UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[redacted] Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. PUMA BIOTECHNOLOGY, INC., ALAN H. AUERBACH, and CHARLES R. EYLER, Defendants.	**No.** **CLASS ACTION** **COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

Plaintiff [redacted] ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Puma Biotechnology, Inc. ("Puma" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of a class consisting of all persons and entities, other than defendants and their affiliates, who purchased Puma securities from July 23, 2014 to May 13, 2015, inclusive (the "Class Period"). Plaintiff seeks to pursue remedies against Puma and certain of its officers and directors for violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Puma is a development stage biopharmaceutical company, focusing on the acquisition, development, and commercialization of products to enhance cancer care. Puma is headquartered in Los Angeles, California and was founded in 2010.

3. The Company's lead product candidate is an investigational drug known as PB272 ("neratinib"), which the Company had touted as an extended adjuvant treatment of human epidermal growth factor receptor 2 ("HER2")-positive ***metastatic breast cancer***.

4. On July 22, 2014, the Company announced positive top line results from the Phase III PB272 (neratinib) trial for the extended adjuvant treatment of breast cancer (known as the "ExteNET Trial"). According to the press release issued that day, the results of the trial purportedly 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 the Company proclaimed as statistically significant with a p-value of 0.0046.

5. Based on these results, Puma further announced on July 22, 2014 that it would file its New Drug Application ("NDA") for regulatory approval of neratinib "in the first half of 2015."

6. Throughout the Class Period, Defendants made false and/or misleading statements, and failed to disclose material adverse facts about the Company's business, operations, prospects and performance. Specifically, during the Class Period, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the Company's NDA filing would be for a positive ***early stage*** breast cancer indication, instead of the previously announced ***metastatic breast cancer***; (2) Puma would need to submit additional safety data from preclinical carcinogenicity studies with its NDA filing, which Puma did not have; (3) the additional required studies would necessarily push the timeline for

filing the NDA into the first quarter of 2016; (4) the Company overstated results from its Phase III ExteNET Trial; and (5) as a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about the Company and its outlook, including in its financial statements and about the ongoing ExteNET trial.

7. On December 2, 2014, the Company announced an update on the timeline for filing its New Drug Application (NDA) for the approval of PB272 (neratinib) in the extended adjuvant treatment of HER2-positive early stage breast cancer. While Puma had previously communicated that it anticipated filing the NDA for PB272 in the first half of 2015, including as recently as November 13, 2014, the December 2, 2014 announcement indicated that Puma intends to delay its proposed timeline for filing the NDA until the first quarter of 2016.

8. Specifically, the Company stated as follows:

> [The first half of 2015 NDA filing] was based on the feedback [Puma] had previously received from regulatory agencies, which had been focused on the proposed clinical indication of HER2-positive metastatic breast cancer. Since the Company's initial NDA ***filing will now be for the extended adjuvant HER2-positive early stage breast cancer indication***, based on the company's recent meetings with the U.S. Food and Drug Administration (FDA), Puma will need to submit data from preclinical carcinogenicity studies with its NDA filing in accordance with International Conference on Harmonization (ICH) guidelines. In order to accommodate this requirement, Puma intends to delay its proposed timeline for filing the NDA until the first quarter of 2016.

9. Thus, despite indicating that Puma would originally seek to apply neratinib for HER2-positive ***metastatic breast cancer***, the Company secretly changed course and instead shocked the market by announcing plans to apply for

extended adjuvant HER2-positive ***early stage breast cancer***. However, this shift required additional safety data, which was unavailable to the Company.

10. On this news, shares of Puma fell $27.33 per share, or over 12%, to close at $197.67 per share on December 3, 2014 on extremely high volume.

11. On May 13, 2015, after the close of trading, Puma released four abstracts for its PB272 (neratinib) breast cancer drug that were to be presented at the American Society of Clinical Oncology ("ASCO") annual meeting.

12. Abstract #508 provides a summary of the ExteNET trial which is a Phase 3 trial comparing Puma's lead product candidate, neratinib, to placebo in HER2+ breast cancer patients who were pre-treated with Roche's Herceptin (trastuzumab). The primary endpoint was the proportion of patients who were disease-free two years after adjuvant treatment as measured by invasive disease-free survival (IDFS). IDFS in the neratinib arm (n=1,409) was 93.9% compared to 91.6% for placebo (n=1,412). The modest difference of only 2.3% (p=0.0046) was lower than the market expected especially given that on July 22, 2014, the Company stated that Neratinib performed 33% better than the placebo.

13. On this news, shares of Puma fell $39.05 per share, or over 18.6%, to close at $170.67 per share on May 14, 2015, on unusually high volume.

14. As a result of defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

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

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

17. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as a significant portion of the defendants' actions, and the subsequent damages, took place within this District.

18. 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 the national securities exchange.

PARTIES

19. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Puma common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

20. Defendant Puma Biotechnology, Inc. is a Delaware corporation that purports to be a development stage biopharmaceutical company, focusing on the acquisition, development, and commercialization of products to enhance cancer care. The Company's principal executive offices are located at 10880 Wilshire

Blvd., Suite 2150, Los Angeles, CA 90024. During the Class Period, the Company's stock traded on the New York Stock Exchange ("NYSE") under the symbol "PBYI."

21. Defendant Alan H. Auerbach ("Auerbach") served as the Company's Chief Executive Officer, President and Chairman of the Board at all relevant times.

22. Defendant Charles R. Eyler ("Eyler") served as the Company's Senior Vice President, Finance and Administration and Treasurer at all relevant times.

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

24. Defendant Puma and the Individual Defendants are referred to herein, collectively, as the "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

25. Puma is a development stage biopharmaceutical company, focusing on the acquisition, development, and commercialization of products to enhance cancer care. Puma is headquartered in Los Angeles, California and was founded in 2010.

26. As a development stage company, Puma currently has no sales or revenues, and will not be able to generate revenues until one of their drug candidates is approved by the FDA.

27. The Company's active portfolio consists of one drug, Neratinib (oral), also known as PB272. Neratinib is being investigated as a treatment for a number of cancers, primarily as an extended adjuvant treatment for advanced stage breast cancer. Puma has two other drugs under development as well, Neratinib (intravenous) and PB357. The latter is a backup compound to PB272, which the Company is evaluating for further development.

28. Neratinib was initially developed by Pfizer, Inc. ("Pfizer"), but was licensed by Puma for development and commercialization in October of 2011. Under the terms of the original agreement, Puma would be financially responsible for all costs of development and commercialization as well as the costs associated with completing any ongoing trials, up to a pre-determined and undisclosed amount. Upon successful commercialization of Neratinib, Puma would pay Pfizer royalties in the range of 10-20%.

29. These terms were amended at the start of the Class Period, when in a press release published on July 22, 2014, the company released positive data from their Phase III trial, ExteNET, which was similarly acquired from Pfizer. ExteNET is a randomized, double-blind, placebo-controlled trial of Neratinib after being treated with trastuzumab (Herceptin) in women with early stage HER-2/Neu positive breast cancer. In this study, over 2000 women with locally advanced breast cancer received surgery, then one year of Herceptin. Following this year, they were randomized to receive a year of Neratinib or placebo.

30. Following the announcement of positive results from ExteNET, the Company's share price tripled. However, the press release was misleading as it

failed to properly describe the results of the ExteNET trial, and also failed to disclose the reversal of the Company's original strategy for obtaining regulatory approval for Neratinib and the critical consequence of that reversal.

31. Prior to the press release issued on July 22, 2014, the Company's announcements solely focused on obtaining regulatory approval for Neratinib as an advanced breast cancer treatment. For example, on February 20, 2013, the Company issued a press release and filed a Form 8-K with the SEC, announcing an agreement with the FDA on a Special Protocol Assessment ("SPA") for Phase III Trial of PB272 (Neratinib) in HER2-Positive Metastatic Breast Cancer Patients. In the press release, the Company stated, in part:

> Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the planned Phase III clinical trial of the Company's lead drug candidate PB272 (neratinib) ***in patients with HER2-positive metastatic breast cancer who have failed two or more prior treatments (third-line disease).*** The SPA is a written agreement between the Company, as the trial's sponsor, and the FDA regarding the design, endpoints and planned statistical analysis approach of the Phase III trial to be used in support of a New Drug Application (NDA) for PB272. The European Medicines Agency (EMA) has also provided follow-on scientific advice (SA) consistent with that of the FDA regarding the Company's Phase III trial design and endpoints to be used and the ability of such design to support the submission of a European Union (EU) Market Authorization Application (MAA).
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> Pursuant to the SPA and SA, the Phase III trial will be a randomized trial of PB272 plus Xeloda versus Tykerb plus Xeloda ***in patients with third-line HER2-positive metastatic breast cancer.*** The trial is expected to enroll approximately 600 patients who will be randomized (1:1) to receive either PB272 plus Xeloda or Tykerb plus Xeloda. The trial will be conducted at approximately 150 sites in North America, Europe and Asia-Pacific. The agreed upon co-primary endpoints of the trial are

> progression-free survival and overall survival. The Company plans to use the progression-free survival data from the trial as the basis for submission of an NDA/MAA for Accelerated/Conditional Approval for PB272 from the regulatory agencies. Puma anticipates that it will begin patient enrollment in this Phase III trial in March or April of this year.
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> Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "Obtaining FDA and EMA agreement on the overall Phase III trial design, and more specifically patient population and primary endpoints, represents an important milestone in the global development of PB272 and for Puma as a company. We look forward to initiating patient enrollment in the Phase III trial shortly."
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> (emphasis added)

32. The press release explicitly stated that the Company planned to apply for approval of Neratinib for the treatment of late stage cancer, as the SPA agreed upon with the FDA provided for enrollment "of patients . . . who have failed two or more prior treatments (third-line disease)." However, during the Class Period, the Company secretly changed course and later shocked the market by announcing plans to instead seek approval as an extended adjuvant treatment in ***early stage breast cancer***, simultaneously announcing that it didn't have the data necessary to apply for that indication.

33. Indeed, as early as October 5, 2011, the Company issued a press release announcing a licensing agreement with Pfizer Inc. ("Pfizer") for the development and commercialization of Neratinib. In the press release, the Company laid out its strategy for Neratinib going forward and the impact that strategy would have on the ExteNET trial, which was inherited from Pfizer as part of the licensing agreement. Since the ExteNET trial was designed to enroll early

stage cancer patients, and the Company was seeking approval for metastatic cancer, the Company decided to cease enrolling patients, terminate the ExteNET trial early, and reduce the follow up period from five years to three years. Specifically, in the press release, the Company stated:

> Puma Biotechnology, Inc., a development stage biopharmaceutical company, today announced an agreement with Pfizer to license the worldwide commercial rights to neratinib, a potent, irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, ErbB1 (EGFR), ErbB2 (HER2) and ErbB4 (HER4) kinases. Neratinib is being studied in the neoadjuvant, adjuvant and metastatic settings in patients with HER2/ErbB2 positive breast cancer.
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> Puma intends to focus the development of neratinib on the treatment of patients with HER2-positive locally advanced or metastatic breast cancer who have received prior trastuzumab-based therapy. Neratinib has previously been tested in numerous clinical trials both as single agent and in combination with other anticancer drugs in this patient population. In these studies, neratinib demonstrated substantial clinical activity and was well tolerated. Based on the results of these studies, Puma intends to initiate clinical trials in this patient population in the first half of 2012.
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> Prior to the licensing agreement with Puma, Pfizer had been sponsoring two clinical trials of neratinib: 1) the NEfERTT trial, a Phase II randomized trial of neratinib in combination with paclitaxel versus trastuzumab in combination with paclitaxel for the treatment of patients who have not received previous treatment for HER2-positive metastatic breast cancer, and 2) the ExteNET trial, a Phase III study investigating the effects of neratinib after adjuvant trastuzumab in patients with early stage breast cancer. ***Consistent with Puma's strategy to refocus clinical development of neratinib in patients with HER2-positive metastatic breast cancer who have received prior lines of trastuzumab-based therapy, Puma intends to stop enrollment of new patients and proceed with winding down both trials.***
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> (emphasis added)

34. In the Company's annual report for the year ended December 31, 2012, filed on Form 10K with the SEC on April 1, 2013, the Company devoted almost the entire section regarding clinical trials to its late stage cancer trials and only in the very last paragraph of that section did it briefly mention its early cancer trials. The only study that the Company was performing on patients with early stage breast cancer was the ExteNET trial inherited from Pfizer, and as the Company reported in October of 2011, the trial was being "wound down". Specifically, the 10-K stated, in part:

> *Discontinued Pfizer Legacy Studies.* Pfizer had previously been sponsoring two additional clinical trials of neratinib. The first trial, referred to as the NEfERTT™ trial, was a Phase II randomized trial of neratinib in combination with the anti-cancer drug paclitaxel versus trastuzumab in combination with paclitaxel for the treatment of patients who have not received previous treatment for HER2-positive metastatic breast cancer. The second trial, referred to as the ExteNET™ trial, was a Phase III study investigating the effects of neratinib after adjuvant trastuzumab in patients with early stage breast cancer. On October 5, 2011, we announced that enrollment in the ExteNET trial was terminated and that both the NEfERTT and the ExteNET trials were going to be wound down. We are responsible for any activities associated with winding down and completing these trials during 2013 and beyond.

35. In an amended registration statement for a public stock offering, filed on Form S-3 with the SEC on February 10, 2014, the Company disclosed that "enrollment in the ExteNET trial was halted at approximately 2,800 patients and the NefERTT trial had completed enrollment at approximately 450 patients. We anticipate that both the ExteNET and NefERTT trials will report their results in the first half of 2014."

36. Thus, in addition to shrinking the size of the ExteNET trial from 3,850 patients to 2,800 patients, Puma also shortened the duration of the study from five years to two years.[1]

37. According to an article published on August 21, 2014 on *Seekingalpha.com*, the current standard of care for patients with early stage breast cancer involves surgery followed by chemotherapy with Herceptin for one year. The primary trial that determined that one year of Herceptin improved outcomes compared to no Herceptin is the HERA trial. This trial showed a statistically significant improvement of disease free survival ("DFS") and overall survival when taking Herceptin as an adjuvant therapy after chemotherapy. The HERA study also investigated using Herceptin as a two year treatment and compared the results to using Herceptin for only one year. Final data from the study representing eight years of follow-up were reported at the 2012 annual meeting of the European Society of Medical Oncology (ESMO) in Vienna.

38. In the ExteNET trial, Neratinib was being administered to patients after completing a year of treatment using Herceptin. Therefore, it would be natural to compare the results of switching to Neratinib after a year of Herceptin to the results of staying on Herceptin itself beyond the first year. In the HERA trial, the DFS at around three years follow-up is 89.1% for patients that received Herceptin for two years and 86.7% for patients placed on the drug for one year. In addition, it appears that until roughly year four the results favored two years of

[1] *See* https://clinicaltrials.gov/archive/NCT00878709/2011_11_07/changes.

Herceptin treatment at which point the DFS rates became almost exactly the same. In other words, even though at year three and four it appeared that second year of Herceptin treatment provided a benefit over only one year of Herceptin treatment, beyond year four the benefit essentially vanished and survival rates were similar. Thus, the DFS statistics associated with both one and two years of Herceptin were very strong in the initial years before tapering off.

39. Therefore, in order for the ExteNET trial to be considered a success, it would not only have to improve on the 89.1% survival rate of using Herceptin for an additional year, it would also have to show that the survival rates continued to be beneficial beyond year four. Yet, this was impossible because Puma had already changed the follow up period for the patients enrolled in ExteNET from three years to five years, and as such, this critical long term data simply did not exist. As discussed below, Puma overstated the results of the ExteNET study and never fully disclosed to investors how it was simply unrealistic to rely on that trial for FDA approval, especially when the SPA agreed upon with the FDA was for late term—not early stage-breast cancer.

Materially False and Misleading Statements Issued During the Period

40. The class period begins on July 22, 2014. On that day, the Company issued a press release and filed a Form 8-K with the SEC, announcing positive top line results from its Phase III PB272 trial in adjuvant breast cancer (the "ExteNET Trial"). In the press release, the Company stated, in part:

> Puma Biotechnology, Inc. (NYSE: PBYI), a development stage biopharmaceutical company, announced top line results from

the Phase III clinical trial of Puma's investigational drug PB272 (neratinib) for the extended adjuvant treatment of breast cancer (ExteNET Trial). The ExteNET trial is a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in women with early stage HER2-positive breast cancer.

More specifically, the ExteNET trial enrolled 2,821 patients in 41 countries with ***early-stage*** HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomized to receive extended adjuvant treatment with either neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of two years after randomization in the trial.

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. The secondary endpoint of the trial was disease free survival including ductal carcinoma in situ (DFS-DCIS). The results of the trial demonstrated that treatment with neratinib resulted in a 37% improvement in disease free survival including ductal carcinoma in situ versus placebo. The hazard ratio was determined to be 0.63 which was statistically significant with a p-value of 0.0009. ***Based on these results from the ExteNET study, Puma plans to file for regulatory approval of neratinib in the extended adjuvant setting in the first half of 2015.***

Full results of the ExteNET trial for PB272 will be presented at a future scientific meeting

"We are very pleased with the results of the ExteNET trial with neratinib. This represents the first trial with a HER2 targeted agent that has shown a statistically significant benefit in the extended adjuvant setting, which we believe provides a meaningful point of differentiation for neratinib in the treatment of HER2 positive breast cancer," said Alan H. Auerbach, Chief Executive Officer and President. "While the use of trastuzumab in the adjuvant setting has led to a reduction in disease recurrence in patients with early stage HER2-positive breast cancer, there remains an unmet clinical need for further

> improvement in outcome in order to attempt to further reduce this risk of recurrence. The results of the ExteNET study demonstrate that we may be able to provide this type of improvement with neratinib to further help the patients with this disease."

41. Thus, despite releasing data that indicated positive results for patients with early stage breast cancer, the Company did not inform investors that they would be changing the indication for which it would apply for regulatory approval for Neratinib.

42. On July 22, 2014 the Company also held a conference call to discuss the results of the ExteNET study. During the conference Call, Defendant Auerbach stated, in part:

> We are obviously continuing to follow the patients and everyone is off treatment obviously, now, we're just in follow-up. And we can continue to follow them for a long period of time. As you correctly point out, the trial obviously hit its primary endpoint. ***So I wouldn't anticipate we need any additional data from a regulatory standpoint***, but we obviously will continue to follow them and we would probably have the first data from that in a couple of years.

43. On August 11, 2014, the Company issued a press release and filed a Form 8-K with the SEC, announcing its financial and operating results for the second quarter ended June 30, 2014. Puma reported a net loss of $38.8 million, or $1.29 per share, compared to a net loss of $12.6 million, or $0.44 per share, for the second quarter of 2013. In the press release the Company stated, in part:

> During the second quarter of 2014, Puma achieved a number of key clinical milestones, including the presentation of Phase II clinical trial data for PB272 for the neoadjuvant treatment of breast cancer (I-SPY 2 TRIAL), the presentation of Phase II clinical trial data for PB272 for the treatment of HER2 positive metastatic breast cancer that has metastasized to the brain and the expansion of the first cohort from the Phase II clinical trial

> of PB272 as a single agent in patients with solid tumors who have an activating HER2 mutation (basket trial). Even more notably, in July 2014 we reported positive top line data from our Phase III trial of PB272 for the extended adjuvant treatment of breast cancer (ExteNET trial). This represents the first trial with a HER2 targeted agent that has shown a statistically significant benefit in the extended adjuvant setting, which we believe provides a meaningful point of differentiation for neratinib in the treatment of HER2 positive breast cancer. We look forward to proceeding with the regulatory filings for PB272 in this indication currently anticipated in the first half of 2015.

44. On August 11, 2014, the Company filed a quarterly report on Form 10-Q with the SEC which was signed by defendants Auerbach and Eyler, and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by defendants Auerbach and Eyler, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

45. On November 10, 2014, the Company issued a press release and filed a Form 8-K with the SEC, announcing its financial and operating results for the third quarter ended September 30, 2014. Puma reported a net loss of $35.8 million, or $1.19 per share, compared to a net loss of $14.3 million, or $0.50 per share, for the third quarter of 2013. In the press release the Company stated, in part:

> We are very proud of the milestones that were achieved by Puma during the third quarter of 2014," said Alan H. Auerbach, Chairman, Chief Executive Officer and President of Puma. "This includes the positive top-line results that were reported during the quarter from the Phase III trial of PB272 (neratinib)

> in extended adjuvant HER2 positive breast cancer (ExteNET trial), which demonstrated that neratinib achieved a statistically significant improvement in disease-free survival and disease-free survival that includes ductal carcinoma in situ. We look forward to proceeding with the regulatory filings for neratinib in extended adjuvant HER2 positive breast cancer currently anticipated for the first half of 2015.

46. On November 10, 2014, the Company filed a quarterly report on Form 10-Q with the SEC which was signed by defendants Auerbach and Eyler, and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by defendants Auerbach and Eyler, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

47. On December 2, 2014, the Company announced an update on the timeline for filing its New Drug Application (NDA) for the approval of Neratinib in the extended adjuvant treatment of HER2-positive early stage breast cancer. While Puma had previously communicated that it anticipated filing the NDA for Neratinib in the first half of 2015, including as recently as November 13, 2014, the December 2, 2014 announcement indicated that Puma intends to delay its proposed timeline for filing the NDA until the first quarter of 2016.

48. Specifically, the Company provided the following explanation for its delay:

> [The first half of 2015 NDA filing] was based on the feedback [Puma] had previously received from regulatory agencies, which had been focused on the proposed clinical indication of HER2-positive metastatic breast cancer. Since the Company's

> initial NDA ***filing will now be for the extended adjuvant HER2-positive early stage breast cancer indication***, based on the company's recent meetings with the U.S. Food and Drug Administration (FDA), Puma will need to submit data from preclinical carcinogenicity studies with its NDA filing in accordance with International Conference on Harmonization (ICH) guidelines. In order to accommodate this requirement, Puma intends to delay its proposed timeline for filing the NDA until the first quarter of 2016.
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> (emphasis added)

49. Thus, despite indicating that Puma would originally seek to apply neratinib for HER2-positive ***metastatic breast cancer***, the Company secretly changed course based on the results announced in the ExteNET trial and instead shocked the market by announcing plans to apply for extended adjuvant HER2-positive ***early stage breast cancer***. However, this shift required additional safety data, including carcinogenicity studies ("CART Data"), which the Company knew it did not have.

50. On December 2, 2014, the Company held a conference call to discuss the updated timeline. During the conference call the Company stated:

> As investors are aware, in July, Puma reported positive top-line results from a Phase III trial of neratinib in the extended adjuvant HER2-positive early-stage breast cancer setting. A trial also referred to as the ExteNET Trial. These Phase III results demonstrated a statistically significant improvement in disease-free survival for neratinib compared to the placebo in patients who have previously been treated with Herceptin in the adjuvant setting. ***Based on this data, the proposed first indication for neratinib changed*** from the HER2-positive metastatic breast cancer setting to the extended adjuvant HER2-positive early-stage breast cancer setting.
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> One of the non-clinical requirements that FDA often requires for NDA filings are carcinogenicity studies. These carcinogenicity studies are preclinical studies performed in, both rats and mice, that are performed in order to determine the

> risk of developing other cancers often referred to as secondary malignancies over the long-term. The FDA does not require carcinogenicity studies to be performed for metastatic cancer indications because the life expectancy of this population is relatively short.
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> However, because the patient population in the extended adjuvant early-stage breast cancer setting has a relatively long life expectancy, the FDA requires the carcinogenicity studies need to be performed for drugs in the early-stage breast cancer indication in order to determine the potential for the drug to increase the risk of cancer over the long-term. Drugs that are small molecules are required to do carcinogenicity studies, large molecules like antibodies are not required to perform carcinogenicity studies. Puma had previously given investors guidance that it anticipated filing the NDA for neratinib in the extended adjuvant setting in the first half of 2015. This was based on the assumption that Puma could submit the data from the carcinogenicity studies with neratinib after the NDA was filed, either during the NDA review period, or post approval as a post-marketing commitment. These carcinogenicity studies with neratinib are anticipated to be completed in November 2015, so submitting the data after the filing fit very well with this proposed timeline.
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> (emphasis added)

51. This disclosure shocked the market. For example, in an article published by *Bloomberg*, it was reported that:

> Puma Biotechnology Inc. fell as much as 24 percent in post-market trading after the company said it would delay filing for U.S. regulatory approval of its experimental breast cancer treatment by as much as a year.
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> Puma said it will file an application with the Food and Drug Administration in the first quarter of 2016, instead of the first half of 2015, the company's previous plan. The company is applying to use the drug in early stage cancer patients as a follow-on treatment after initial therapy, and the company said in a statement today that the FDA wanted long-term data on whether or not the drug caused other cancers during pre-clinical tests in animals.

* * *

> Puma originally said it would apply to use neratinib for HER2-positive metastatic breast cancer, a sicker, higher-risk group, and now plans to apply first for extended adjuvant HER2-positive early stage breast cancer, the company said. HER2 is a genetic mutation that can drive a cancer's growth.

52. Another article published by *SeekingAlpha.com* reported that:

> The company says the change in timeline is due to the change in indication and the additional data required by the change. The original indication for PB272 was the treatment of HER2-positive metastatic breast cancer. After discussions with the FDA, the new indication will be the extended adjuvant treatment of HER2-positive early stage breast cancer. The new indication requires Puma to submit data from preclinical carcinogenicity studies.

53. At an earnings call later that day, analysts pressed the Company as to when it knew that it had insufficient data to proceed on an NDA for early stage cancer. One analyst asked defendant Auerbach whether the Company knew that the changed primary indication would cause the FDA to ask for additional data that the company didn't have:

> **<Q – [Analyst]>:** So let me ask you, I mean, I understand that the six previous drugs which are approved for early-stage breast cancer, submitted their CART data either, as you noted, ahead of time, or at the time of NDA filing. If you look at the ICH Guidelines which I'm sure you've read a million times, it basically provides that only in circumstances where there's significant cause for concerns, you have to submit it to support clinical studies. Obviously that wasn't done because there was no need to, but the guidelines essentially note that you can submit these post-approval. So I'm trying to get a sense why aren't they following the guidelines? And then I have a follow up?
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> **<A - Alan H. Auerbach>:** And to your question, their view was that they didn't want to – my perception is, they didn't want to set precedence. Everyone else did, so should we.

54. Thus, despite the fact that the six previous drugs which are approved for early-stage breast cancer all submitted CART data prior to or simultaneously with their NDA, Puma led investors to believe it could submit that data subsequent to their NDA filing.

55. On this news, shares of Puma fell $27.33 per share, or over 12%, to close at $197.67 per share on December 3, 2014 on extremely high volume.

56. On March 2, 2015, the Company issued a press release and filed a Form 8-K with the SEC, announcing its financial and operating results for the fourth quarter and full year ended December 31, 2014. For the fourth quarter, Puma reported a net loss of $47.5 million, or $1.57 per share, compared to a net loss of $15.9 million, or $0.55 per share, for the fourth quarter of 2013. For the full year, Puma reported a net loss of $142.0 million, or $4.73 per share, compared to a net loss of $54.6 million, or $1.90 per share, for the full year 2013.

57. On March 2, 2015, the Company filed an annual report on Form 10-K with the SEC which was signed by defendants Auerbach and Eyler, and reiterated the Company's previously announced quarterly and year-end financial results and financial position. In addition, the Form 10-K contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by defendants Auerbach and Eyler, stating that the financial information contained in the Form 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

58. On May 11, 2015, the Company issued a press release and filed a Form 8-K with the SEC, announcing its financial and operating results for the first

quarter ended March 31, 2015. For the fourth quarter, Puma reported a net loss of $52.5 million, or $1.66 per share, compared to a net loss of $19.8 million, or $0.67 per share, for the first quarter of 2014.

59. On May 11, 2015, the Company filed an annual report on Form 10-Q with the SEC which was signed by defendants Auerbach and Eyler, and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by defendants Auerbach and Eyler, stating that the financial information contained in the Form 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

60. The statements referenced in ¶¶ 40, 42–46, and 56–59 above were materially false and misleading because Defendants made false and/or misleading statements, and failed to disclose material adverse facts about the Company's business, operations, prospects and performance. Specifically, during the Class Period, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the Company's NDA filing would be for a positive ***early stage*** breast cancer indication, instead of the previously announced ***metastatic breast cancer***; (2) Puma would need to submit additional safety data from preclinical carcinogenicity studies with its NDA filing, which Puma did not have; (3) additional required studies would necessarily push the timeline for filing the NDA into the first quarter of 2016; (4) the Company overstated the results from its Phase III ExteNET Trial; and (5) as a result of the foregoing, Defendants lacked a

reasonable basis for their positive statements about the Company and its outlook, including those contained its financial statements and regarding the ongoing ExteNET trial.

61. On May 13, 2015, after the close of trading, Puma released four abstracts for its PB272 (neratinib) breast cancer drug that were to be presented at the ASCO annual meeting.

62. Abstract #508 is a summary of the ExteNET trial which is a Phase 3 trial comparing Puma's lead product candidate, neratinib, to placebo in HER2+ breast cancer patients who were pre-treated with Roche's Herceptin (trastuzumab). The primary endpoint was the proportion of patients who were disease-free two years after adjuvant treatment as measured by invasive disease-free survival (IDFS). IDFS in the neratinib arm (n=1,409) was 93.9% compared to 91.6% for placebo (n=1,412). The modest difference of only 2.3% (p=0.0046) was lower than the market expected, especially given that on July 22, 2014, the Company stated that Neratinib performed 33% better than the placebo. The Company has yet to explain this discrepancy.

63. On this news, shares of Puma fell $39.05 per share, or over 18.6%, to close at $170.67 per share on May 14, 2015, on unusually high volume.

64. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant damages.

PLAINTIFF'CLASS ACTION ALLEGATIONS

65. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Puma securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

66. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Puma Class Period, securities of Puma were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Puma or their transfer agents and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

67. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law complained of herein.

68. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class action and securities litigation.

69. 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:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Puma;
- whether the Individual Defendants caused Puma to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Puma securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and,
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

70. 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 make it impossible for 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.

71. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Puma securities are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NYSE, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased and/or sold Puma securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

72. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

73. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

74. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

75. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

76. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Puma securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Puma securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

77. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Puma securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Puma's finances and business prospects.

78. By virtue of their positions at Puma, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

79. Defendants were personally motivated to make false statements and omit material information necessary to make the statements not misleading in order to personally benefit from the sale of Puma securities from their personal portfolios.

80. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of Puma, the Individual Defendants had knowledge of the details of Puma's internal affairs.

81. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Puma. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Puma's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Puma securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Puma's business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Puma securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

82. During the Class Period, Puma securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the

market, purchased or otherwise acquired shares of Puma securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Puma securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Puma securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

83. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

84. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

85. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

86. During the Class Period, the Individual Defendants participated in the operation and management of Puma, and conducted and participated, directly and indirectly, in the conduct of Puma's business affairs. Because of their senior positions, they knew the adverse non-public information about Puma's misstatement of income and expenses and false financial statements.

87. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Puma's financial condition and results of operations, and to correct promptly any public statements issued by Puma which had become materially false or misleading.

88. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Puma disseminated in the marketplace during the Class Period concerning Puma's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Puma to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Puma within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Puma securities.

89. Each of the Individual Defendants, therefore, acted as a controlling person of Puma. By reason of their senior management positions and/or being directors of Puma, each of the Individual Defendants had the power to direct the

actions of, and exercised the same to cause, Puma to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Puma and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

90. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Puma.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: June 3, 2015

Respectfully submitted,