, Auerbach and Eyler received

nearly $22.3 million in salary and incentive-based annual compensation in 2014 alone, all materially enhanced as a result of deceiving the investing public about the very performance measures for which they were being rewarded.

Defendants' Efforts to Sell Puma Before the Disclosure of the Truth

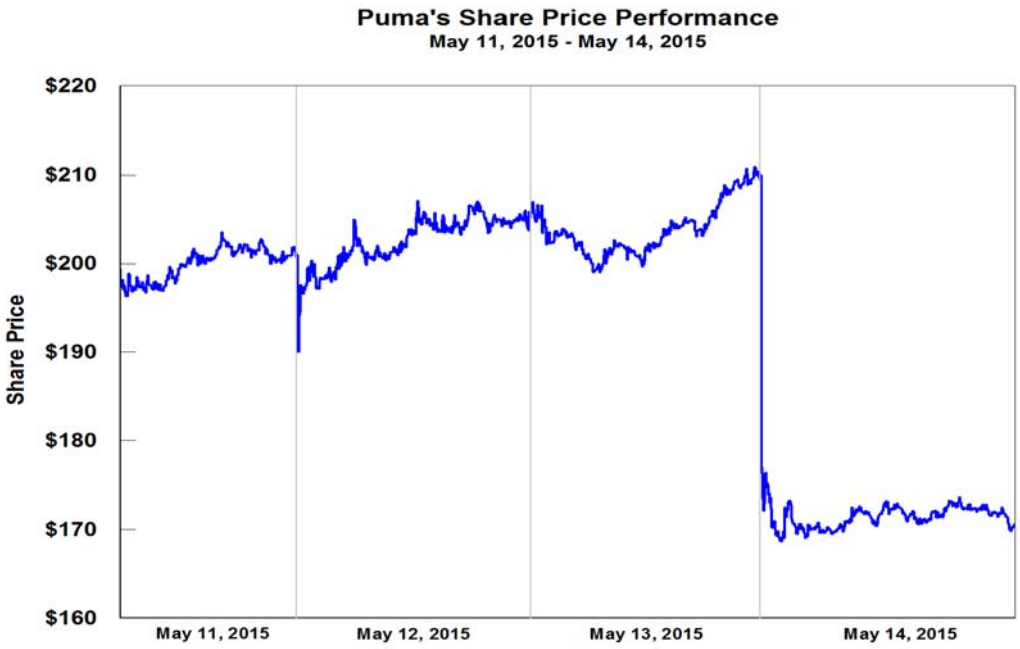
84. Following the false and misleading statements on July 22, 2014 that artificially inflated Puma's stock price, Auerbach actively sought to have Puma acquired by a larger pharmaceutical company. Pursuant to Auerbach and Eyler's contracts with Puma, the sale of the Company would trigger a change of control provision. Under that provision, Auerbach and Eyler's options would immediately vest and all of their shares, totaling at least 4,690,000 and 175,500, respectively, would be cashed in at the acquisition price. In addition, a change of control would allow Auerbach to exercise a warrant to acquire an additional 2,116,250 shares of Puma common stock at $16.00/share and cash those in at the acquisition price. As of December 31, 2014, a sale of Puma would also have triggered change of control payments to Auerbach in excess of $27 million, largely due to accelerated equity awards.

LOSS CAUSATION/ECONOMIC LOSS

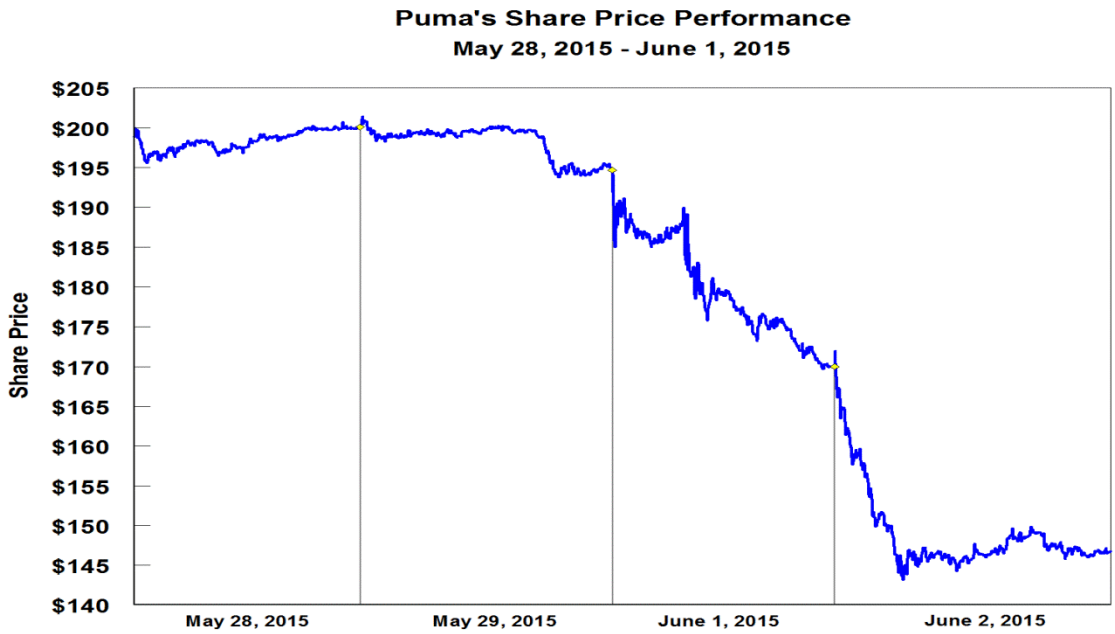
85. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive investors and the market and a course of conduct that artificially inflated the price of Puma stock and operated as a fraud or deceit on Class Period purchasers of Puma stock by misrepresenting and omitting material information about neratinib and the ExteNET trial. When Defendants' prior misrepresentations and omissions were disclosed to the market, beginning on the evening of May 13, 2015, Puma's stock price fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of Puma stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

86. Defendants' misleading statements and omissions, identified herein at ¶¶49-50, 52-54, 57, 59-63, had the intended effect and caused Puma's stock to trade at artificially inflated levels during the Class Period.

87. As a direct result of the disclosures that began the evening of May 13, 2015 and are detailed in ¶66, Puma's stock price suffered a significant decline. As set forth in the chart below, on May 14, 2015, the price of Puma stock traded on the NYSE plunged $39.05 per share:



88. The disclosures on June 1, 2015, detailed in ¶¶71-72, also had a direct impact on Puma's stock price. As set forth in the chart below, the price of Puma stock fell $21.98 per share on June 1, 2015 and an additional $23.32 on June 2, 2015 in response to the disclosure of the truth about neratinib and the results of the ExteNET trial:



89. The declines in Puma's stock price on May 14, 2015 and June 1-2, 2015 were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market. The timing and magnitude of Puma's stock price decline negates any inference that the losses suffered by Plaintiff and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific factors unrelated to Defendants' fraudulent conduct. Indeed, on May 14, 2015, the Dow Jones Industrial Average ("DJIA") was up 1.0% and the Dow Jones U.S. Pharmaceuticals Index ("DJUSPR") was up 0.9%, and over June 1-2, 2015, the DJIA had virtually no net change and the DJUSPR was down a mere 0.002%.

90. The economic losses suffered by Plaintiff and other members of the Class were a direct result of Defendants' fraudulent scheme to inflate Puma's stock price and the subsequent decline in the value of that stock when Defendants' prior misrepresentations and omissions were revealed.

APPLICABILITY OF THE PRESUMPTION OF RELIANCE

91. Plaintiff and the Class are entitled to a presumption of reliance pursuant to *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and the fraud-on-the-market doctrine

because, during the Class Period, Puma stock traded in an efficient market on the NYSE, the material misstatements and omissions alleged herein would induce a reasonable investor to misjudge the value of Puma stock and without knowledge of the misrepresented or omitted material facts, Plaintiff and other members of the Class purchased or acquired Puma stock between the time Defendants misrepresented and failed to disclose material facts about neratinib and the ExteNET trial and the time the true facts were disclosed. Accordingly, Plaintiff and other members of the Class relied, and are entitled to have relied, upon the integrity of the market for Puma common stock, and are entitled to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Class Period.

92. Plaintiff and the Class are also entitled to a presumption of reliance under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact for which there was a duty to disclose.

CLASS ACTION ALLEGATIONS

93. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons or entities who purchased or otherwise acquired the common stock of Puma between July 22, 2014 (after 6:00 p.m., EDT) and May 29, 2015, inclusive (the "Class"). Excluded from the Class are Defendants and their families, the officers and directors of Puma, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

94. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Throughout the Class Period, Puma common stock was actively traded on the NYSE, the largest stock exchange in the world. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are

thousands of members in the proposed Class. During the Class Period, there were more than 30 million shares of Puma common stock outstanding and the average daily trading volume was over 403,000 shares. Record owners and other members of the Class may be identified from records maintained by Puma or its transfer agent(s) and may be notified of the pendency of this action using the form of notice similar to that customarily used in securities class actions.

95. There is a well-defined community of interest in the questions of law and fact involved in this case. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

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

(b) Whether statements made by Defendants to the investing public during the Class Period misrepresented and omitted material facts about neratinib and the ExteNET trial; and

(c) To what extent the members of the Class have sustained damages and the proper measure of damages.

96. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages as a result of Defendants' wrongful conduct.

97. Plaintiff will adequately protect the interests of the Class and has retained counsel who is experienced in securities and class action litigation. Plaintiff has no interests which conflict with those of the Class.

98. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for all members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

99. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. Count I is brought pursuant to §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

100. During the Class Period, Puma, through its officers, management and agents, including defendants Auerbach and Eyler, made or were responsible for the statements specified in ¶¶49-50, 52-54, 57, 59-63, which they knew or recklessly disregarded were misleading in that they failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

101. Defendants and the Company's officers, management and agents directly and indirectly, by the use of means and instrumentalities of interstate commerce, the mails and/or the facilities of a national securities exchange: (a) employed devices, schemes and artifices to defraud; (b) made misleading statements and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Puma common stock during the Class Period. All Defendants are sued as primary participants in the wrongful and illegal conduct charged herein and as controlling persons as alleged below.

102. Defendants and the Company's officers, management and agents did not have a reasonable basis for their alleged false statements and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Puma common stock during the Class Period.

103. Puma is liable for all materially false and misleading statements and omissions made during the Class Period, as alleged above, including the false and misleading statements made by the Company's officers and agents, as alleged above, as the maker of such statements and under the principle of *respondent superior*.

104. Defendants and the Company's officers, management and agents, individually and in concert, directly and indirectly, engaged and participated in a continuous course of conduct to conceal adverse material information about the results of the ExteNET trial.

105. The allegations above establish a strong inference that Puma, as an entity, acted with corporate scienter throughout the Class Period, as its officers and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the truth about neratinib and the results of the ExteNET trial. By concealing these material facts from investors, Puma's share price was artificially inflated during the Class Period.

106. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing the truth about the results of the ExteNET trial and artificially inflating the price of Puma common stock.

107. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Puma common stock. Plaintiff and the Class would not have purchased Puma common stock at the prices

they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and omissions.

108. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Puma common stock during the Class Period.

COUNT II

For Violation of §20(a) of the Exchange Act Against All Defendants

109. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein. Count II is brought pursuant to §20(a) of the Exchange Act, 15 U.S.C. §78t(a).

110. Defendants Auerbach and Eyler acted as controlling persons of Puma within the meaning of §20(a) of the Exchange Act. Puma controlled all of its employees and Auerbach and Eyler. By virtue of their high-level positions, and their ownership and contractual rights, participation in and awareness of the ExteNET trial, as well as their intimate knowledge of the false statements and omissions made by the Company and disseminated to the investing public, defendants Auerbach and Eyler had the power to influence and control and did influence and control, directly or indirectly, the Company's decision-making, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Defendants Auerbach and Eyler participated in the conference calls with investors and analysts, described herein at ¶¶50, 52-54, 57-58, 60, 62-63, and/or prepared and approved the Company's SEC filings and press release, described herein at ¶¶49, 59, 61, alleged by Plaintiff to be misleading.

111. In particular, Defendants had direct and supervisory involvement in the Company's day-to-day operations and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations

as alleged herein, and exercised the same. By reason of such conduct, Defendants are liable pursuant to §20(a).

112. As set forth above, Defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of Puma common stock during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, and certifying Plaintiff as Class representative under Federal Rule of Civil Procedure 23 and Plaintiff's counsel as Class counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' violations of the federal securities laws, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such equitable, injunctive or other and further relief as the Court may deem just and proper, including, but not limited to, rescission.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: June 6, 2017

ROBBINS GELLER RUDMAN
& DOWD LLP
TOR GRONBORG
TRIG R. SMITH
SUSANNAH R. CONN
J. MARCO JANOSKI GRAY
DEBASHISH BAKSHI

TRIG R. SMITH

655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)

Lead Counsel for Plaintiff