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8 UNITED STATES DISTRICT COURT
9 CENTRAL DISTRICT OF CALIFORNIA
10 SOUTHERN DIVISION

11 HSINGCHING HSU, Individually and)
on Behalf of All Others Similarly)
12 Situated,)

13 Plaintiff,)

14 vs.)

15 PUMA BIOTECHNOLOGY, INC., et)
al.,)

16 Defendants.)
17

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

CLASS ACTION

CONSOLIDATED COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS

DEMAND FOR JURY TRIAL

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1 **JURISDICTION AND VENUE**

2 1. The claims asserted herein arise under and pursuant to §§10(b) and 20(a)
3 of the Securities Exchange Act of 1934 (“Exchange Act”) (15 U.S.C. §§78j(b) and
4 78t(a)), and Rule 10b-5 promulgated thereunder by the U.S. Securities and Exchange
5 Commission (“SEC”) (17 C.F.R. §240.10b-5).

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

8 3. Venue is proper in this District pursuant to §27 of the Exchange Act and
9 28 U.S.C. §1391(b) because a significant portion of Defendants’ actions, and the
10 subsequent damages, took place within this District.

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

15 **INTRODUCTION AND OVERVIEW**

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

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

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

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

13 8. Puma is a development-stage pharmaceutical company formed in
14 September 2010 with a primary focus on acquiring and developing drug products.
15 Since its formation, the Company has not received marketing approval for any drug
16 product and has not produced any revenue. Puma’s primary focus has been on the
17 development of the drug PB272 (“neratinib”). Neratinib was initially developed by
18 Wyeth and Pfizer, and Puma acquired the rights to license the drug in 2011. As of
19 2015, neratinib is in various phases of clinical trials for the treatment of early- and
20 late-stage human epidermal growth factor receptor 2 (“HER2”) breast cancer in the
21 adjuvant, metastatic, neoadjuvant and HER2 mutation settings.

22 9. Puma’s Phase III clinical trial for neratinib as an extended adjuvant
23 treatment for HER2-positive breast cancer, known as the ExteNET trial, was
24 completed in October 2013. The primary endpoint for the ExteNET trial was
25 improved disease-free survival (“DFS”) of patients taking the drug versus placebo at
26 two years. During the Class Period, Defendants made false and misleading statements
27 regarding the results of the ExteNET trial and the efficacy of neratinib. Specifically,
28 beginning on July 22, 2014, Defendants publicly claimed that the ExteNET trial

1 demonstrated that the absolute difference in DFS rates between neratinib patients
2 versus placebo patients was 5% – approximately 91% compared to 86% – and, as a
3 result, “treatment with neratinib resulted in a 33% improvement in disease free
4 survival versus placebo.” Defendants further claimed that the drug and placebo DFS
5 rates were “in line” with prior Herceptin Adjuvant Studies and that the DFS Kaplan-
6 Meier curves widened year-over-year, meaning that the absolute difference between
7 neratinib and placebo was actually improving over the course of the trial.

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

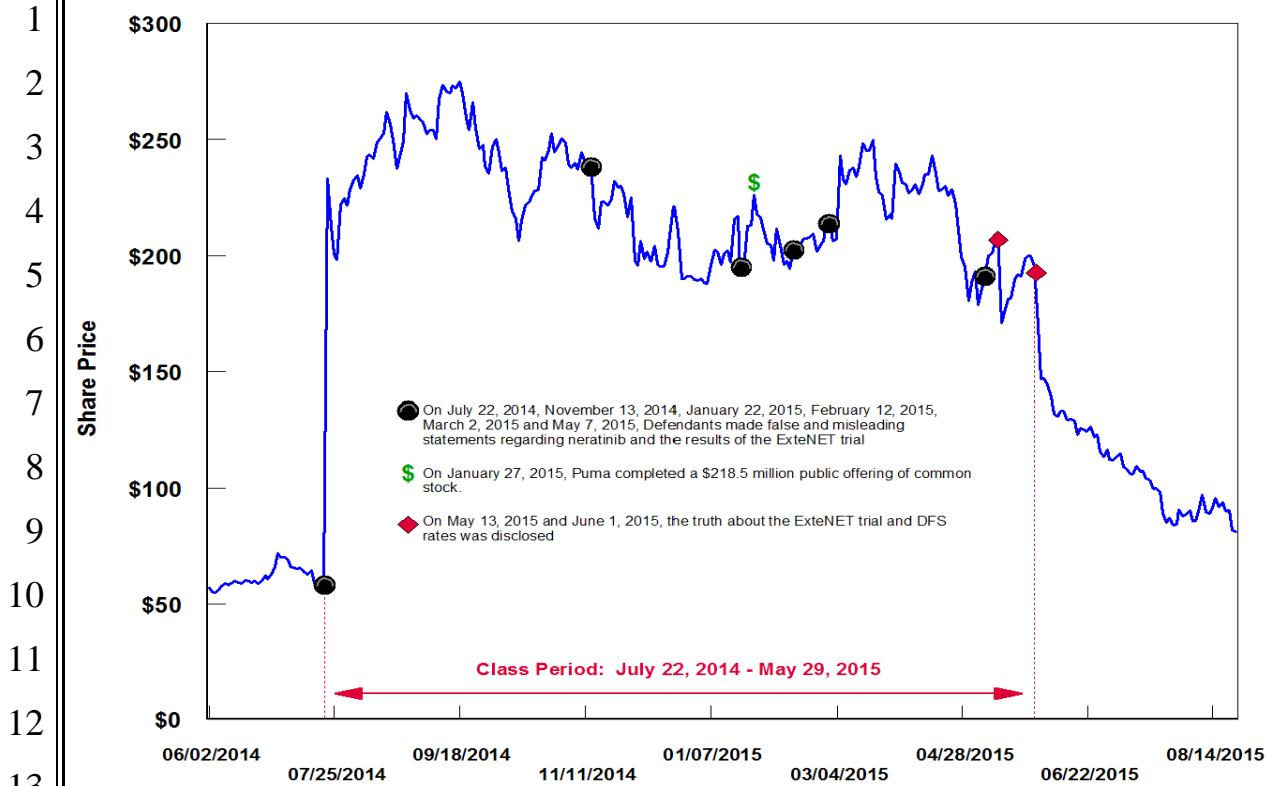
14 11. Defendants’ statements had their intended effect. On July 23, 2014
15 alone, Puma’s stock price more than quadrupled. Indeed, between July 22 and 23,
16 2014, the Company’s stock price increased \$174.40 per share, from \$59.03 to
17 \$233.43, as more than 8 million shares changed hands. Over the following months, as
18 Defendants repeated their statements about the purportedly positive ExteNET trial
19 results, Puma’s shares continued to trade at inflated levels up to and exceeding
20 \$250.00 per share. Taking advantage of this artificial inflation, in January 2015
21 Defendants sold 1.15 million shares of Puma stock for proceeds of \$218.5 million in
22 a secondary offering – money desperately needed to cover the Company’s escalating
23 overhead costs. The Individual Defendants also lined their own pockets, collecting
24 more than \$22.3 million in salary and bonuses that were predicated on the supposedly
25 positive ExteNET trial results and resulting stock price increase.

26 12. After Puma’s secondary offering and after the Individual Defendants had
27 collected their bonuses, the true facts about neratinib and the ExteNET trial began to
28 be revealed. Following the close of the New York Stock Exchange (“NYSE”) on May

1 13, 2015, it was announced that Abstract #508 for the ExteNET trial had been posted
2 on the American Society of Clinical Oncology (“ASCO”) website. Abstract #508
3 revealed, for the first time, that the difference in DFS rates between ExteNET trial
4 patients on neratinib versus placebo was not 5%, but *only 2.3%*, and, therefore, there
5 was not a 33% improvement in DFS over placebo. As *Reuters* reported on the
6 evening of May 13, 2015, Abstract #508 disclosed that “**93.9 percent of neratinib**
7 **patients were alive without their disease progressing, compared with 91.6 percent of**
8 **patients with a placebo,”** and “**Puma had previously disclosed that treatment with**
9 **neratinib had resulted in a significant 33 percent improvement in disease-free**
10 **survival.”** Another article headlined that the disclosure left “Investors Growling in
11 Disbelief.” The response of those investors was swift and severe. On May 14, 2015
12 alone, Puma’s stock price fell 18.6%, or \$39.05 per share, on extremely heavy trading
13 volume.

14 13. Two weeks later, at the ASCO conference, the false and misleading
15 nature of Defendants’ statements was further revealed. In a June 1, 2015 presentation,
16 Dr. Arlene Chan disclosed that the Kaplan-Meier curves for the actual DFS rates from
17 the ExteNET trial did not widen year-over-year and that the DFS rates for ExteNET
18 were not close to being “in-line” with the Herceptin Adjuvant Studies. These
19 disclosures were met with more investor disbelief and further declines in Puma’s stock
20 price. Over June 1 and 2, 2015, Puma’s stock price plummeted an additional \$48.80
21 per share, or over 24%, on heavy trading volume. All told, Plaintiff and investors who
22 purchased or acquired Puma stock during the Class Period suffered damages of up to
23 \$87.85 per share and collectively suffered hundreds of millions of dollars in damages.

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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. 35, Exs. B-C.

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.

1 **Defendants**

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

8 17. **Alan H. Auerbach:** Defendant Alan H. Auerbach ("Auerbach") served
9 as the Company's CEO, President and Chairman of the Board at all relevant times.
10 Prior to founding Puma, Auerbach served as the founder and CEO of Cougar
11 Biotechnology, Inc. ("Cougar") – a pharmaceutical company he sold to Johnson &
12 Johnson in 2009. Puma's April 30, 2015 Proxy Statement emphasized Auerbach's
13 "significant experience as an executive and research analyst in the biotechnology
14 industry." In 2014, as a result of the fraudulent scheme alleged herein, Auerbach
15 received \$17.8 million in executive bonuses and compensation.

16 18. Prior to the Class Period, Auerbach was responsible for the content and
17 approval of Puma's Code of Business Conduct and Ethics ("Code of Ethics"). The
18 Code of Ethics required that the Company's officers and employees ensure "the
19 disclosure of accurate and complete information regarding the Company's business,
20 financial condition and results of operations" and further warned that "[i]naccurate,
21 incomplete or untimely reporting will not be tolerated and can severely damage the
22 Company and result in legal liability."

23 19. Auerbach made or had authority over the content and dissemination of
24 the false statements and omissions set forth herein at ¶¶47-48, 50, 53-59, and is liable
25 for those false statements and omissions. Auerbach is also a control person of Puma
26 within the meaning of §20(a) of the Exchange Act.

27 20. **Charles R. Eyler:** Defendant Charles R. Eyler ("Eyler") served as the
28 Company's Senior Vice President of Finance and Administration and Treasurer

1 (Principal Financial and Accounting Officer) at all relevant times. Prior to joining
2 Puma, Eyler served as Chief Financial Officer (“CFO”) and Chief Operating Officer
3 (“COO”) of Hayes Medical, Inc. In 2014, as a result of the fraudulent scheme alleged
4 herein, Eyler received \$4.5 million in executive bonuses and compensation.

5 21. Prior to the Class Period, Eyler was also responsible for the content and
6 approval of Puma’s Code of Ethics. The Code of Ethics required that the Company’s
7 officers and employees ensure “the disclosure of accurate and complete information
8 regarding the Company’s business, financial condition and results of operations” and
9 further warned that “[i]naccurate, incomplete or untimely reporting will not be
10 tolerated and can severely damage the Company and result in legal liability.”

11 22. Eyler made or had authority over the content and dissemination of the
12 false statements and omissions set forth herein at ¶¶47, 55, 57, and is liable for those
13 false statements and omissions. Eyler is also a control person of Puma within the
14 meaning of §20(a) of the Exchange Act.

15 23. Defendants Auerbach and Eyler are referred to herein, collectively, as the
16 “Individual Defendants.”

17 24. Defendants Puma, Auerbach and Eyler are referred to herein,
18 collectively, as “Defendants.”

19 **BACKGROUND AND PRE-CLASS PERIOD EVENTS**

20 **Puma and Neratinib**

21 25. Defendant Auerbach started Puma in 2010 with the intent to acquire,
22 develop and market pharmaceutical products for use in treating cancer. As of October
23 2015, the Company has no products for sale and only one drug – neratinib – which it
24 had acquired from Pfizer and was developing to sell as a treatment option for patients
25 with breast cancer and solid tumors.

26 26. Neratinib is intended to be an irreversible inhibitor of the HER2 receptor
27 tyrosine kinase with potential antineoplastic activity. The drug binds to the HER2
28 receptor irreversibly, thereby reducing what is known as “autophosphoylation” in

1 cells, apparently by targeting a cysteine residue in the ATP-binding pocket of the
2 receptor. Treatment of cells with neratinib is intended to result in inhibition of
3 downstream signal transduction events and cell cycle regulatory pathways, arrest of
4 the cell division cycle and, ultimately, decreased cellular proliferation.

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

8 **The Market for Neratinib as a Cancer Treatment**

9 28. Breast cancer is the second leading cause of cancer deaths among
10 women, with approximately 230,000 new cases reported each year in the United
11 States. Between 20% and 25% of breast cancer tumors show “over-expression” of the
12 HER2 protein and women with these tumors are at a greater risk for disease
13 progression and death than women whose tumors that do not over-express HER2.
14 Most patients with HER2-positive breast cancer develop resistance to the drugs
15 currently approved by the U.S. Food and Drug Administration (“FDA”) – *e.g.*,
16 trastuzumab (Herceptin), pertuzumab and T-DM1 – thereby limiting treatment
17 options. As a result, there is a recognized need for alternative treatments to block
18 HER2 signaling pathways.

19 29. According to the Company’s 2014 Form 10-K, neratinib has a large
20 potential market with approximately 36,000 patients in the United States and 34,000
21 patients in the European Union diagnosed with HER2-positive breast cancer per year.
22 Given the size of the potential market and the drug’s potential to replace FDA-
23 approved drugs on the market when a resistance develops, neratinib was expected to
24 be a blockbuster drug if it could demonstrate a meaningful clinical benefit and
25 ultimately be approved for use and marketing. Based on conversations with
26 Defendants, analysts expected Puma would charge patients \$6,500 a month, or
27 \$78,000 a year, for neratinib, a premium of over 40% over the cost of Herceptin.
28 Defendant Auerbach, in a January 12, 2015 conference call with JP Morgan Chase

1 analysts, touted that “neratinib will basically have the extended adjuvant setting all to
2 itself with no competitive threats” and “[c]urrently Herceptin in year one of the
3 adjuvant setting does approximately \$4.3 billion, and all of those patients would be
4 eligible for neratinib in year two.” As *Bloomberg* reported, at the prices Puma
5 intended to charge, neratinib could reap \$2.5 billion in annual sales by 2020. The
6 investment banking firm Cowen and Company also estimated that neratinib could
7 generate total global sales for Puma of up to \$6.0 billion by 2028.

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

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

17 31. The key metric in evaluating DFS rates across studies is the absolute
18 benefit or absolute difference between the treatment arm and placebo arm in each
19 study – the difference between the DFS rates for those on the drug and those on
20 placebo. As a Leerink Partners equity analyst explained following Defendants’ July
21 22, 2014 statements: “the magnitude of benefit (HR=0.63-0.67 depending on how
22 disease-free survival [DFS] is measured, likely 4% absolute improvement in DFS on
23 top of 1-year Herceptin) is among best-case scenarios that could be envisioned.”
24 Echoing Auerbach’s statements, the analyst reported that “DFS for the control arm
25 was in line with historical Herceptin adjuvant studies, likely in the range of 86-87%,
26 which suggests a ~91% DFS in the drug arm, or absolute difference of ~4%.” Leerink
27 Partners also reported that in a conference call with key opinion leaders discussing
28 Defendants’ statements regarding the ExteNET trial results, the medical consultants

1 “were enthusiastic about the magnitude of benefit seen for neratinib, and commented
2 that the study could be practice-changing.”

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

7 Given prior comments from PBYI, investors had expectation of at least a
8 3% absolute benefit, and perhaps a benefit as high as 4-5%. In addition,
9 some physicians are focused on absolute benefits as much as relative risk
10 reductions. Given neratinib is associated with significant tolerability
11 issues, some consultants have commented that they would like to see at
12 least 3-4 women cured per 100 treated. Hence the 2.3% figure could
13 lead to lower penetration in the marketplace.

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

16 Neither of our consultants were enthusiastic about the ExteNET
17 dataset. They noted that the prognosis for HER2+ early stage patients is
18 already very good with currently available therapies, therefore even
19 though the hazard ratio targets were met, *the absolute magnitude of*
20 *difference in DFS was “trivial.” Neratinib’s use is likely to be limited*
21 *to a small subset, most likely in ER/PR+ node positive disease.*

22 * * *

23 *Both consultants believe that the market share for this drug is likely to*
24 *be “very small” in the extended adjuvant setting* because (1) patients do
25 very well on existing therapies, (2) neratinib has significant tolerability
26 issues, even with imodium prophylaxis, [and] (3) the vast majority [of
27 patients] (~80%) are node negative, where the drug is likely to only
28 show a modest benefit

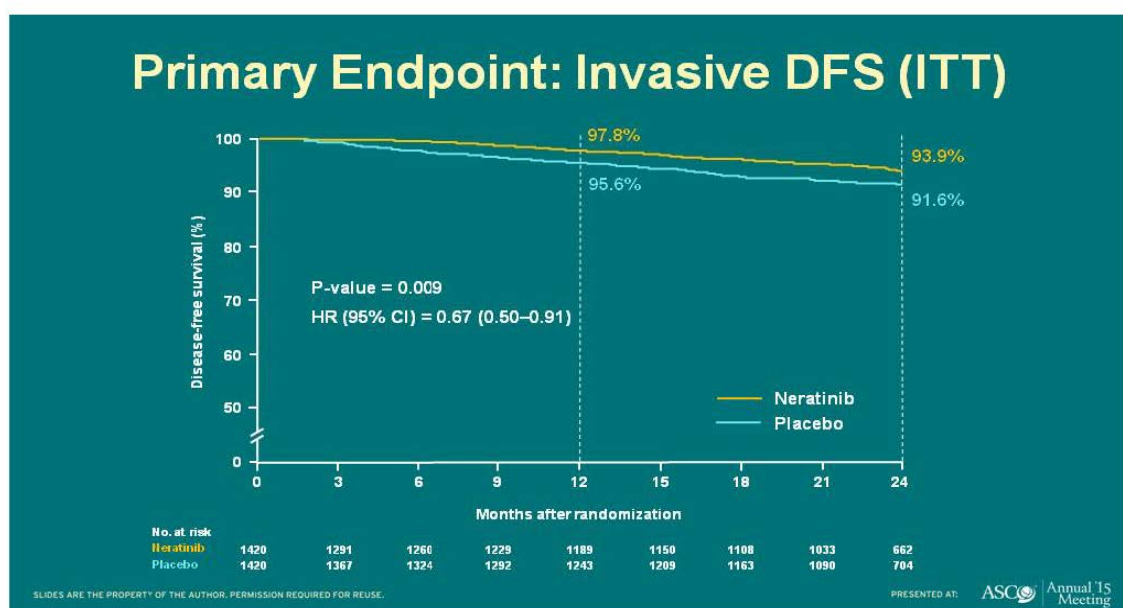
1 33. **Kaplan-Meier Curves:** In 1958, Edward L. Kaplan and Paul Meier
2 published a seminal paper describing how “Kaplan-Meier curves” deal with differing
3 survival times (“times-to-event”) when not all study participants continue to the end of
4 a clinical study. See E.L. Kaplan & P. Meier, *Nonparametric Estimation from*
5 *Incomplete Observations*, J. Amer. Stat. Assoc. (1958, vol. 53:457-81). Kaplan and
6 Meier’s academic research provided important examples of when survival times are
7 key to certain studies, such as in cancer treatment trials.

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

20 35. Further, the distance between the Kaplan-Meier curves in the above-
21 noted hypothetical can be said to be increasing or “widening” over time because at the
22 end of the first period, the DFS rate for treatment versus placebo was 100% and 90%
23 (an absolute difference of 10%), respectively, and at the end of the second period, the
24 DFS rate for treatment versus placebo was 90% and 78% (an absolute difference of
25 12%). A widening of the Kaplan-Meier curves would be seen as a key, positive result
26 in a trial like ExteNET. A pharmaceutical analyst at UBS Securities explained
27 following Defendants’ July 22, 2015 statements: “[C]ommentary on the call adds to
28

1 our confidence: the DFS curves apparently widen over time, and neratinib appears
 2 active in all subgroups examined, suggesting broad utilization.”

3 36. Below is a graphical depiction of the Kaplan-Meier curves for the
 4 ExteNET study, as shown at the end of the Class Period at the 2015 Annual Meeting
 5 of ASCO:



Presented By Artene Chan at 2015 ASCO Annual Meeting

21 **The ExteNET Trial and License Agreement with Pfizer**

22 37. Neratinib, like other pharmaceutical products, is subject to a series of
 23 clinical trials to evaluate its effectiveness and safety for particular treatments prior to
 24 obtaining marketing approval. Clinical trials progress through distinct phases, and
 25 Phase III trials are the most significant for testing the efficacy and safety of a drug.
 26 The Phase III clinical trial of neratinib for the extended adjuvant treatment of HER2-
 27

1 positive breast cancer, the ExteNET trial, was conducted between April 2009 and
2 October 2013.

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

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

20 40. The primary endpoint for the ExteNET trial was the DFS of patients
21 taking the drug versus placebo. On July 22, 2014, Defendants announced that the
22 ExteNET trial had hit its primary endpoint. Specifically, Defendants claimed that
23 treatment with neratinib demonstrated a 33% improvement in DFS over placebo –
24 based on DFS rates of roughly 91% and 86% and an absolute difference of 5% – and
25 that the Kaplan-Meier curves continued to widen year after year. These purported
26 results were enthusiastically greeted by investors and practitioners.

27 41. On July 22, 2014, the same day that Defendants made their
28 announcement about the ExteNET DFS results, Puma also disclosed that it had

1 reached an agreement with Pfizer to amend the licensing agreement. Under the new
2 terms, Pfizer would no longer be obligated to fund the legacy clinical trials –
3 including post-trial expenses with ExteNET – in consideration for lowering its
4 royalties from “10-20%” to a fixed rate in the “low- to mid-teens.” It was not
5 disclosed whether Pfizer saw the actual ExteNET DFS data before retreating from its
6 investment position on neratinib.

7 **The Herceptin Adjuvant Studies –**
8 **HERA, NSABP, NCCTG and BCIRG**

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

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

25 44. The NSABP B-31 and NCCTG N9831 studies were designed primarily
26 to investigate the clinical efficacy of combining Herceptin with the drug paclitaxel
27 following AC chemotherapy. Because of the similar design of the two studies, both
28 sets of data from the studies were analyzed jointly after discussion with the FDA. At

1 three and a half years follow-up, the joint analysis found that one year of Herceptin
2 resulted in an absolute benefit of **15.3%** over AC chemotherapy followed by just
3 paclitaxel.

4 45. The BCIRG 006 study was designed to investigate the clinical utility of
5 Herceptin treatment in post-surgery patients with HER2-positive EBC in two different
6 settings: (i) following AC chemotherapy in combination with the drug docetaxel; or
7 (ii) in combination with the drugs docetaxel and carboplatin. At three years follow-
8 up, both settings demonstrated that Herceptin had an absolute benefit of **5.7%** and
9 **4.0%**, respectively, over AC chemotherapy followed by just docetaxel.

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

21 **DEFENDANTS' MISLEADING STATEMENTS**
22 **AND MATERIAL OMISSIONS**

23 47. After the market closed on July 22, 2014, Puma issued a press release and
24 thereafter filed a Form 8-K, signed by defendant Auerbach and attaching the press
25 release, with the SEC. The press release, reviewed and approved for publication by
26 Auerbach and Eyler, was entitled "Puma Biotechnology Announces Positive Top-line
27 Results from Phase III PB272 Trial in Adjuvant Breast Cancer (ExteNET Trial):
28 Neratinib Achieves Statistically Significant Improvement in Disease Free Survival

1 Company Plans to File for Regulatory Approval in First Half of 2015.” The press
2 release reported: “*The results of the trial demonstrated that treatment with neratinib*
3 *resulted in a 33% improvement in disease free survival versus placebo.*”

4 48. Immediately after the Company issued its July 22, 2014 press release,
5 Puma held a conference call with analysts and investors to further discuss the top-line
6 results of the ExteNET trial. Auerbach participated in the conference call. During the
7 call, Auerbach engaged in the following exchange with Yaron Werber, a Citi Research
8 equity analyst:

9 [WERBER:] Congrats on this fantastically and, in many ways,
10 unexpected data. So I have a ton of questions. Maybe I’ll just take two,
11 if you don’t mind. One is, give us a little bit of a sense, what was the
12 DFS on the control arm, first. And then second, help us understand,
13 what do you know about the safety profile?

14 [AUERBACH:] Okay. *So in terms of the DFS of the placebo*
15 *arm of the trial, it was in line with other reported trials. So it’s inline*
16 *with the Herceptin adjuvant studies.* And then in terms of the safety
17 profile, we haven’t yet fully validated the safety database.

18 * * *

19 [WERBER:] *You’re thinking that, if I’m correct, the DFS is*
20 *probably around mid to high 80s, around 86% or so in the control*
21 *arm?*

22 [AUERBACH:] *I would be comfortable with that number.*

23 [WERBER:] *And one would imagine you probably had to show*
24 *around 90% or 91% [in the treatment arm]? Is that reasonable?*

25 [AUERBACH:] *Yes. I think you can do a 33% improvement in*
26 *DFS and come up with that calculation, given the numbers we gave.*

27 49. With these statements, Auerbach asserted that the DFS of the placebo
28 arm was “in line” with the Herceptin Adjuvant Studies at roughly 86%. Auerbach

1 also confirmed that the treatment arm demonstrated a DFS of 90%-91%. As a result,
2 analysts and investors understood the 33% improvement claim was based on an
3 absolute DFS benefit of approximately 5% – a magnitude of benefit that would
4 support widespread clinical use of neratinib.

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

8 [LIANG:] Congratulations, Alan, and your team. So can you – *I*
9 *assume you have seen the curves for the two arms*. Can you give us a
10 sense as to whether the separation is widening over time? Or how would
11 you describe the curve separation?

12 [AUERBACH:] *Yes*, Thanks for that question, Howard. Okay, so
13 the [ExteNET] trial started in April of 2009, and this data cut is as of
14 October 2013. So that's essentially the last patient was followed for 2
15 years. So from those numbers, you can see we have a lot of patients who
16 have been in for much more than that 2-year cutoff. *If we look at the*
17 *curves going out beyond that, it looks like the curves are continuing to*
18 *separate*.

19 *And to give a little more detail on that, if you look at the curves*
20 *in the Herceptin adjuvant trials – so the HERA study, the BCIRG*
21 *study, et cetera – the absolute difference in disease-free survival*
22 *increases as you go out year over year. So, for instance, in the BCIRG*
23 *trial, the DFS difference was 6% at 2 years and 7% at 3 years, then 8%*
24 *at 4 years*

25 *We're seeing the same preliminary trend in the ExteNET trial,*
26 *where the curves appear to be continuing to separate as you go out*
27 *year over year, and the absolute DFS difference is increasing year over*
28 *year as well.*

1 51. In response to the Company's press release and conference call
2 concerning the top-line DFS results in the ExteNET trial, Puma's stock price
3 skyrocketed, increasing \$174.37 per share by the close of the market on July 23, 2014,
4 a one day increase of over 295%.

5 52. Media reports flagged Puma's stock price increase and tied it to
6 Defendants' statements regarding the ExteNET trial results. For example, on July 23,
7 2014, an *MTNewswires* article entitled "Puma Biotechnology Up More Than 220% in
8 Early Pre-Market on Results of Cancer Drug Trial," reported "[t]he results of the trial
9 demonstrated that treatment with neratinib resulted in a 33% improvement in disease
10 free survival, the primary endpoint, versus placebo." Similarly, a *MarketWatch* article
11 entitled "Puma Biotech's blast-off is not a typical short squeeze," reported the
12 Company's stock "soared \$170.83, or 289%, to \$229.86 in midday trading [on July
13 23, 2014] The blast-off follows the company's announcement late Tuesday of
14 positive results from a Phase 3 trial of its breast cancer treatment."

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

21 54. Following the close of trading on December 2, 2014, Puma held a
22 conference call with analysts and investors for the purpose of updating the market
23 regarding the filing of the New Drug Application ("NDA") for neratinib as an
24 extended adjuvant treatment for breast cancer. During the call, Auerbach confirmed
25 that the FDA had requested Puma to submit the results of the two-year DFS data from
26 the ExteNET trial and again acknowledged that the Company maintained and had
27 direct knowledge of the DFS rates for the treatment and placebo arms: "***That's***
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1 *correct. The data that was provided [to the FDA] was the full DFS data – so the*
2 *Kaplan-Meier curves, [all the] endpoints, the DFS rates, the whole nine yards.”*

3 55. On January 20, 2015, Defendants filed a Form S-3ASR Registration
4 Statement with the SEC for a follow-on offering of securities, including common
5 stock, debt securities and warrants. On January 22, 2015, Defendants filed a Form
6 424B2 Prospectus with the SEC for the sale of 1.15 million shares of Puma stock.
7 Defendants Auerbach and Eyler signed the Form S-3ASR Registration Statement and
8 wrote, adopted and approved of the contents of the Form 424B2 Prospectus. With
9 regard to the ExteNET trial, the Form 424B2 Prospectus stated that “[t]he results of
10 *the trial demonstrated that treatment with neratinib resulted in a 33% improvement*
11 *in disease free survival versus placebo.”* The January 2015 Registration Statement,
12 moreover, incorporated by reference the Company’s July 22, 2014 press release
13 announcing the top-line results of the ExteNET trial.

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

19 57. On March 2, 2015, the Company filed its 2014 Form 10-K with the SEC.
20 Defendants Auerbach and Eyler signed the Form 10-K and, pursuant to §302 of the
21 Sarbanes-Oxley Act of 2002, certified that the Form 10-K “does not contain any
22 untrue statement of a material fact or omit to state a material fact necessary to make
23 the statements made, in light of the circumstances under which such statements were
24 made, not misleading.” With regard to the ExteNET trial, Defendants stated in the
25 Form 10-K that “[t]he results of the trial demonstrated that treatment with neratinib
26 *resulted in a 33% improvement in disease free survival versus placebo.”*

27 58. On March 3, 2015, Puma held another conference call with analysts and
28 investors for the purpose of updating the market regarding the status and results of the

1 Company's clinical trial programs. During the call, Auerbach stated: "*So we*
2 *announced the results in July of 2014, where we announced that the trial hit the*
3 *primary endpoint. So, 33% improvement in disease free survival*"

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

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

13 61. Defendants' Class Period statements, set forth in ¶¶47-48, 50, 53-59,
14 which succeeded in artificially inflating Puma's stock price, were false and misleading
15 when made. Defendants falsely informed investors that the absolute difference in
16 DFS rates between neratinib and placebo was approximately 5%, purportedly
17 demonstrating a 33% improvement in disease-free survival, and that the Kaplan-Meier
18 curves (the difference between drug and placebo DFS rates) were separating. The true
19 facts, that Defendants knew but failed to disclose during the Class Period, were that
20 the actual absolute difference in DFS rates was only 2.3%, which did not represent a
21 33% improvement and was not in line with the Herceptin Adjuvant Studies, and that
22 at the end of the two-year ExteNET trial the Kaplan-Meier curves were not separating
23 and were actually narrowing.

24 **DISCLOSURE OF THE TRUTH ABOUT THE EXTENET TRIAL**

25 62. After the market closed on May 13, 2015, it was announced that Puma
26 had released Abstract #508, the summary of a journal reprint regarding the ExteNET
27 trial, on the ASCO website, www.abstract.asco.org. Abstract #508 revealed that the
28 DFS for patients in the treatment arm of ExteNET was 93.9%, while the DFS for

1 patients receiving placebo was 91.6%. This difference in DFS – **only 2.3%** – was
2 materially lower than what the market had been led to believe by Defendants’ false
3 and misleading statements.

4 63. As *Reuters* reported in a May 13, 2015 article entitled “Puma Biotech
5 breast cancer trial detailed, shares fall 25 pct”:

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

9 * * *

10 It found that after two years, 93.9 percent of neratinib patients
11 were alive without their disease progressing, compared with 91.6 percent
12 of patients treated with a placebo.

13 Puma had previously disclosed that treatment with neratinib had
14 resulted in a significant 33 percent improvement in disease-free survival.

15 64. On May 14, 2015, *FierceBiotech* published an article entitled “The
16 ASCO roundup: Thumbs down for Puma, up for Roche, mixed for Bristol-Meyers.”
17 The article referenced the ASCO abstract, noting it scored “the percentage of women
18 who were free of invasive disease [and] the neratinib group hit 93.9% compared to
19 91.6% in the placebo arm. ***Analysts did a double take on the meager 2.3% difference***
20 ***and quickly turned thumbs down on the data.***”

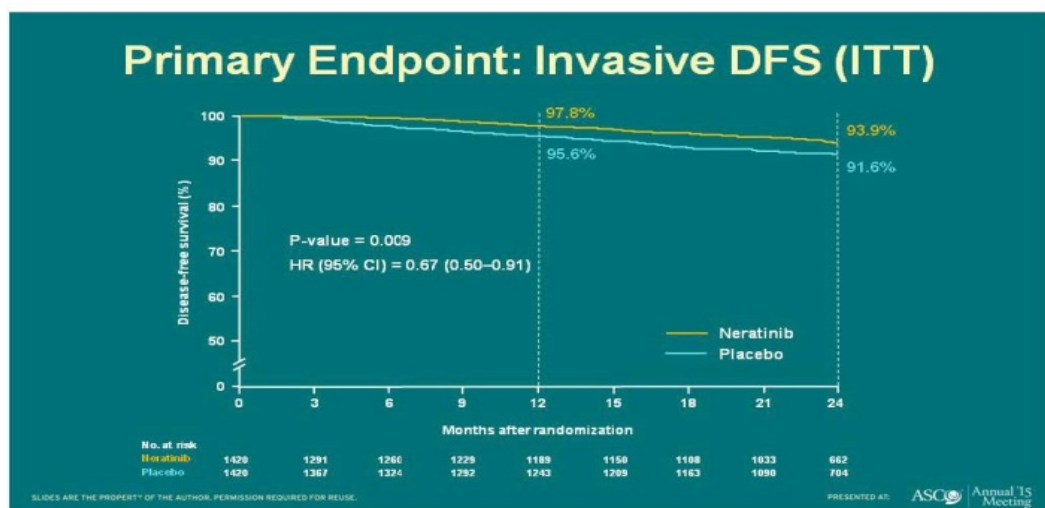
21 65. As a result of investors learning the truth about the actual difference in
22 DFS rates in the ExteNET trial, Puma’s stock priced dropped by \$39.05 per share on
23 May 14, 2015. This 18.6% decline came on massive volume, as the number of shares
24 traded increased to 3.1 million, a 948% increase over Puma’s average daily trading
25 volume for the prior 90 days.

26 66. On May 28, 2015, in an article entitled “Puma Bio Restricting Access to
27 Breast Cancer Event at ASCO Chicago,” *TheStreet.com* reported that certain securities
28 analysts with bearish positions on Puma stock were being excluded by the Company

1 from attending the ASCO event. *TheStreet.com* noted “[r]estricting access to a
2 corporate event might not be such a big deal if not for Puma’s penchant for
3 selectively disclosing important information” to investors concerning the ExteNET
4 trial. *TheStreet.com* further reported that a “full presentation of the neratinib study
5 results is scheduled for Sunday morning during the ASCO meeting.”

6 67. On June 1, 2015, the full data from the ExteNET trial was revealed in an
7 oral presentation by Dr. Arlene Chan at ASCO. As previously disclosed in Abstract
8 #508, the results showed that the absolute difference in DFS rates at two years was
9 only 2.3%. The data presented also revealed, for the first time, the Kaplan-Meier
10 curves for the ExteNET trial. This newly disclosed data showed essentially flat curves
11 between the neratinib and placebo arms, with no trend of separation. In fact, one-year
12 follow-up from randomization showed an absolute DFS difference of only 2.2%
13 (97.8% vs. 95.6%). Thus, between years one and two of observation, the absolute
14 benefit experienced by study participants increased by only 0.1%, and the curves were
15 actually narrowing by the end of year two – inconsistent with Auerbach’s prior claims
16 that “the curves are continuing to separate” and “the absolute DFS difference is
17 increasing year over year.” The actual trajectory of the DFS curves, as presented at
18 ASCO, is set forth below:

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Presented By Arlene Chan at 2015 ASCO Annual Meeting

68. 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.”

69. 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.”

70. 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,

1 Puma's stock price continued falling and dropped an additional \$23.32 during trading
2 hours, closing at \$146.65. This two-day 23.6% decline came on massive volume, as
3 the number of shares traded increased to 2.9 million and 3.6 million over June 1 and 2,
4 2015, respectively – representing increases of 647% and 818% over Puma's average
5 trading volume for the prior 90 days. The stock price continued falling after
6 disclosure of the truth about neratinib and the ExteNET trial and currently trades for
7 less than \$85 per share.

8 **DEFENDANTS' MOTIVE AND OPPORTUNITY**
9 **TO DEFRAUD INVESTORS**

10 **Puma's \$218.5 Million in Stock Sales**

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

20 72. In addition, as a result of the licensing amendment with Pfizer signed
21 July 2014 – which obligated Puma to accept full financial responsibility for all
22 ongoing legacy trials with neratinib – Puma began realizing even greater net losses.
23 Puma incurred losses of \$19.8 million, \$38.8 million and \$35.8 million through the
24 first three fiscal quarters of 2014, respectively. At year's end, Puma had burned
25 through \$142 million, and only had \$149.4 million remaining in total current assets.
26 At the rate Puma was burning through its cash and liquid assets, the Company's
27 operations could barely last another year without an injection of capital.
28

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

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

17 75. According to the Company's 2014 Form 10-K, Defendants sold 1.15
18 million shares of Puma common stock – at an artificially inflated price of \$190 per
19 share – for total proceeds of \$218.5 million in the January 2015 offering. This
20 funding was vital for Puma to continue its operations, as the Company continued to
21 report increased losses in 2015 – more than \$117 million in net losses in the first two
22 quarters alone. But for Defendants' deliberate decision to misstate and withhold the
23 actual DFS rates associated with the ExteNET trial, however, Puma's Class Period
24 stock price would have been substantially lower, and Puma would have been unable to
25 obtain the \$218.5 million in funds.

26 **Defendants' Class Period Compensation**

27 76. The Individual Defendants were also highly motivated to materially
28 misstate the efficacy results of neratinib in the ExteNET trial by the terms of their

1 employment agreements with Puma. The Individual Defendants' compensation was
2 directly tied to Puma's "performance on both a short-term and long-term basis,"
3 including "results intended to create value for stockholders" such as share price and
4 clinical results – the very measures that were improperly manipulated by the
5 Individual Defendants during the Class Period. The personal wealth of each of the
6 Individual Defendants was enhanced by the repeated dissemination of materially
7 misleading statements regarding the ExteNET study results.

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

19 78. As a result of their false and misleading statements, the Individual
20 Defendants personally profited. For 2014, Auerbach received \$17.8 million in
21 executive compensation – an increase of more than 229% from the \$5.4 million he
22 earned in 2013. Similarly, Eyler pocketed \$4.5 million in 2014, an increase of 246%
23 over the \$1.3 million he received in 2013. In total, Auerbach and Eyler received
24 nearly \$22.3 million in salary and incentive-based annual compensation in 2014 alone,
25 all materially enhanced as a result of deceiving the investing public about the very
26 performance measures for which they were being rewarded.

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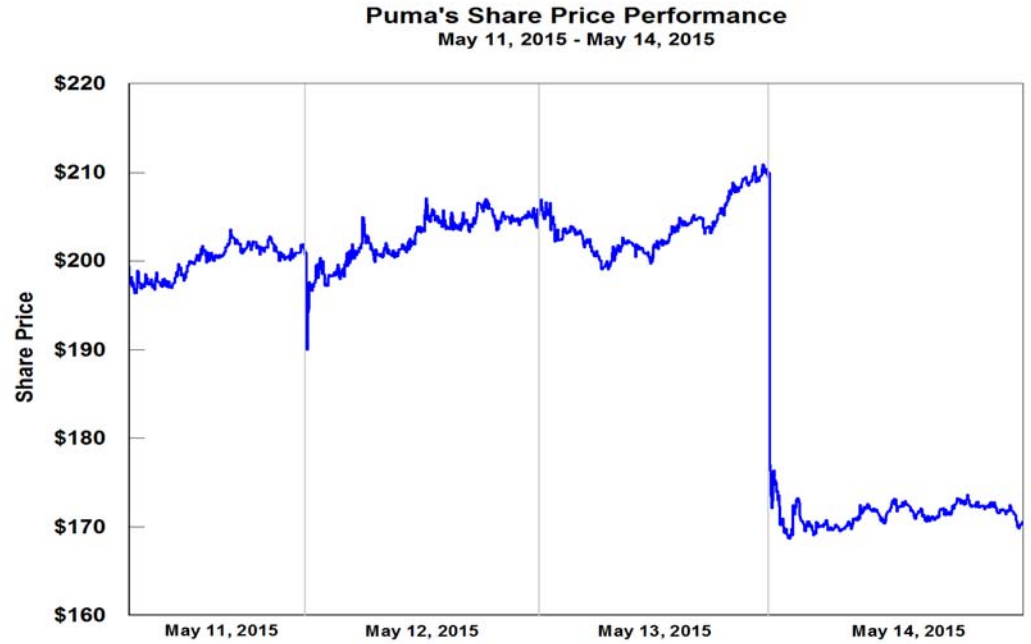
LOSS CAUSATION/ECONOMIC LOSS

79. 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.

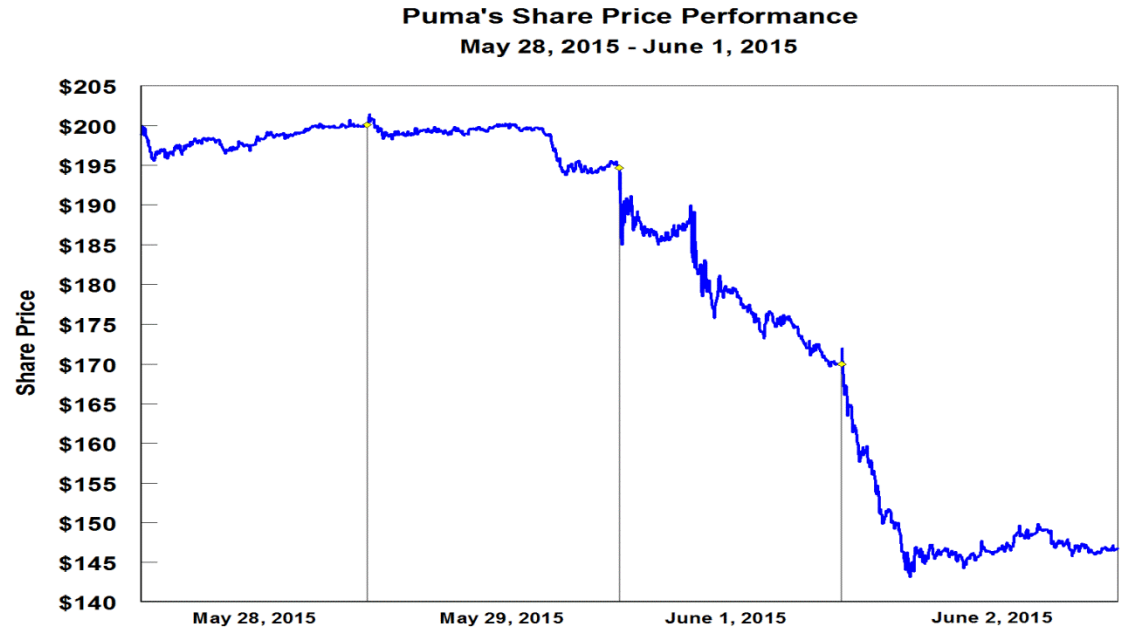
80. Defendants’ misleading statements and omissions, identified herein at ¶¶47-48, 50, 53-59, had the intended effect and caused Puma’s stock to trade at artificially inflated levels during the Class Period.

81. As a direct result of the disclosures that began the evening of May 13, 2015 and are detailed in ¶¶62-65, 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:

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82. The disclosures on June 1, 2015, detailed in ¶¶67-69, 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:



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

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

15 **APPLICABILITY OF THE PRESUMPTION OF RELIANCE**

16 85. Plaintiff and the Class are entitled to a presumption of reliance pursuant
17 to *Basic Inc. v. Levinson*, 485 U.S. 224 (1988), and the fraud-on-the-market doctrine
18 because, during the Class Period, Puma stock traded in an efficient market on the
19 NYSE, the material misstatements and omissions alleged herein would induce a
20 reasonable investor to misjudge the value of Puma stock and without knowledge of
21 the misrepresented or omitted material facts, Plaintiff and other members of the Class
22 purchased or acquired Puma stock between the time Defendants misrepresented and
23 failed to disclose material facts about neratinib and the ExteNET trial and the time the
24 true facts were disclosed. Accordingly, Plaintiff and other members of the Class
25 relied, and are entitled to have relied, upon the integrity of the market for Puma
26 common stock, and are entitled to a presumption of reliance on Defendants' materially
27 false and misleading statements and omissions during the Class Period.

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

5 **CLASS ACTION ALLEGATIONS**

6 87. Plaintiff brings this action as a class action pursuant to Rule 23 of the
7 Federal Rules of Civil Procedure on behalf of all persons or entities who purchased or
8 otherwise acquired the common stock of Puma between July 22, 2014 and May 29,
9 2015, inclusive (the “Class”). Excluded from the Class are Defendants and their
10 families, the officers and directors of Puma, members of their immediate families and
11 their legal representatives, heirs, successors or assigns, and any entity in which
12 Defendants have or had a controlling interest.

13 88. The members of the Class are so numerous that joinder of all members is
14 impracticable. The disposition of their claims in a class action will provide substantial
15 benefits to the parties and the Court. Throughout the Class Period, Puma common
16 stock was actively traded on the NYSE, the largest stock exchange in the world.
17 While the exact number of Class members is unknown to Plaintiff at this time and can
18 only be ascertained through appropriate discovery, Plaintiff believes that there are
19 thousands of members in the proposed Class. During the Class Period, there were
20 more than 30 million shares of Puma common stock outstanding and the average daily
21 trading volume was over 403,000 shares. Record owners and other members of the
22 Class may be identified from records maintained by Puma or its transfer agent(s) and
23 may be notified of the pendency of this action using the form of notice similar to that
24 customarily used in securities class actions.

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

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

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

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

8 90. Plaintiff’s claims are typical of those of the Class because Plaintiff and
9 the Class sustained damages as a result of Defendants’ wrongful conduct.

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

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

19 **COUNT I**

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

22 93. Plaintiff repeats and realleges each and every allegation contained above
23 as if fully set forth herein. Count I is brought pursuant to §10(b) of the Exchange Act,
24 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

25 94. During the Class Period, Puma, through its officers, management and
26 agents, including defendants Auerbach and Eyler, made or were responsible for the
27 statements specified in ¶¶47-48, 50, 53-59, which they knew or recklessly disregarded
28 were misleading in that they failed to disclose material facts necessary in order to

1 make the statements made, in light of the circumstances under which they were made,
2 not misleading.

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

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

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

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

26 99. The allegations above establish a strong inference that Puma, as an entity,
27 acted with corporate scienter throughout the Class Period, as its officers and agents
28 had actual knowledge of the misrepresentations and omissions of material facts set

1 forth herein, or acted with reckless disregard for the truth because they failed to
2 ascertain and to disclose such facts, even though such facts were available to them.
3 Such material misrepresentations and omissions were done knowingly or with
4 recklessness, and without a reasonable basis, for the purpose and effect of concealing
5 the truth about neratinib and the results of the ExteNET trial. By concealing these
6 material facts from investors, Puma's share price was artificially inflated during the
7 Class Period.

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

15 101. Plaintiff and the Class have suffered damages in that, in reliance on the
16 integrity of the market, they paid artificially inflated prices for Puma common stock.
17 Plaintiff and the Class would not have purchased Puma common stock at the prices
18 they paid, or at all, if they had been aware that the market prices had been artificially
19 and falsely inflated by Defendants' misleading statements and omissions.

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

23 **COUNT II**

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

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

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

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

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

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

12 **JURY DEMAND**

13 Plaintiff hereby demands a trial by jury.

14 DATED: October 16, 2015

ROBBINS GELLER RUDMAN
& DOWD LLP
TOR GRONBORG
TRIG R. SMITH

17 s/ TRIG R. SMITH

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CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2015, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on October 16, 2015.

s/ TRIG R. SMITH
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- (No manual recipients)