

1 LATHAM & WATKINS LLP
Michele D. Johnson (Bar No. 198298)
2 *michele.johnson@lw.com*
Kristin N. Murphy (Bar No. 268285)
3 *kristin.murphy@lw.com*
650 Town Center Drive, 20th Floor
4 Costa Mesa, CA 92626-1925
Tel: (714) 540-1235
5 Fax: (714) 755-8290

**FILED UNDER SEAL
PURSUANT TO
ORDER
OF THE COURT
DATED
JULY 12, 2018**

6 LATHAM & WATKINS LLP
Colleen C. Smith (Bar No. 231216)
7 *colleen.smith@lw.com*
12670 High Bluff Drive
8 San Diego, CA 92130-3086
Tel: (858) 523-5400
9 Fax: (858) 523-5450

10 LATHAM & WATKINS LLP
Andrew Clubok (*pro hac vice*)
11 *andrew.clubok@lw.com*
Sarah A. Tomkowiak (*pro hac vice*)
12 *sarah.tomkowiak@lw.com*
555 Eleventh Street NW, Suite 1000
13 Washington, DC 20004-1304
Tel: (202) 637-2200
14 Fax: (202) 637-2201

15 *Additional counsel on signature page*

16 *Attorneys for Defendants*
Puma Biotechnology, Inc., Alan H. Auerbach,
17 *and Charles R. Eyler*

18 UNITED STATES DISTRICT COURT
19 CENTRAL DISTRICT OF CALIFORNIA
20

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

23 Plaintiff,

24 v.

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

27 Defendants.
28

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

**STATEMENT OF
UNCONTROVERTED FACTS AND
CONCLUSIONS OF LAW IN
SUPPORT OF DEFENDANTS'
MOTION FOR SUMMARY
JUDGMENT**

Date: September 24, 2018
Time: 10:00 a.m.
Courtroom: 10D

Trial Date: November 6, 2018

Pursuant to Local Rule 56-1 of the Local Civil Rules for the United States District Court for the Central District of California and Federal Rule of Civil Procedure 56, Defendants Puma Biotechnology Inc. (“Puma”), Alan Auerbach, and Charles Eyler (collectively, “Defendants”) submit this Statement of Uncontroverted Facts and Conclusions of Law (“Statement”) in support of their Motion for Summary Judgment. This Statement sets forth the material facts as to which Defendants contend there is no genuine issue, and is based on the declaration of Kristin N. Murphy and accompanying exhibits; all records and files in this case; and on other and further evidence that the Court may consider at or before the hearing on the motion.

I. UNCONTROVERTED FACTS

UNCONTROVERTED FACT	EVIDENCE
1. Breast cancer is the second-leading cause of cancer deaths among women, and approximately 230,000 new cases are reported each year in the United States.	<ul style="list-style-type: none"> • Plaintiff’s First Amended Complaint (“AC”) ¶ 28 (Dkt. No. 138).
2. HER2+ breast cancers make too much of the human epidermal growth factor receptor-2 (HER2+) protein.	<ul style="list-style-type: none"> • AC ¶ 28 (Dkt. No. 138).
3. Approximately 20-25% of women with breast cancer are HER2+.	<ul style="list-style-type: none"> • Declaration of Kristin N. Murphy (“Murphy Decl.”) Ex. 78 (Puma 2014 Form 10-K (Mar. 2, 2015) at 2 (Dep. Ex. 104)). • AC ¶ 28 (Dkt. No. 138).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
4. HER2+ breast cancers tend to be aggressive and difficult to treat.	<ul style="list-style-type: none"> • AC ¶ 28 (Dkt. No. 138).
5. Puma is a biopharmaceutical company that acquires and develops therapeutics primarily to treat breast cancer.	<ul style="list-style-type: none"> • Declaration of Alan Auerbach (“Auerbach Decl.”) ¶ 3. • AC ¶ 16 (Dkt. No. 138).
6. Alan Auerbach founded Puma in September 2010.	<ul style="list-style-type: none"> • Auerbach Decl., ¶ 2. • AC ¶ 17 (Dkt. No. 138). • Murphy Decl. Ex. 78 (Puma 2014 Form 10-K (Mar. 2, 2015) at F-8, F-15 (Dep. Ex. 104)).
7. Alan Auerbach is Puma’s largest individual stockholder and serves as Puma’s CEO, President, and Chairman.	<ul style="list-style-type: none"> • Auerbach Decl., ¶¶ 2, 4. • AC ¶ 17 (Dkt. No. 138).
8. Mr. Auerbach founded Cougar Biotechnology, Inc. (“Cougar”).	<ul style="list-style-type: none"> • Auerbach Decl., ¶ 5. • AC ¶ 17 (Dkt. No. 138).
9. Alan Auerbach led the development of the drug candidate abiraterone, now known as Zytiga®, while at Cougar.	<ul style="list-style-type: none"> • Auerbach Decl., ¶ 5. • Auerbach Decl. Ex. 188 (Puma 2015 Form DEF 14A (Apr. 30, 2015) at 5).
10. In July 2009, Johnson & Johnson acquired Cougar.	<ul style="list-style-type: none"> • Auerbach Decl., ¶ 6. • AC ¶ 17 (Dkt. No. 138).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
11. Charles Eyler is Puma’s Senior Vice President of Finance and Administration.	<ul style="list-style-type: none"> • AC ¶ 20 (Dkt. No. 138).
12. In August 2011, Puma bought (via a license) the rights to the compound neratinib, now known as the drug Nerlynx®.	<ul style="list-style-type: none"> • AC ¶ 8 (Dkt. No. 138). • Murphy Decl. Ex. 82 (NERLYNX U.S. Food and Drug Administration (“FDA”) Label (PUMA00281830-52)).
13. Neratinib is an irreversible inhibitor that blocks cancers cells’ ability to receive growth signals through the HER2 protein.	<ul style="list-style-type: none"> • AC ¶ 26 (Dkt. No. 138).
14. The main side effect of neratinib is diarrhea.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 82 (NERLYNX FDA Label (PUMA00281830-52) at 8, Table 6). • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -83). • Auerbach Decl. Ex. 212 (April 7, 2014, Puma Biotechnology Conference Call Transcript (PUMA00008915) at -916 (“In the neratinib treated arm of the trial, 39% of the patients experienced grade 3/4 diarrhea. . . .”)). • Murphy Decl. Ex. 48 (I-SPY 2 Trial Results Presentation (PUMA00059372) at -405).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 79 (ODAC Sponsor Briefing Document (PUMA00453097-248) at -114). • Murphy Decl. Ex. 81 (FDA Briefing Document (PUMA00281785-817) at -788).
<p>15. Clinical trials completed after July 22, 2014 have shown that the incidence and severity of diarrhea caused by treatment with neratinib can be reduced through treatment with loperamide, also known as Imodium.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. 176) at 17 (“Grade 3 diarrhea can be reduced to 0-17% with intensive loperamide prophylaxis.”)). • Auerbach Decl. Ex. 196 (Sarah Hurvitz et al., <i>Effects of adding budesonide or colestipol to loperamide prophylaxis on neratinib-associated diarrhea in patients with HER2+ early-stage breast cancer: The CONTROL trial</i>, presented at SABCS on December 7, 2017). • Murphy Decl. Ex. 6 (Chan Tr. 64:24-65:16 (explaining in ExteNET “there had been no specific anti-diarrhea prophylaxis and it was obvious to those of us conducting the trial that diarrhea was likely to be the most common side effect, so prior to [the ASCO presentation] presentation, there were a number of small studies looking at the fact that if one introduced prophylaxis with loperamide, and . . . there was the ability to

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>reduce the severity and the frequency of diarrhea if one treated the patients with prophylaxis”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 106 (July 22, 2014 Investor Teleconference (Dep. Ex. 103) at 5 (“In the current trials that we’re doing, neratinib monotherapy, we’ve been very, very successful in being able to reduce the grade 3 diarrhea rates using the Imodium prophylaxis.”)). • Murphy Decl. Ex. 128 (Ustaris <i>et al.</i>, Effective Management and Prevention of Neratinib-Induced Diarrhea, AMERICAN JOURNAL OF HEMATOLOGY/ ONCOLOGY (November 2015)).
<p>16. The ExteNET Trial was a randomized, double-blind, phase III clinical trial.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 51 (Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -599). • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA0236461) at -61). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -72, -84, -85).
<p>17. Before ExteNET, the standard of care for HER2+ breast cancer patients was</p>	<ul style="list-style-type: none"> • AC ¶ 43 (Dkt. No. 138). • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA0236461) at -501).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>surgery and chemotherapy, followed by “adjuvant” treatment with trastuzumab, also known as Herceptin, for one year.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -98-99). • Murphy Decl. Ex. 32 (Adelson Report at 7-8 (“As of July 2014, there was no adjuvant or extended adjuvant treatment that was proven to produce better outcomes . . . than finishing treatment with 1 year of adjuvant treatment with trastuzumab. Thus, the standard of care for treatment with HER2+ breast cancer was chemotherapy followed by 1 year of treatment with trastuzumab.”)). • Murphy Decl. Ex. 1 (Adelson Tr. 56:12-25 (“Q: I see. But there are certainly thousands of patients like that around the country? A: Yes. Q: Correct? A: Correct. Q: For those thousands of patients who are out there around the country, who have been through chemo and Herceptin and are at the high risk that you recognize, and they now came into your office, there are many of those thousands for which neratinib would be part of an appropriate standard of care in your opinion, correct? A: Considering neratinib would be part of an appropriate standard of care.”)).
<p>18. The ExteNET trial was designed to test neratinib’s efficacy for HER2+ breast</p>	<ul style="list-style-type: none"> • AC ¶¶ 38, 40 (Dkt. No. 138).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>cancer patients after surgery and adjuvant treatment with Herceptin—i.e., in the “extended adjuvant” setting.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -97). • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA0236461) at -484-486). • Murphy Decl. Ex. 44 (Trial Protocol Amendment 7 (PUMA00235382-496) at -424). • Murphy Decl. Ex. 45 (Trial Protocol Amendment 11 (PUMA00126358-442) at -386). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172-256) at -199). • Murphy Decl. Ex. 81 (FDA-ODAC Briefing Document (PUMA00281785) at -797, -816).
<p>19. At the time Part A of the ExteNET trial was conducted, there were no approved drugs available to reduce risk of recurrence for HER2+ breast cancer patients in the extended adjuvant setting.</p>	<ul style="list-style-type: none"> • AC ¶ 40 (Dkt. No. 138). • Murphy Decl. Ex. 81 (FDA-ODAC Briefing Document (PUMA00281785-817) at -789). • Murphy Decl. Ex. 32 (Adelson Report at 7-8, 10 (“As of July 2014, there was no adjuvant or extended adjuvant treatment of HER2+ breast cancer that was proven to produce better outcomes for patients than

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>finishing treatment with 1 year of adjuvant treatment with trastuzumab. . . . As noted, without systemic HER2-directed therapy, HER2+ breast cancer is an aggressive form of the disease and women are at high risk of recurrence.”)).</p>
<p>20. A clinical trial protocol is a document that describes how a clinical trial will be conducted, and is intended to ensure the safety of the trial subjects and integrity of the data collected.</p>	<ul style="list-style-type: none"> • 21 C.F.R. §§ 312, et seq. (Investigational New Drug Application (IND)); 21 C.F.R. § 312.23 (IND Content and Format); 21 C.F.R. § 312.30 (Protocol Amendments). • Murphy Decl. Ex. 43 (Original Protocol (PUMA0236461)). • Murphy Decl. Ex. 34 (Jewell Report ¶¶ 18, 39 (citing and discussing the ExteNET Trial Protocol)).
<p>21. Before the inception of a clinical study on humans, a drug sponsor must submit the clinical trial protocol to the FDA for review as part of an Investigational New Drug Application.</p>	<ul style="list-style-type: none"> • 21 C.F.R. §§ 312, et seq. (Investigational New Drug Application); 21 C.F.R. § 312.23 (IND Content and Format). • Murphy Decl. Ex. 81 (FDA-ODAC Briefing Document (PUMA00281785) at -795 (“Wyeth submitted Study 3004 (ExteNET) to the IND” in 2009)).
<p>22. The clinical trial protocol for the ExteNET trial included a pre-specified objective, referred to as the “primary endpoint.”</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -185).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -597, -599). • Murphy Decl. Ex. 34 (Jewell Report ¶ 39 (“The primary efficacy endpoint was invasive DFS at 2 years after randomization.”)).
<p>23. The primary endpoint of the ExteNET trial was to “compare disease free survival (‘DFS’) of women . . . following trastuzumab in the adjuvant setting, receiving neratinib against that of women receiving placebo.”</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -484, -503, -527). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -185. • AC ¶ 41 (Dkt. No. 138)). • Murphy Decl. Ex. 27 (Wong Tr. (Oct. 27, 2017) 42:2-9 (confirming that “the primary endpoint of the study” is “DFS”)). • Murphy Decl. Ex. 20 (Segal Tr. (Nov. 30, 2017) 51:17-19 (“You can read what’s in the protocol. The primary endpoint is the comparison of DFS between the two treatment arms.”); 123:21-124:8 (testifying that the primary endpoint is the “comparison of DFS between the placebo and neratinib group”)).
<p>24. The trial protocol, together with the statistical analysis plan (“SAP”), pre-specified the</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532). • Murphy Decl. Ex. 51 (ExteNET Statistical

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>statistical methods that would determine whether the ExteNET trial met its primary endpoint.</p>	<p>Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -597).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 12 (Jewell Tr. 52:25-53:7 (“Q. And then you write, ‘Typically, clinical trials, protocol, and/or Statistical Analysis Plan will prespecify a precise analysis for the primary endpoint before patients are enrolled and before any data are examined.’ Do you agree with that? A. Yes. That’s, again, a very broad generalization, but I agree with it”)). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 257:8-25 (stating that Sections 3.1.1 and 9.3.1 of the SAP describe the methodology and evaluation of the primary endpoint)). • Murphy Decl. Ex. 20 (Segal Tr. (Nov. 30, 2017) 51:17-19 (“You can read what’s in the protocol. The primary endpoint is the comparison of DFS between the two treatment arms.”); 71:2-12 (the SAP “says how the primary endpoint will be analyzed”)).
<p>25. Both the original clinical trial protocol for ExteNET, as well as the amended version operative as of July 2014 stated: “The primary endpoint, DFS,</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA001101727) at -232).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>will be analyzed using a 1-sided log-rank test to compare the 2 treatment groups. The statistical significance of the log-rank test will be determined using the stopping boundaries described in the subsection for interim analysis. The hazard ratio and the corresponding 2-sided 95% confidence interval will be estimated using a Cox proportional hazards regression model. The proportion of subjects surviving free of recurrence as defined for DFS will be plotted for each treatment group using the Kaplan-Meier method.”</p>	
<p>26. The logrank test, used to measure the primary endpoint and statistical significance, yields a “p-value.” The lower the p-value, the more statistically significant the result.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532). • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -597). • Murphy Decl. Ex. 12 (Jewell Tr. 61:12-68:2 (stating, in relevant part: “Q: And so p-value would show whether or not your result

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>is statistically significant; is that right? A: If you so choose to use that, yes.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 34 (Jewell Report ¶ 21 (discussing p-value as a measure of statistical significance)). • Murphy Decl. Ex. 13 (Kornak Tr. 89:22-90:5 (“The log rank test[,] p value[,] and Cox proportional hazards model were the a priori defined measure of the primary endpoint.”)). • Murphy Decl. Ex. 37 (Kornak Report ¶¶ 34, 54 (discussing the logrank test for statistical significance)). • Murphy Decl. Ex. 121 (David Kleinbaum and Mitchel Klein, Survival Analysis: A Self-Learning Text 15, 67-73 (3rd ed. 2012) (KORNAK00000532) (discussing log rank test for comparing two treatment groups)). • Murphy Decl. Ex. 122 (Eric Vittinghoff et al., Regression Methods in Biostatistics 210, 60-61 (2nd ed. 2012) (KORNAK00000531) (same)).
<p>27. To achieve a statistically significant positive result, the ExteNET trial had to demonstrate a p-value lower than 0.025.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -533). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA001101727) at -190, -232).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -597, -602-03). • Murphy Decl. Ex. 37 (Kornak Report ¶ 34 (noting the 0.025 significance level “is equivalent to 2-sided testing at the 0.05 level”)).
<p>28. The Cox proportional hazards regression model yields a statistic called a hazard ratio.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532). • Murphy Decl. Ex. 12 (Jewell Tr. 83:10-15 (noting that one measurement of the primary outcome is the Cox proportional hazards model which generates the hazard ratio)). • Murphy Decl. Ex. 37 (Kornak Report ¶¶ 34, 37, 50, 55 (discussing the Cox proportional hazards model, and observing “The Cox proportional hazards model is able to provide estimates of effects via the hazard ratio”)). • Murphy Decl. Ex. 116 (Spruance, Spotswood et al., “Hazard Ratio in Clinical Trials,” <i>Antimicrobial Agents and Chemotherapy</i> 48 (8): 2787–2792, at 2787 (2004) (“The Cox model, a regression method for survival data, provides an estimate of the hazard ratio and its confidence interval.”))

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>(ADELSON0000052-57)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 129 (Arlene Chan et al., <i>Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): a multicenter, randomized, double-blind, placebo-controlled phase 3 trial</i>, <i>Lancet Oncology</i>, 4 (Feb. 10, 2016) (PUMA00232538-548) (Dep. Ex. 516) at -521).
<p>29. The hazard ratio quantifies the difference in risk of cancer recurrence between the placebo and treatment groups over time.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 34 (Jewell Report ¶ 28 (stating that a hazard ratio that “compares the hazard rates in two or more groups of a clinical trial – by dividing one by the other – provides a relative comparison that may vary by time”)). • Murphy Decl. Ex. 37 (Kornak Report ¶ 11 (“the [hazard ratio] takes into account all events over a specified period of time and is not highly susceptible to random fluctuations in events that may occur at any point(s) in time”); ¶ 34 (“estimated hazard ratio for a treatment effect from the Cox proportional hazards model is used to describe the size of the difference in DFS rates” for the measured period)). • Murphy Decl. Ex. 116 (Spruance,

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>Spotswood et al., “Hazard Ratio in Clinical Trials,” <i>Antimicrobial Agents and Chemotherapy</i> 48 (8): 2787–2792 (2004) (ADELSON0000052-57) (“The hazard ratio is an estimate of the ratio of the hazard rate in the treated versus the control group. The hazard rate is the probability that if the event in question has not already occurred, it will occur in the next time interval, divided by the length of that interval. The time interval is made very short, so that in effect the hazard rate represents an instantaneous rate. An assumption of proportional hazards regression is that the hazard ratio is constant over time. Thus, in a clinical trial where disease resolution is the endpoint, the hazard ratio indicates the relative likelihood of disease resolution in treated versus control subjects at any given point in time.”)).</p>
<p>30. A hazard ratio of less than one means that the risk of death—or in the case of ExteNET, disease recurrence—is lower in the treatment group than the control group.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -504, -533). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA001101727) at -190, -232). • Murphy Decl. Ex. 35 (Lavin Report ¶ 23

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>(“In general, the HR is favorable when HR<1 and is unfavorable when HR>1.”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 34 (Jewell Report ¶ 28 (explaining “an HR of <1 indicates a consistently reduced mortality rate in a specific group at all times”)). • Murphy Decl. Ex. 37 (Kornak Report ¶ 43 (“A HR of 1.0 corresponds to no difference in risk between the treatment groups. A hazard ratio of 0.67 is a relative reduction in risk at any point in time that directly translates into a 33 percent improvement in DFS or reduction in risk.”)). • Murphy Decl. Ex. 32 (Adelson Report at 11 (“A hazard ratio of 1 means there is no difference between the groups; a hazard ratio of less than 1 means the intervention group fared better than the placebo group. A hazard ratio of greater than 1 would mean the intervention group did worse than placebo group.”)).
<p>31. In order to achieve its primary endpoint, ExteNET had to show a hazard ratio of less than 1 and a p-value of less than 0.025.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -533). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA001101727) at -190, -232).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -597, -602-03).
<p>32. Kaplan Meier curves provide a graphical depiction of the estimate of patients in each group who remain disease free at particular points in time.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -532). • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -597, -602, -603, -619 (“Kaplan-Meier Methods will be used to graphically display DFS curves”)). • Murphy Decl. Ex. 35 (Lavin Report ¶¶ 21-22 (“the KM Lifetable is the primary graphical depiction of estimates of time to events for patients”)). • Murphy Decl. Ex. 34 (Jewell Report ¶ 31 (“The Kaplan-Meier estimated survival curve is usually presented graphically by plotting estimated percentage of patients who are still event free at a specified point in time against time.”)). • Murphy Decl. Ex. 19 (Puma 30(b)(6) (Segal) Tr. (Aug. 30, 2017) 166:1-9 (agreeing with the statement that the hazard ratio “measures the difference in risk between two groups from the beginning of randomization till the end of the study; right? I mean, it’s a

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>measurement of difference between the Kaplan-Meier curve along the entire time containment.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 12 (Jewell Tr. 59:18-60:16 (agreeing with the statement that “a Kaplan-Meier curve is a graphical representation of the estimated percentage of patients who are still alive up to a specified point in time.”)). • Murphy Decl. Ex. 37 (Kornak Report ¶ 34 (“Kaplan-Meier curve estimates provide visual descriptions of the raw data”)).
<p>33. In the ExteNET trial, Kaplan Meier curves were not used to measure whether any observed difference between patient groups is statistically significant.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -532 (noting that the “Kaplan-Meier method will be used to graphically depict the proportion of subjects remaining free of disease recurrence” at particular points in time)). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -232 (same)). • Murphy Decl. Ex. 12 (Jewell Tr. 133:9-134:15 (explaining “Puma chose” to measure statistical significance with log-rank test not Kaplan-Meier curves)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 14 (Lavin Tr. 57:9-21 (“Kaplan-Meier curve is a methodology for constructing alive over at-risk. It’s not comparative. It’s strictly intended to be a constructive technique for indicating the probability of remaining event-free over the follow-up interval of the study.”)). • Murphy Decl. Ex. 37 (Kornak Report ¶ 34 (“Kaplan-Meier curve estimates provide visual descriptions of the raw data, but are not proposed to be used directly to estimate survival differences or determine whether there is a statistically significant difference in DFS between the two groups.”)).
<p>34. The ExteNET trial was designed to analyze the efficacy of neratinib in three parts: disease-free survival at two years (Part A), disease-free survival at five years (Part B), and “overall survival” (Part C).</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -532). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -85-86). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 118:18-119:10 (“So Part A was, you know here, here are the data for the study for subjects whose last visit was two years that continued to be on the study up through October. Then Part B was re-consenting patients because the protocol for the study was that they were only to be followed for the

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>two years plus 28 days. So the idea was perhaps before they were completely off study to re-consent them so that you had that follow-up thereafter. So that was Part B. And I think Part C is the overall survival aspect of the study.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 19 (Puma 30(b)(6) (Segal) Tr. (Aug. 30, 2017) 62:7-63:16 (confirming that Part A contained “the top line results” and “the primary endpoint”; Part B “had to do with extended DFS measurements”; and Part C “was the overall survivability”)).
<p>35. On July 7, 2014, the clinical trial database for Part A of the ExteNET trial was locked for analysis.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 110:8-17 (noting that the database lock occurred on July 7 2014)). • Murphy Decl. Ex. 52 (July 8, 2014 email re: Database soft lock official!!! (PUMA00239122) at -23).
<p>36. On July 7, 2014, Dr. Sherman and Rho each received a database snapshot containing all patient data collected as of October 2013, and the randomization code, which specified which patients received neratinib and placebo.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 89 (July 7, 2014 email re: 3004 uncoded data extract (07Jul14) (RHO0010620)). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 113:10-11 (“So with regard to the last patient visit, last visit in October [2013],

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	that was all the data for two years”); 262:8-263:5 (same)).
<p>37. The July 7, 2014 database snapshot contained data for some patients who had been followed for more than two years.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 83 (ExteNET Trial July 7, 2014 Snapshot Kaplan-Meier Curves (PUMA00539366)). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 262:12-263:5 (explaining patients would have had data “for more than three years”); 264:3-6 (“Q. Were there patients included in that data snapshot for whom Puma had information extending up to or through three years of follow-up? A. Yes.”)). • Murphy Decl. Ex. 14 (Lavin Tr. 85:14-86:10 (“We also saw from the database which we received that there were eight additional events observes [sic] following month 25.”); 145:9-148:8 (explaining analysis of those events showed 2.7% absolute difference in DFS rates at three years)).
<p>38. Puma and Rho separately analyzed the efficacy data.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 7 (Clark Tr. 14:11-18 (“My role for Puma was to help validate some of their efficacy analysis.”); 21:16-25 (“I was contracted as part of Rho to create a set of validation programs for their efficacy analyses, both for their analysis datasets and any displays associated with them.”); 35:7-

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>36:16 (detailing the analysis of results); 61:18-62:8 (same); 67:23-70:5 (same)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 16 (Rho 30(b)(6) (Pate) Tr. 45:1-46:21 (“Puma’s independent” and “planned to match the same numbers in our tables when they do it on their end . . . Puma is doing their independent work and they are determining that their results match ours.”)). • Murphy Decl. Ex. 53 (July 11, 2014 email re: File Request - Study 3004 - Efficacy analyses (PUMA0066288)). • Murphy Decl. Ex. 90 (July 11, 2014 email re: File Request - Study 3004 - Efficacy analyses (RHO0010770)).
<p>39. Dr. Sherman prepared a document reflecting the ExteNET efficacy results titled “Topline Efficacy Analyses—Part A.”</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 56 (Topline Efficacy Analyses—Part A, (PUMA00014625-56)). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 22:15-19 (“Q. And was part of your job at Puma the provision of top-line reports of study results that would include the ExteNET trial top-line results in July of 2014; correct? A. That’s correct.”)).
<p>40. On July 17, 2014, the “Topline Efficacy Analyses—Part A” was sent to Alan Auerbach and others at Puma.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 56 (Topline Efficacy Analyses—Part A, (PUMA00014625-56)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>41. The “Topline Efficacy Analyses—Part A” report reflected the results of the primary, secondary, and exploratory efficacy endpoints specified in the ExteNET SAP and trial protocol.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 56 (Topline Efficacy Analyses—Part A, (PUMA00014625-14656)). • Murphy Decl. Ex. At 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -603, -610-11). • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -190, -232).
<p>42. The “Topline Efficacy Analyses—Part A” report showed that the ExteNET trial met its primary endpoint.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 56 (Topline Efficacy Analyses—Part A, (PUMA00014625-14656)). • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -190, -232). • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -603, -610-11). • Murphy Decl. Ex. 20 (Segal Tr. (Nov. 30, 2017) 50:21-23 (“[W]ith regards to the ExteNET study, the key piece of data for the efficacy results of the study was the hazard

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>ratio and the p-value.”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 66:1-67:18 (identifying the primary endpoint in the Topline Efficacy Analyses report)).
<p>43. The “Topline Efficacy Analyses—Part A” report reflected a p-value for the primary, intent-to-treat (“ITT”) study population of 0.0046, which demonstrates a statistically significant difference in DFS between patients taking neratinib and patients taking placebo.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 56 (Topline Efficacy Analyses-Part A, (PUMA00014625-14656) at -648). • Murphy Decl. Ex. 43 (Original Trial Protocol (PUMA00236461) at -489, -532-33). • Murphy Decl. Ex. 46 (Trial Protocol Amendment 13 (PUMA00110172) at -190, -232). • Murphy Decl. Ex. 51 (ExteNET Statistical Analysis Plan (PUMA00122587) (Dep. Ex. 129) at -602-03, -610-11). • Murphy Decl. Ex. 37 (Kornak Report ¶ 37 (“The 1-sided p-value was 0.0046, indicating that the primary endpoint would have been met even if the 1-sided test had been performed at the 0.005 level or a 2-sided test at the 0.01 level. This implies very strong evidence in the dataset for a treatment effect, way beyond the level of evidence that was set <i>a priori</i> as being adequate to conclude a statistically significant treatment effect.”)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 35 (Lavin Report ¶ 20) (discussing ExteNET study results and p-value). • Murphy Decl. Ex. 14 (Lavin Tr. 29:22-30:1 (explaining that he reconstructed the trial database and reproduced analyses); Tr. 32:2-12 (“we were successful at reconstructing the life tables and the hazard ratio and the p-value that were reported by Clair[e Sherman].”)).
<p>44. The “Topline Efficacy Analyses—Part A” report reflected a hazard ratio over two years (and 28 days) for the ITT population of 0.67.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 56 (Topline Efficacy Analyses—Part A, (PUMA00014625-14656) at -654-56). • Murphy Decl. Ex. 14 (Lavin Tr. 29:22-30:1 (explaining that he reconstructed the trial database and reproduced analyses); 32:2-12 (“we were successful at reconstructing the life tables and the hazard ratio and the p-value that were reported by Clair[e Sherman].”); Tr. 169:20-170:7 (“We saw that the study had a 0.67 hazard ratio”); 171:7-172:8 (“[I]f someone were to ask me concretely is that the way -- if you ran the analysis, did you produce a 0.67 hazard ratio when I ran the same programs as Puma then yes, I did get that same number”)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>45. A hazard ratio of 0.67 is equivalent to a 33% reduction in risk of disease recurrence in the treatment group as compared to the placebo group.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 59 (July 22, 2014 Puma Press Release (Dep. Ex. 102)). • Murphy Decl. Ex. 12 (Jewell Tr. 145:18-22 (“Q: So your – your interpretation of the hazard ratio is that it reduces the risk of disease reoccurrence in the entire population by 33 percent? A: On average, yes.”)). • Murphy Decl. Ex. 24 (Werber Tr. 112:23-25 (“Given that the drug showed a hazard ratio of .67, it shows a 33 percent improvement in DFS.”)). • Murphy Decl. Ex. 135 (Pl.’s Am. Response to Interrogatory No. 27 (0.67 hazard ratio “would translate into a 33% relative reduction in the risk of disease recurrence”)).
<p>46. A 33% reduction in risk of disease recurrence is equivalent to a 33% relative improvement in disease free survival in the treatment group as compared to the placebo group.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 37 (Kornak Report ¶¶ 27, 44 (“a reduction in risk and an improvement in DFS are the same thing”)). • Murphy Decl. Ex. 6 (Chan Tr. 56:18-20 (Q: And is it accurate to describe the 0.67 hazard ratio as a 33% improvement in disease-free survival? A: It is.)). • Murphy Decl. Ex. 32 (Adelson Report at 11 (“The percent improvement in survival is 1 minus the hazard ratio – that is, a hazard ratio

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	of 0.75 translates into a 25% improvement.”)).
<p>47. A 33% improvement in DFS means that for every patient who would have experienced a recurrence within two-years, approximately one in three of those patients would remain disease-free if treated with neratinib.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 12 (Jewell Tr. 148:4-17 (confirming “[t]he 9 percent who, under placebo, would have experienced an event, on average . . . that number would be reduced by approximately a third”)). • Murphy Decl. Ex. 37 (Kornak Report ¶ 46 (“The trial results of an estimated 33 percent improvement in DFS (or relative reduction in hazard) over two years means that close to one in three patients that would have had breast cancer recurrence within 2 years will avoid the recurrence of this deadly disease.”)).
<p>48. On July 15, 2014, Puma received topline safety tables that had been generated and validated by Rho.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 91 (July 15, 2014 email re: 3004 (RHO0011035-036) (Dep. Ex. 132)). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 190:4-15 (confirming that Sherman received the safety tables from Kevin Clark at Rho, Inc., on July 15, 2014). • Murphy Decl. Ex. 27 (Wong Tr. (Oct. 27, 2017) 35:8-13 (Q: Okay. Do you recall approximately when you received these tables from Rho in relations to sending them to the executives? A: I don’t recall. Q: Okay. Does July 15th sound about right? A:

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	Yeah.”).
<p>49. The topline safety tables included information regarding ExteNET patients’ safety experience, including information regarding adverse events such as diarrhea.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 57 (July 18, 2014 email re: Topline Analysis – 3004 (PUMA00014833-15081) (Dep. Ex. 124)).
<p>50. For the ExteNET trial, Puma’s plan was to complete an internal validation process to check the results it received from its outside clinical research organization, Rho.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 103:9-111:4 (describing Puma’s practice for validation); 273:20-275:22 (describing reasons for validating all tables provided by Rho)). • Murphy Decl. Ex. 19 (Puma 30(b)(6) (Segal) Tr. (Aug. 30, 2017) 34:3-18 (“And from a statistician's perspective, ‘validation’ means that we have programmed it all in-house and that our numbers match what Rho produced.”); 125:8-10 (“[T]he plan was that we would internally validate everything that Rho sent us.”); 122:18-123:6 (“The tables before Rho sends them to Puma . . . they are internally validated at Rho. They go through their processes, whether it’s code walk-through, double program, any different means of validation, and they bless them and say they’re validated, and then Kevin sent them to

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>Claire because that’s the only means to get them to Puma. Rho has one point of contact, and it was sent to Claire. And it was part of, you know, whatever the contract was with Rho as to what they would send when. Once Puma received the tables, it was then on us to do our internal validation of safety. And there are other documents that will indicate that our timeline was actually through January 30th, 2015, to complete that validation.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 16 (Rho 30(b)(6) (Pate) Tr. 45:15-46:21 (“Puma’s independent” and “planned to match the same numbers in our tables when they do it on their end. . . .Puma is doing their independent work and they are determining that their results match ours.”); 69:10-12 (“Rho is producing the validation displays and . . . the final validation would occur at Puma.”)).
<p>51. As of July 22, 2014, Puma had not yet internally validated the safety results of the ExteNET trial.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 19 (Puma 30(b)(6) (Segal) Tr. (Aug. 30, 2017) 79:18-20 (“The validation of the efficacy results in July was separate from the validation of the safety result that took place through the beginning of 2015.”)). • Murphy Decl. Ex. 7 (Clark Tr. 99:10-

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>102:11 (discussing an email from Dr. Sherman to Kevin Clark in which she states that “she is still looking at the safety and ha[d] not had a chance to fully check all the numbers”); 107:7-108:5 (noting that Clark would have expected to hear from Dr. Sherman had she validated the safety tables)).</p> <ul style="list-style-type: none">• Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 189:23-193:5 (stating, in part: “Q: Did you tell [Rho] before [July] 18th whether you saw anything amiss [with the safety tables]? A: No, because I don’t think I got around to actually checking them. I mean, I eyeballed them, but that’s not sufficient for me. So I generally do additional programming to make sure that everything lines up so it was left up to me to deal with all of the validation of the results from the programming that Rho had done.”); 268:1-269:13 (confirming Puma had not “validated one top-line safety tables as of July 14, 2014”); 271:9-19 (noting sometime in “September there were differences amongst the safety tables provided by Rho and what I had put together for validation”)).• Murphy Decl. Ex. 60 (August 19, 2014 email re: Study 3004 (PUMA00070561)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>(noting “We are currently working on validating some of the safety tables that were provided a few weeks ago.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 61 (August 19, 2014 email re: Patient profiles for legacy and new studies for safety narratives (PUMA00073174) (noting preliminary diarrhea statistics that had not been validated)). • Murphy Decl. Ex. 71 (January 30, 2015 email re: Puma 3004 Safety and QOL (PUMA00085292) at -293-94 (detailing final validation of safety results)).
<p>52. Puma did not begin its own validation of the top-line safety tables until August 2014.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 60 (August 19, 2014 email re: Study 3004 (PUMA00070561) (noting “We are currently working on validating some of the safety tables that were provided a few weeks ago.”)). • Murphy Decl. Ex. 61 (August 19, 2014 email re: Patient profiles for legacy and new studies for safety narratives (PUMA00073174) (noting preliminary diarrhea statistics that had not been validated)). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 192:18-192:22 (“I don’t think I got

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>around to actually checking [the safety tables]. I mean, I eyeballed them, but that’s not sufficient for me. So I generally do additional programming to make sure that everything lines up.”); 223:15-226:9 (“I would have done the validation [of the safety tables] and I hadn’t.”); 269:8-13 (“And then the safety validation that occurred at Puma sometime August/September [2014]”).</p>
<p>53. Puma’s biostatisticians identified errors in Rho’s topline safety tables, including that Rho had not employed the correct definition for treatment emergent adverse events.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 62 (September 24, 2014 email re: Treatment Emergent AEs (PUMA00073740) (Depo. Ex. 293)). • Murphy Decl. Ex. 63 (September 2014 email exchange re: Treatment Emergent AEs (PUMA00073780) at -82 (“We are also working on incorporating updated TEAE definition into 3004 safety datasets and displays. We will send you the updated topline AE table to validate, before we rerun all safety displays.”)). • Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 246:5-21 (“What I do know is that the definition for treatment emergent adverse events had been modified, so the statistical analysis plan that I had written or had amended, I used the standard definition for all

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>Puma clinical trials.”); 271:15-272:10 (confirming that she identified errors in the validation process, and “and one was the definition of treatment emergent adverse event, which was different between what Rho had programmed when the sponsor was Wyeth and Pfizer versus Puma.”); 273:3-10 (Is treatment emergent adverse event something that's included in the top-line safety tables? A.: Yes. Q.: So if there was a change in the definition of treatment emergent adverse event, you would have to rerun the top-line safety tables; isn't that right? A. That's right.”)).</p> <ul style="list-style-type: none">• Murphy Decl. Ex. 16 (Rho 30(b)(6) (Pate) Tr. 98:16-99:6 (Q. . . . did anyone from Puma ever tell you that any of the numbers in the [topline safety tables] were incorrect? A. Yes, but not as directly as you’re addressing me at this point. Throughout the fall, Rho and Puma continued with the safety outputs and changes were made, and the final CSR outputs were not provided from Rho to Puma until January of 2015. So, yes, these numbers were not correct [in the topline tables] because changes were required . . . We had to modify the definition or the programming for

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	the definition of treatment emergent adverse event[s]. . . And we modified the denominator in one of the [topline] tables.”)).
54. Puma completed its validation of the ExteNET trial safety results on January 30, 2015.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 71 (January 30, 2015 email re: Puma 3004 Safety and QOL (PUMA00085292) at -293-94). • Murphy Decl. Ex. 72 (Feb. 2, 2015 email re: 3004 Rho deliverables as of Jan 30, 2015 (PUMA00256848)). • Murphy Decl. Ex. 20 (Segal Tr. (Nov. 30, 2017) 16:14-20 (explaining that results were not validated by September 24, 2014)). • Murphy Decl. Ex. 19 (Puma 30(b)(6) (Segal) Tr. (Aug. 30, 2017) 122:10-123:6 (explaining validation process was not complete until January 30, 2015); 144:11-19 (“The final validation occurred or was completed by January 30th [2015], and at that point all the safety tables were regenerated”)). • Murphy Decl. Ex. 16 (Rho 30(b)(6) (Pate) Tr. 98:16-99:3 (“Throughout the fall [of 2014], Rho and Puma continued with the safety outputs and changes were made, and the final CSR outputs were not provided from Rho to Puma until January of 2015.”); 101:3-14 (discussing how the safety data changed

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	and were not validated until “late January 2015”).
<p>55. On July 22, 2014, Puma issued a press release that announced “Positive Top Line Results” from the ExteNET Trial with the headline, “Neratinib Achieves Statistically Significant Difference in Disease-Free Survival.”</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 59 (Puma July 22, 2014 Puma Press Release (Dep. Ex. 102)).
<p>56. Press releases issued by some other oncology-focused biotechnology companies have disclosed achievement of the primary endpoint, the hazard ratio, and p-value, without also disclosing DFS rates or the difference in DFS rates.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 161 (Press Release “Phase III APHINITY study shows Roche’s Perjeta® regimen helped people with an aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy,” March 2, 2017 (https://www.roche.com/media/releases/med-cor-2017-03-02.htm)). • Murphy Decl. Ex. 153 (Press Release, “Novartis reports positive results from Phase III trial of Kisqali® (ribociclib) combination therapy in premenopausal women with HR+/HER2- advanced or metastatic breast cancer,” November 8, 2017 (FRYKMAN00002554)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> <li data-bbox="816 247 1507 604">• Murphy Decl. Ex. 154 (Press Release, “Exelixis’ Phase 3 CELESTIAL Trial of Cabozantinib Meets Primary Endpoint of Overall Survival in Patients with Advanced Hepatocellular Carcinoma,” October 16, 2017 (FRYKMAN00002523)). <li data-bbox="816 625 1507 1045">• Murphy Decl. Ex. 155 (Press Release, “Karyopharm Announces Successful Outcome from Phase 2 Portion of Phase 2/3 SEAL Study Evaluating Selinexor in Patients with Previously Treated Advanced Dedifferentiated Liposarcoma,” September 20, 2017 (FRYKMAN00001063)). <li data-bbox="816 1066 1507 1486">• Murphy Decl. Ex. 156 (Press Release, “Exelixis Announces Positive Top-Line Results from METEOR, the Phase 3 Pivotal Trial of Cabozantinib versus Everolimus in Patients with Metastatic Renal Cell Carcinoma,” July 20, 2015 (FRYKMAN00001131)). <li data-bbox="816 1507 1507 1927">• Murphy Decl. Ex. 157 (Press Release, “Takeda and Seattle Genetics Report Positive Phase 3 ALCANZA Clinical Trial Data of ADCETRIS® (Brentuximab Vedotin) for CD30-Expressing Cutaneous T-Cell Lymphoma,” December 3, 2016 (FRYKMAN00001647)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 158 (Press Release, “Lilly Announces CYRAMZA™ Phase III Second-Line Colorectal Cancer Trial Meets Primary Endpoint of Overall Survival,” September 12, 2014 (FRYKMAN00001448)). • Murphy Decl. Ex. 159 (Press Release, “Abraxane Demonstrates Statistically Significant Improvement in Overall Survival for Patients with Advanced Pancreatic Cancer In Phase III Study,” November 9, 2012 (FRYKMAN00001456)). • Murphy Decl. Ex. 160 (Press Release, “Arqule Announces Tivantinib Meets Primary Endpoint, Significantly Extending Time to Progression in Phase 2 Trial in Second- Line Hepatocellular Carcinoma,” January 17, 2012 (FRYKMAN00001453)).
<p>57. Limiting the amount of information Puma disclosed in the press release announcing ExteNET results preserved Puma’s ability to present the full data later in a medical conference.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 59 (Puma July 22, 2014 Puma Press Release (Dep. Ex. 102)). • Murphy Decl. Ex. 106 (Puma July 22, 2014 Investor Teleconference (Dep. Ex. 103) at 4 (“Puma plans to present the full results of ExteNET study at a future scientific conference.”); <i>id.</i> at 8 (“So I don’t want to comment too much on the data, Howard,

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>because I don't want to jeopardize it being presented.”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 2 (Auerbach Tr. (Jan. 28, 2018) 35:7-11 (“If you just announce [clinical trial results] to announce them, you are going to shut yourself out of medical conferences, which is a very, very, very important aspect of the scientific and medical validation of the industry); 43:4-10 (noting Mr. Auerbach’s concern that Puma “did not want to jeopardize [ExteNET] being presented at ASCO or any other medical conference”); 80:24-81:3 (“If we had disclosed any more information than that, we would not have been able to get into the ASCO meeting or any other medical meeting, and that would have been serious damage to the investors.”); 294:24-295:1 (“If we put in the DFS rates or delta, you were crossing the line into a medical conference would say you’ve already presented this data.”); 323:24-324:1 (“We can’t disclose too much information because if we do, we have the risk of being thrown out of a medical conference.”)). • Murphy Decl. Ex. 27 (Wong Tr. 207:2-9 (Oct. 27, 2017) (“In my experience, [the Press Release] is exactly up to par with other press

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>releases that I’ve seen” that “disclosed top-line results of clinical trials.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 5 (Bryce Tr. 168:20-170:14 (discussing why it was not misleading to omit certain information in the Press Release)). • Murphy Decl. Ex. 29 (Yao Tr. 228:12-230:6 (“[M]ost companies would like to be able to highlight their data at these presentations. And not only just to highlight – because there will be different categories; there will be the most desired plenary session, there will be an [oral] presentation, and there will be posters. Of course, plenary session would be the most desirable. So my experience was that if a company, in a press release, disclosed data deemed by ASCO as being too much, the company would likely not get a spot in some of the desirable presentations, like plenary or even some of the oral presentations [W]e want to restrict the data, make it confidential, so the results doesn’t -- so the results do not go out in the public domain that would jeopardize some of these opportunities.”)). • Murphy Decl. Ex. 25 (Wilson Tr. 253:11-255:3 (explaining that if you violate

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>confidentiality policy, “You’re not going to get the opportunity to publicize the drug at the inter- -- the largest international oncology conference.”)).</p> <ul style="list-style-type: none">• Murphy Decl. Ex. 8 (Drynan Tr. 85:21-86:24 (“Q. In your experience, is there a typical time frame in which a company will release the full results of a clinical trial after announcing the top line results? . . . THE WITNESS: There’s not a typical time frame. One of the challenges, if you’re a biopharmaceutical company, you would have a press release that is top line data, but you cannot actually give the full data out in the press release, or you will not be able to present the data at the medical meeting. So the answer is not – there’s not a typical time frame, because it would depend on what the rules were for that particular meeting in terms of timing for acceptance, when is the next medical meeting. . . Q. [] So your expectation of when the full trial results would be disclosed might depend on when the next major medical conference was. Is that fair? A. Correct. And the timing criteria that is required for that medical meeting organization. Q. Because presenting too

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>many details could jeopardize your ability to present at the medical conference? . . . THE WITNESS: Absolutely.”)).</p>
<p>58. Medical conference presentations provide a platform for drug companies to educate doctors regarding the benefits and potential uses of a particular drug.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 2 (Auerbach Tr. (Jan. 28, 2018) 35:1-36:7 (describing medical conferences as “a very, very, very important aspect of the scientific and medical validation of the industry”); 80:24-81:3 (“If we had disclosed any more information than that, we would not have been able to get into the ASCO meeting or any other medical meeting, and that would have been serious damage to the investors.”)). • Murphy Decl. Ex. 8 (Drynan Tr. 134:24-135:11 (“I mean, ASCO is always important to communicate with doctors” and scientific meetings “are always important.”)). • Murphy Decl. Ex. 5 (Bryce Tr. 106:15-107:5 (describing audience at ASCO as “30,000 oncologists, practicing oncologists or cancer researchers”); 105:2-19 (explaining Puma wanted to be “a plenary presentation is the main oral presentation in the mail hall. It’s basically the highlight, the highlight act . . . because I believe this is practice changing

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>data, and that we should make it as impactful as it deserves to be.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 29 (Yao Tr. 229:10-230:4 (“[M]ost companies would like to be able to highlight their data at these presentations. And not only just to highlight – because there will be different categories; there will be the most desired plenary session, there will be an [oral] presentation, and there will be posters. Of course, plenary session would be the most desirable. So my experience was that if a company, in a press release, disclosed data deemed by ASCO as being too much, the company would likely not get a spot in some of the desirable presentations, like plenary or even some of the oral presentations [W]e want to restrict the data, make it confidential, so the results doesn’t -- so the results do not go out in the public domain that would jeopardize some of these opportunities.”)). • Murphy Decl. Ex. 6 (Chan Tr. 51:16-52:8 (“It was important information that should be presented at a major medical oncology meeting, and that was the most appropriate one” because it was “practice changing”)). • Murphy Decl. Ex. 25 (Wilson Tr. 68:7-

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>69:17 (explaining companies “hope” to present at ASCO because “[i]t’s going to get the greatest visibility there”); 253:11-255:3 (explaining that if you violate confidentiality policy, “You’re not going to get the opportunity to publicize the drug at the inter- - the largest international oncology conference.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 1 (Adelson Tr. 39:8-15 (noting Dr. Adelson first heard about neratinib at a scientific conference)). • Murphy Decl. Ex. 18 (Schwab Tr. 53:16-54:4 (learned about neratinib at a scientific conference)). • Murphy Decl. Ex. 38 (Frykman Amended Report at 9-12).
<p>59. The ASCO annual conference participation requirements include confidentiality restrictions, which state that, “for a study to be eligible . . . information contained in the abstract and to be presented about the study at the ASCO meeting must not be disclosed” prior to the ASCO annual conference.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 94 (<i>Confidentiality Policy, 2015 ASCO Annual Meeting</i> (HsuvPumaASCO_000004020-23) (Dep. Ex. 116) (“For a study to be eligible for acceptance into an ASCO Meeting, information contained in the abstract, as well as additional data and information to be presented about the study at the ASCO Meeting, must not be disclosed before the findings have been publicly released in

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>conjunction with the ASCO Meeting. If information from the abstract or additional study data are disclosed in advance of public release in conjunction with an ASCO Meeting, the abstract will be subject to rejection or removal unless an official Confidentiality Policy Exception Applies.”)).</p>
<p>60. Violating ASCO’s Confidentiality Policy could result in a submission being rejected for presentation, or, if already accepted, removed from being presented at the conference.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 94 (<i>Confidentiality Policy</i>, 2015 ASCO Annual Meeting (HsuvPumaASCO_000004020-23) (Dep. Ex. 116)). • Murphy Decl. Ex. 23 (ASCO 30(b)(6) (Von Roenn) Tr. 52:1-53:17 (“Q: What are the consequences of a violation of the confidentiality policy? A: So there aren’t specific consequences, though as is noted in the abstract submitter, at any time ASCO has the choice to position an abstract differently because it may not be felt to be as much in need of peer review if it’s already been presented elsewhere, and it can be pulled from the meeting. If it’s already been presented, that already breaks -- it breaks the policy and it’s not necessarily of value to the audience. Q: So it’s fair to say that violating the confidentiality policy could jeopardize a

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>presenter’s ability to present at ASCO? A: Yes.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 29 (Yao Tr. 229:10-230:4 (“So my experience was that if a company, in a press release, disclosed data deemed by ASCO as being too much, the company would likely not get a spot in some of the desirable presentations, like plenary or even some of the oral presentations [W]e want to restrict the data, make it confidential, so the results doesn’t -- so the results do not go out in the public domain that would jeopardize some of these opportunities.”); 88:22-89:8 (noting that Yao would “[a]bsolutely not” disclose the Kaplan-Meier curve prior to a scientific conference)). • Murphy Decl. Ex. 8 (Drynan Tr. 85:21-86:24 (“One of the challenges, if you’re a biopharmaceutical company, you would have a press release that is top line data, but you cannot actually give the full data out in the press release, or you will not be able to present the data at the medical meeting.)). • Murphy Decl. Ex. 2 (Auerbach Tr. (Jan. 28, 2018) 34:19-36:7 (explaining “[w]hen it comes to clinical trial data, we have to be very careful because the more you disclose,

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>the less chance you have that it can be presented at a medical conference” and, “if you don’t [present at a medical conference], you have done significant harm to your company and significant harm to your shareholders”); 41:14-23 (“Our main concern was we had had a Phase 3 trial that had the opportunity to be presented at a major medical conference. That’s very, very important, scientific and medical validation in this industry. When you present at any medical conference, you have to check a box that says, ‘We did not present all of this data publicly, it has never been published before, it is not available in the public forum.’”); 80:10-81:3 (“The material nonpublic information was whether or not the trial hit its primary endpoint or did not hit its primary endpoint. If we had disclosed any more information than that, we would not have been able to get into the ASCO meeting or any other medical meeting, and that would have been serious damage to the investors.”); 295:2-22 (explaining ASCO usually asks for any public disclosures regarding the trial); 323:4-324:25 (“We can’t disclose too much information because if we do, we have the</p>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>risk of being thrown out of a medical conference.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 150:14-18 (noting that, if information was leaked prior to ASCO, it could jeopardize the oral presentation); 276:19-277:1 (same)).
<p>61. There have been occasions when ASCO has removed a presentation from its conference program because the presenter or sponsor had disclosed too much of the data in advance of the meeting.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 23 (ASCO 30(b)(6) (Von Roenn) Tr. 52:18-53:2 (“Q: The situation where you described where you position an abstract differently, has that ever occurred? A: Yes, it has. Q: Can you provide me with an example? A: So I can think of one where it was pulled altogether. I can’t think of a specific one that was repositioned. Two years ago an abstract was pulled altogether when it was realized it had been presented in a large meeting and it was published from that meeting.”)). • Murphy Decl. Ex. 29 (Yao Tr. 230:7-24 (“Q: You mentioned, based on your experience, that if too much information were disclosed publicly, that ASCO or ESMO might not permit the company to – to attain one of these desired presentations slots. Do you have a specific experience in mind? A:

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>This was – this would date back quite a long time ago. So I – I think I would want this to be considered anecdotal. And I think it was one of the projects I worked on – Vectibix – I think was one of the Amgen products – oncology, treating colorectal cancer patients. And I believe, from my understanding working with the team, that because in our press release – I do not recall exactly which press release, at what time – there was more information – just a little bit more information – that was shared, that we were denied the spot to present at ASCO.”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 2 (Auerbach Tr. (Jan. 28, 2018) 296:7-20 (“Q: And are you aware -- talking about ASCO specifically, are you aware of any ASCO policy or procedure that made you believe you could not disclose the DFS rate delta? A: Yeah. ASCO has -- in the past has thrown companies out of ASCO if they found out you disclosed too much information.”)). • Murphy Decl. Ex. 17 (Schmidt Tr. 204:6-14 (“[Companies] have an interest in presenting full results in a medical conference in order to communicate those results to a broad range of physicians. And they often are

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>required to wait until such a conference in order to gain entrance to the conference. If they give away too many details in advance, they're not accepted for presentation at the conference.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 8 (Drynan Tr. 86:20-24 (“Q: [P]resenting too many details could jeopardize [a company’s] ability to present at the medical conference? A: Absolutely.”); 131:13-15 (“[Y]ou can press release top line data, but if you do anything beyond that, then you can get embargoed from the meeting.”)). • Murphy Decl. Ex. 130 (Feuerstein, Adam, <i>Immunomedics Kicked Out of Prestigious ASCO Cancer Conference</i>, THESTREET (June 3, 2016), https://www.thestreet.com/story/13594991/1/immunomedics-kicked-out-of-prestigious-asco-cancer-conference.html).
<p>62. On July 22, 2014, Puma held an investor conference call, which was transcribed.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 106 (Puma July 22, 2014 Investor Teleconference (Dep. Ex. 103).
<p>63. The 2.3% absolute difference in DFS rates at two years observed in the ExteNET trial is consistent with an overall 33% improvement in DFS as</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 56 (Topline Efficacy Analyses—Part A, (PUMA00014625-4656) (Dep. Ex. 127)). • Murphy Decl. Ex. 12 (Jewell Tr. 170:6-10 (“[I]f you say it’s a 33 percent reduction in

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>defined by the hazard ratio of 0.67.</p>	<p>risk and an absolute difference of 2.3 percent, and people walk out and think, Are those the same thing? Well, they are. That is actually the truth in this trial.”); 168:4-10 (Q. A bit earlier before the break, you discussed the difference between a 33 percent reduction in risk and the 2.3 percent absolute difference in DFS rates, and explained how those are different measures of risk. A. Different ways of expressing the difference in the survival rates, correct.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 14 (Lavin Tr. 29:22-30:1 (explaining that he reconstructed the trial database and reproduced analyses using trial data produced); 32:2-12 (“we were successful at reconstructing the life tables and the hazard ratio and the p-value that were reported by Clair[e Sherman].”)). • Murphy Decl. Ex. 6 (Chan Tr. 58:8-10 (“Q. Is a 2.3% absolute difference in DFS inconsistent with a 0.67 hazard ratio? A. No.”)). • Murphy Decl. Ex. 134 (Plaintiff’s Response to Request for Admission No. 25 (Plaintiff is “unable to either admit or deny this Request [that 0.67 hazard ratio in the ExteNET trial at two years after randomization for the ITT

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>population is not inconsistent with a 2.3% absolute difference in DFS rates] because Defendants are in exclusive possession, custody or control of all nonpublic information that would enable Plaintiff to determine whether the referenced hazard ratio and percentage difference in disease-free survival rates in the ExteNET trial is accurate or how it was derived”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 129 (<i>Arlene Chan et al., Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): a multicenter, randomized, double-blind, placebo-controlled phase 3 trial</i>, Lancet Oncology (Feb. 10, 2016)).
<p>64. Analyst reports issued after the July 22, 2014 conference call, discuss a range of possible DFS rates.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 109 (<i>The Cat with Nerat(inib) Strikes Back</i>, Cowen (July 23, 2014) (CW000025-34) (Dep. Ex. 299) at -25 (“We estimate a 3-year DFS rate of 85-87% for the control arm, so it is likely the 3-year DFS on neratinib approached the low 90%...Our consultants have indicated that a 2-3% absolute improvement in DFS is clinically meaningful as the prevention of recurrence is tantamount to a cure in this

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>setting.”)).</p> <ul style="list-style-type: none"> • Auerbach Decl. Ex. 198 (<i>PBYI Strong ExteNET Results</i>, Leerink (July 23, 2014) (PUMA00001557) (“Although we did not see a positive neratinib ExteNET outcome in adjuvant breast cancer (met both primary and second endpoints with statistical significance) as a complete surprise (LINK), we believe the magnitude of benefit (HR=0.63-0.67 depending on how disease-free survival [DFS] is measured, likely 4% absolute improvement in DFS on top of 1-year Herceptin) is among best-case scenarios that could be envisioned...With planned filing in 1H:15 for neratinib, we would anticipate a potential FDA approval YE:15/1Q:16.”)). • Murphy Decl. Ex. 108 (<i>PBYI Trial Hits</i>, Citi (July 23, 2014) (Dep. Ex. 417) (CGMI000415) (“We estimate that neratinib achieved a 2yr DFS rate of ~90%-91% vs 86% for placebo (HR 0.67).”)). • Murphy Decl. Ex. 107 (<i>Company Update</i>, Stifel (July 22, 2014) (Dep. Ex. 239) (STIFEL0005146-152) at -146 (“We estimate neratinib met its primary endpoint with a 92% disease-free survival rate based on the reported 33% improvement over our estimate

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>of historical 86% DFS at 3-years”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 24 (Werber Tr. at 113:12-22 (“Q: And at this time, did you think that the 33 percent improvement was an approximate 4 to 5 percent difference in DFS rates between the neratinib arm and the placebo arm? A: There was a possibility, based on the potential expectations at the time, that that could have been one of the ranges that's possible, as denoted by a hazard ratio of .67 and 33 percent improvement over control.”); 146:2-10 (“Q. And at this time in your report, you estimated that the absolute DFS difference in the ExteNET trial would be 4 to 5 percent; is that right? A. I think the physician noted that the placebo arm is expected to be in the 86 to 88 percent range. And so, within that context, a 33 percent benefit should -- should be 4 to 5 percent.”)).
<p>65. A widening of Kaplan-Meier curves suggests that the treatment being studied—in this case neratinib—has an increasing benefit to patients over time.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 37 (Kornak Report ¶ 77 (“Survival curves that stay separate show that the benefit subjects receive is maintained over time.”)). • Murphy Decl. Ex. 14 (Lavin Tr. 231:21-232:1 (“Curves continuing to separate would be evidenced by near parallel lines in each

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>arm.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 2 (Auerbach Tr. (Jan. 28, 2018) 373:6-375:16 (describing importance of continued separation of Kaplan-Meier curves)). • Murphy Decl. Ex. 1 (Adelson Tr. 142:5-146:4 (explaining importance of Kaplan-Meier curves to evaluate benefit and that “today I would absolutely look at information in the Kaplan-Meier curves going beyond two years”)). • Murphy Decl. Ex. 129 (Arlene Chan et al., <i>Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): a multicenter, randomized, double-blind, placebo-controlled phase 3 trial</i>, Lancet Oncology (Feb. 10, 2016)).
<p>66. Prior to July 22, 2014, Mr. Auerbach received an analysis of DFS rates extending past two years.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 2 (Auerbach Tr. (Jan. 28, 2018) 373:18-375:16 (recalling that in the three year Kaplan-Meier analysis he saw “the absolute DFS benefit went from 2.3 percent at year two to somewhere around 3.4 or 3.5 percent at year three; again, based on a very, very small number of patients.”); 380:7-380:18 (recalling that the three year Kaplan-

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>Meier analysis he saw “showed we went from 2.3 percent to either, like, 2.4 or 3.5 percent. It was a gain of 1 percent over that year.”).</p> <ul style="list-style-type: none">• Murphy Decl. Ex. 27 (Wong Tr. (Oct. 27, 2017) 78:8-80:4 (confirming data past two years was available and had been unblinded and “when we first broke the blind and we did the analyses, we gave the top-line data. And during some meetings we were discussing, well, at two years it's like this, but what happens if you take off the filter of the two-year, 28-day.”); 85:5-21 (explaining “there was a number of sheets of paper. Because we did multiple analyses, is the way we work, to look at every aspect of the curves to see how stable they are, reasons for censoring, reasons for why the curves looked the way they did.”)).• Murphy Decl. Ex. 28 (Wong Tr. (April 16, 2018) 238:2-239:11 (recalling seeing a “printed out” analysis of Kaplan-Meier curves extending past two years); 245:1-14 (recalling seeing analysis of Kaplan-Meier curves extending past two years at a meeting with Alan Auerbach)).• Murphy Decl. Ex. 21 (Sherman Tr. (Oct. 24, 2017) 183:20-184:8 (explaining “when

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>that study was cut off at two years, the first subjects randomized had follow-up data to three and a half years, and I was privy to that being unblinded. As was everybody that looks at the data, you can see what's happening at three and a half years, you just don't know what their treatment is.”); 262:8-263:5 (explaining database snapshot contained data past two-years and 28 days for certain subjects); 266:1-267:7 (explaining she ran “a variety of analyses in the database snapshot” between July 7 and July 22, 2014, “it’s possible” she analyzed Kaplan-Meier curves extending past two years and 28 days, and that “someone could have been presented with results extending past two years and 28 days for the portion of the patients included in the database snapshot for whom Puma had information extending up to or through three years without having access to the randomization code”)).</p>
<p>67. Kaplan-Meier curves based on data available to Puma as of July 2014 show continued separation on a year over year basis between two and three years.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 83 (ExteNET Trial July 7, 2014 Snapshot Kaplan-Meier Curves (PUMA00539366) (showing 3.5% separation at three years)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Murphy Decl. Ex. 14 (Lavin Tr. 85:14-86:10 (“We also saw from the database which we received that there were eight additional events observes [sic] following month 25.”); 145:9-148:8 (analysis of those events showed 2.7% absolute difference in DFS rates at three years)).
<p>68. Kaplan-Meier curves created based on data available to Puma as of July 2014 show a 3.5% absolute difference in DFS rates at three years.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 83 (ExteNET Trial July 7, 2014 Snapshot Kaplan-Meier Curves (PUMA00539366)).
<p>69. Clinical trials conducted prior to July 2014 showed grade 3 diarrhea rates ranging from 20%-51%.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 48 (I-SPY 2 Trial Results Presentation (PUMA00059372) at - 405 (I-SPY 2 Trial Results show 39% grade 3 diarrhea rate)). • Murphy Decl. Ex. 131 (Lecia V. Sequist, et al., Neratinib, an Irreversible Pan-ErbB Receptor Tyrosine Kinase Inhibitor: Results of a Phase II Trial in Patients with Advanced Non-Small-Cell Lung Cancer, JOURNAL OF CLINICAL ONCOLOGY (June 2010) (50% rate of grade 3 diarrhea)). • Murphy Decl. Ex. 132 (Kwok-K Wong, et al., A Phase I Study with Neratinib (HKI-272), an Irreversible Pan ErbB Receptor

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>Tyrosine Kinase Inhibitor, in Patients with Solid Tumors, CLINICAL CANCER RESEARCH JOURNAL (April 2009) (39% rate of grade 3 diarrhea)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 133 (R. Abbas et al., A Double-Blind, Randomized, Multiple-Dose, Parallel-Group Study to Characterize the Occurrence of Diarrhea Following Two Different Dosing Regimens of Neratinib, an Irreversible Pan-ErbB Receptor Tyrosine Kinase Inhibitor, CANCER, CHEMOTHERAPY AND PHARMACOLOGY JOURNAL (July 2012) (28%)). • Murphy Decl. Ex. 136 (Pfizer Press Release, Pfizer Announces Neratinib Data in HER2 Positive Breast Cancer. (December 12, 2009) (28% rate of grade 3 diarrhea)). • Auerbach Decl. Ex. 212 (April 7, 2014, Puma Biotechnology Conference Call Transcript (PUMA00008915) at -916 (“In the neratinib treated arm of the trial, 39% of the patients experienced grade 3/4 diarrhea. . . .”)).
<p>70. On July 28, 2014, Citi held an investor conference call, hosted by analyst Yaron Werber,</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 110 (<i>Even the Skeptics May Get on Board: Key Takeaways +</i>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>which was transcribed. During that call, Dr. Werber and a physician speculated that the difference in DFS rates for the ExteNET trial could be between 2-8%.</p>	<p><i>Transcript from our Recent ExteNET Physician Call, Citi (July 28, 2014) (CGM1000469-496) at -74 (“That is to say if the control arm had an 88% disease free survival at three or four years, what does the Neratinib arm look like? Is it 96% or is it, you know 90% with such that there’s only a 2% difference?”) (Dep. Ex. 420)).</i></p>
<p>71. In Forms 10-K filed annually between 2012-2015, Puma informed investors that it would need to raise capital periodically and that “for the foreseeable future,” it would be necessary to fund all of its operations “from cash on hand, licensing fees and grants, and potentially future offerings of our securities.”</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 179 (Puma 2011 Form 10-K (March 29, 2012) at 18 (“We currently have no product revenues or products approved for marketing . . . for the foreseeable future we do not expect to achieve any product revenues and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, and potentially future offerings of our securities.”); Auerbach Decl. Ex. 181 (Puma 2012 Form 10-K filed April 1, 2013, at 22 (same)); Auerbach Decl. Ex. 184 (Form 10-K filed March 3, 2014, at 24 (same)). • Murphy Decl. Ex. 78 (Puma 2014 Form 10-K (March 2, 2015) (Dep. Ex. 104) at 21 (“We currently have no product revenues or products approved for marketing We do not expect to achieve any product revenues

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>for at least the next 18 to 24 months, if ever, and will have to fund all of our operations and capital expenditures from cash on hand, licensing fees and grants, and potentially, future offerings of our securities.”));</p> <p>Auerbach Decl. Ex. 189 (Puma 2015 Form 10-K (Feb. 29, 2016) at 24 (same)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 15 (Malley Tr. 125:3-10 (“No, but I think we would always take a look at the cash and then we would talk about the fact that we’re a development-stage biotech company with no revenues, so eventually there will have to be an offering.”)). • Murphy Decl. Ex. 15 (Malley Tr. 129:13-18 (“Q. Okay. Was there any other fund-raise that would occur other than a stock offering. A. No.”)).
<p>72. Puma conducted its capital raises through periodic public stock offerings, completed on October 24, 2012, February 14, 2014, January 27, 2015, and October 20, 2016.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 180 (Puma Form 424B3 filed October 24, 2012, at Item 1.01 (“The net proceeds received by the Company from the sale of 8,625,000 shares of Common Stock were approximately \$129.1 million after deducting the underwriting discount and estimated offering expenses payable by the Company.”)). • Auerbach Decl. Ex. 181 (Puma 2012 Form 10-K (April 1, 2013) at 40-41 (“On October

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>18, 2012, our Registration Statement on Form S-1, as amended (File No. 333-184187), was declared effective for our first registered offering, pursuant to which we registered the offering and sale of an aggregate of 8,625,000 shares of common stock, par value \$0.0001 per share, at a price of \$16.00 per share. . . The offering [] closed on October 24, 2012[.]”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 78 (Puma 2014 Form 10-K (March 2, 2015) (Dep. Ex. 104) at 45 (“On February 14, 2014, we completed an underwritten public offering of 1,126,530 shares of our common stock (including an additional 146,938 shares of our common stock issued and sold pursuant to the underwriters’ option to purchase additional shares) at a price of \$122.50 per share, less the underwriting discount. The net proceeds received by us were approximately \$129.4 million after deducting the underwriting discount and estimated offering expenses payable by us.”)). • Auerbach Decl. Ex. 189 (Puma 2015 Form 10-K (February 29, 2016) at 48 (“On January 27, 2015, we completed an underwritten public offering of 1,150,000 shares of our

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>common stock (including an additional 150,000 shares of our common stock issued and sold pursuant to the underwriters’ option to purchase additional shares) at a price of \$190.00 per share, less the underwriting discount. The net proceeds received by us were approximately \$205.0 million after deducting the underwriting discount and estimated offering expenses payable by us.”)).</p> <ul style="list-style-type: none"> • Auerbach Decl. Ex. 193 (Puma 2016 Form 10-K (Mar. 1, 2017) at 56 (“On October 19, 2016, we entered into an underwriting agreement in connection with the public offering, issuance and sale by us of 3,750,000 shares of our common stock at a public offering price of \$40.00 per share, less underwriting discounts and commissions. Under the terms of the underwriting agreement, we also granted the underwriters an option exercisable for 30 days to purchase up to an additional 562,500 shares of our common stock at the public offering price, less underwriting discounts and commissions. On October 20, 2016, the underwriters exercised their option to purchase additional shares in full. We received net proceeds from the offering of approximately \$161.9 million,

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>after deducting underwriting discounts and commissions and estimated offering expenses.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 69:23-70:1 (“All biotechnology companies need to raise capital, almost on an annual basis, at most once every two years because they’re consumers of capital.”)).
<p>73. Biotechnology companies sometimes conduct a stock offering after announcing positive top-line clinical trial results.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 147:1-5 (“Q. How common is it for that company or those companies to conduct an offering in between the release of top line results and the presentation of the full data at a medical conference? A. It happens. It’s happened before.”)). • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 274:13-19 (“Q. (BY MS. SMITH) So in your experience, have public offerings taken place during this period of time between the announcement of top line data and presentation at a medical conference? A. It happens. Those -- that’s -- the majority of the financings in our industry happen like that, actually.”)). • Murphy Decl. Ex. 137 (Press Release, Evoke Provides Additional Data

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>Demonstrating Statistically Significant Benefit for Gimoti in Moderate to Severe Patients in Phase 3 Diabetic Gastroparesis Trial, January 4, 2017 (FRYKMAN00001631)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 138 (Press Release, Evoke Pharma Announces Pricing of Public Offering of Common Stock, February 16, 2017 (FRYKMAN00001516)). • Murphy Decl. Ex. 139 (Press Release, Evoke Pharma Presents Gimoti Efficacy and Safety Data from Phase 3 Trial as Late Breaker at Digestive Disease Week 2017, May 10, 2017 (FRYKMAN00001634)). • Murphy Decl. Ex. 140 (Press Release, La Jolla Pharmaceutical Company Announces Positive Top-Line Results from ATHOS-3 Phase 3 Study of LJPC-501, February 27, 2017 (FRYKMAN00001601)). • Murphy Decl. Ex. 141 (Press Release, La Jolla Pharmaceutical Company Announces Pricing of Public Offering of Common Stock, March 23, 2017 (FRYKMAN00001503)). • Murphy Decl. Ex. 142 (Press Release, Results of ATHOS-3 Phase 3 Study of LJPC-501 Published in the New England Journal of Medicine, May 21, 2017

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>(FRYKMAN00001605)).</p> <ul style="list-style-type: none">• Murphy Decl. Ex. 143 (Press Release, Omeros’ Ophthalmology Product OMS302 Achieves Primary and Secondary Endpoints in Phase 3 Clinical Trial, March 13, 2012 (FRYKMAN00001045-47)).• Murphy Decl. Ex. 144 (Press Release, Omeros Prices \$30 Million Public Offering of Common Stock, June 27, 2012 (FRYKMAN00001101)).• Murphy Decl. Ex. 145 (Press Release, Omeros Reports OMS302 Clinical Data Presented at the Annual ASCRS and ASOA Symposium and Congress, April 25, 2013 (FRYKMAN00001139)).• Murphy Decl. Ex. 146 (Press Release, Radius Announces Positive Phase 3 Top-Line Results for Its Investigational Drug Abaloparatide-SC in Postmenopausal Women With Severe Osteoporosis, December 21, 2014 (FRYKMAN00001141)).• Murphy Decl. Ex. 147 (Press Release, Radius Health, Inc. Announces Closing of Public Offering of Common Stock and Full Exercise of Underwriters’ Option to Purchase Additional Shares, January 28, 2015 (FRYKMAN00001103)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> <li data-bbox="816 247 1502 604">• Murphy Decl. Ex. 148 (Press Release, Radius Health, Inc. Announces Closing of Public Offering and Full Exercise of Underwriters’ Option to Purchase Additional Shares, July 28, 2015 (FRYKMAN00001104)). <li data-bbox="816 625 1502 919">• Murphy Decl. Ex. 149 (Press Release, Radius Announces Publication of Additional Positive Results from the Phase 3 ACTIVE Trial of Abaloparatide-SC in JBMR, September 18, 2016 (FRYKMAN00001145)). <li data-bbox="816 940 1502 1360">• Murphy Decl. Ex. 150 (Press Release, Spring Bank Pharmaceuticals Announces Top-Line Results from the Initial Cohort of the Phase 2a Segment of the ACHIEVE Trial, a Global Phase 2 Clinical Trial for Chronic Hepatitis B Virus (HBV), May 23, 2017 (FRYKMAN00001585)). <li data-bbox="816 1381 1502 1612">• Murphy Decl. Ex. 151 (Press Release, Spring Bank Pharmaceuticals Prices \$37.5 Million Public Offering of Common Stock, June 22, 2017 (FRYKMAN00001499)). <li data-bbox="816 1633 1502 1927">• Murphy Decl. Ex. 152 (Press Release, Spring Bank Pharmaceuticals Announces Positive Top-Line Results from the Second Cohort of Part A of the Phase 2 ACHIEVE Trial, November 15, 2017

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	(FRYKMAN00001588)).
<p>74. J.P. Morgan Securities LLC (“J.P. Morgan”) and Merrill Lynch, Pierce, Fenner & Smith Inc. (“Merrill Lynch”) (collectively, the “underwriters”) were the lead book-running managers and representatives of the underwriters for the January 2015 Offering. Citigroup Global Markets acted as joint book-running manager. Leerink Partners LLC and Cowen and Co., LLC acted as co-managers.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 124 (January 20, 2015 Prospectus Supplement (PUMA00245171) at -71, -90 (identifying underwriters)). • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 208:1-7 (“A. To bring in the co-managers into the transaction, so the folks outside of J.P. Morgan, the banks outside of J.P. Morgan and B of A involved in the transaction. Q. Okay. And that would be Citi, Leerink and Cowen and Company? A. Correct.”)).
<p>75. Underwriters facilitate public stock offerings by purchasing stock from public companies and selling the shares to the market.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 187 (Puma Form 424B2 (Jan. 22, 2015) at S-17 (“Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased.”)). • Murphy Decl. Ex 86 (Underwriting Agreement (BAML000001-37)).
<p>76. Underwriters conduct due diligence to ensure that the public offering disclosures</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 107:1-8 (“Q. Okay. And in your time working on the investment bank field,

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>provided to investors are complete and accurate.</p>	<p>what is your general understanding of the purpose of due diligence in connection with a stock offering? A. To make sure that the -- to make sure that the public disclosures -- any material – nonpublic information’s disclosed in the public documents or the offering statement.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 44:17-24 (“Q. Based on your 11 years of experience with J.P. Morgan, what is your understanding of the general purpose of due diligence? A. For the underwriters to understand the state of the business for the purposes of telling the story to investors and verifying that the disclosure in the prospectus is complete and accurate.”)).
<p>77. The underwriters conducted due diligence in connection with Puma’s January 2015 stock offering.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 96 (JPM000160 (Commitments Committee Memorandum) (identifying diligence topics)). • Murphy Decl. Ex. 97 (BAML000743 (BAML commitment committee memo) (identifying diligence topics)). • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 77:12-17 (“Q. Okay. And that would have been in January 2015, when the transaction was actually going

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>forward? A. I’m not sure, because we did some diligence in the fall and we did some diligence late December, early January.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 46:19-47:1 (“Who from J.P. Morgan was responsible for conducting the diligence for that follow-on offering? A. It was jointly done by the healthcare coverage team and Mintz Levin. The other banks would have been involved in those calls and diligence discussions, too, obviously along with the company and its counsel.”)).
<p>78. William Hicks of Mintz, Levin, Cohn, Ferris Glovsky & Popeo, P.C., served as counsel to the underwriters in the January 2015 Offering.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 187 (Puma Form 424B filed January 22, 2015 at S-24). • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 95:6-10 (“Q. Okay. And who is William Hicks? A. He was underwriter’s counsel. Q. Okay. Was he retained specifically by BAML? A. Correct.”)).
<p>79. Mr. Auerbach met with Mr. Hicks on January 14, 2015.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 99 (William Hicks Calendar (PUMA000002) at -03). • Murphy Decl. Ex. 69 (January 9, 2015 email between A. Auerbach and B. Hicks (PUMA00477915)). • Murphy Decl. Ex. 98 (William Hicks Timesheets (PUMA000001)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none">• Murphy Decl. Ex. 3 (Auerbach Tr. (Jan. 29, 2018) 712:6-713:10 (“Q. Okay. When you say they were presented to him, how were they presented to him? A. At the JPMorgan meeting. So when you go to these investment conferences, you will usually -- say, you present on a Monday -- and when institutional investors attend the conference, they will say what companies they would like to meet with. And usually what they’ll do is for the day that you’re presenting, they’ll connect you with one-on-one meetings. Now, at a big meeting like the JPMorgan health care meeting, you’re going to get way more requests than you can handle. So they’ll usually say to you, “All right, for the day you’re presenting, we’ll take care of your meetings. For the rest, go get a hotel room somewhere else, have them knock out all the beds and all the furniture and just put meeting rooms in there,” and so you’ll get a separate meeting room somewhere else. So at the time, we had a -- the meeting took place in the Westin St. Francis Hotel in San Francisco. We had a separate meeting room at what used to be the Pan Pacific and is now the JW Marriott Hotel and Bill Hicks and I had a meeting that I believe took place on a

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>Wednesday somewhere around 5:00 or 6:00 p.m., where Bill came in and we did a face-to-face meeting, where I went over the slides with him.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 51:9-16 (“[Alan Auerbach] was afraid of confidentiality breaches, given the sensitive nature of the data. So that was an issue we worked around and ultimately agreed that our underwriter’s counsel at Mintz, Bill Hicks, would do the review.”)). • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 122:7-10 (“Q. And what is the proposal that you had for diligence with regard to the ExteNET trial? A. We had put in a procedure to have Bill Hicks review the ExteNET data.”)).
<p>80. During this meeting on January 14, 2015, Mr. Auerbach presented the ExteNET trial results to Mr. Hicks.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 66 (ExteNET Academic Steering Committee slides (PUMA00274484) at 8, 10, 23). • Murphy Decl. Ex. 3 (Auerbach Tr. (Jan. 29, 2018) 711:6-712:5 (“... So Bill Hicks was the attorney for the underwriters, so he was underwriters’ counsel. So we agreed that Bill Hicks would meet with me under CDA, and we would go through the ASCO -- the data

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>that would be presented at ASCO. So what I actually went over with Bill Hicks was -- we had had a meeting of our Academic Steering Committee. This may have been either the meeting that took place at LAX in January or the meeting that took place at the San Antonio breast cancer meeting in December. So I just went over those slides with him because that, essentially, was the data that was presented to the Academic Steering Committee, to make the decision to present at ASCO. So those slides were presented to Bill Hicks.”); 715:11-13 (“Q. And did Mr. Hicks ask you any questions about any of this data? A. Yes, he did.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 51:9-16 (“[Alan Auerbach] was afraid of confidentiality breaches, given the sensitive nature of the data. So that was an issue we worked around and ultimately agreed that our underwriter’s counsel at Mintz, Bill Hicks, would do the review.”)). • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 122:7-10 (“Q. And what is the proposal that you had for diligence with regard to the ExteNET trial? A. We had put

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	in a procedure to have Bill Hicks review the ExteNET data.”)).
<p>81. After his January 14, 2015 meeting with Mr. Auerbach, on January 15 and 19, 2015, Mr. Hicks had phone calls with members of the J.P. Morgan deal team to advise regarding the ExteNET trial due diligence.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 57:5-12 (“We had a call with Bill after he saw the data.”); 58:15-21 (“Q. Okay. So we’re -- so you said after Mr. Hicks reviewed the data, he had a call with Mitzi alone? A. That’s right. Q. And then after that, he had a call with the broader J.P. Morgan team; is that right? A. Right.”)). • Murphy Decl. Ex. 96 (JPM Commitment Memo (JPM000160) (AEO) at -206 (Identifying “Debrief on Clinical Data Review with Mintz Levin” on January 19, 2015)). • Murphy Decl. Ex. 98 (William Hicks Timesheets (PUMA000001) (Hicks’ billing records indication that he billed 5.1 hours on January 19, 2015 to “Launch; data debrief”)).
<p>82. After his January 14, 2015 meeting with Mr. Auerbach, Mr. Hicks had a phone call with members of the Merrill Lynch deal team to advise them regarding the ExteNET trial due diligence.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 167:19-168:1 (“On review of -- on --on discussing ExteNET with Bill Hicks, I had a separate conversation with BAML just because of logistical issues, so that’s what I’m referring to. Q. (Okay. So BAML had a separate date -- a call with Mr. Hicks

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>regarding the ExteNET data? A. Correct.”); 178:16-21 (“Q: Okay. And the procedures you have in place, that would be the procedure for Mr. Auerbach to show the nonpublic data for Hicks -- to Hicks, and then for Hicks to have the calls with both J.P. Morgan and BAML? A. Correct.”)).</p>
<p>83. Based on their discussions with Mr. Hicks and other diligence, the underwriters concluded that Puma’s disclosures were adequate and approved of proceeding with the January 2015 Offering.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 102:9-104:1 (“... And do you know if BAML ever received a favorable opinion and negative assurance letter pursuant to Section 5B of this agreement? A. Yes, we would have received -- would have been typical to receive one in the context of this offering. Q. Okay. Do you know who at BAML would have been responsible for receiving those items? A. No. Q. Do you have any idea where those items would be housed now at BAML? A. No. Q. Is there a central deal file those would be saved in? A. There would, but I don’t know where -- where that would be. Q. Okay. But it wouldn’t be destroyed; those -- those records would be kept, correct? A. I don’t know the answer to that. I don’t know what the retention policy is for Bank of America. Q. Okay. Do you

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>know if BAML ever received a favorable opinion from Mintz Levin pursuant to Section 5D of this agreement? A. Yes. That would have been typical, as well. Q. Okay. Would -- do you know if the deal would have went forward if the underwriters had not received that favorable opinion from Mintz Levin? A. The deal would -- would not have gone forward without giving that opinion. Q. Okay. And what about the officer's certificate pursuant to Section 5E? Do you know if BAML received that from PUMA? A. We would also have received that.”)).</p> <ul style="list-style-type: none">• Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 55:4-55:18 (“Q. Generally speaking, if the commitments committee reviewed the due diligence findings and had concerns, could they prevent the deal from going forward? A. The committee could theoretically ask us to go back and do additional diligence, yes.”)).• Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 125:18-126:22 (“Q. So the question is, with respect to the data that Puma shared with Mintz Levin, did J.P. Morgan make an independent assessment of whether that information should be disclosed as part of

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>the prospectus? . . . A. I don't know. We were -- we were comfortable.”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 179:9-16 (“Yeah, yeah. So we put the procedures in place to make sure that we were comfortable that the public disclosures were accurate.”)). • Murphy Decl. Ex. 98 (William Hicks Timesheets (PUMA000001)).
<p>84. Mintz Levin provided an opinion letter certifying that there were no material misstatements in Puma’s public disclosures.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex 86 (Underwriting Agreement (BAML000001) at -020). • Murphy Decl. Ex 88 (Table of Contents for Offering & Closing Documents (JPM000155) at -158). • Murphy Decl. Ex. 26 (BAML 30(b)(6) (Wolff) Tr. 102:9-104:1 (“ . . . And do you know if BAML ever received a favorable opinion and negative assurance letter pursuant to Section 5B of this agreement? A. Yes, we would have received -- would have been typical to receive one in the context of this offering. Q. Okay. Do you know who at BAML would have been responsible for receiving those items? A. No. Q. Do you have any idea where those items would be housed now at BAML? A. No. Q. Is there a

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>central deal file those would be saved in? A. There would, but I don't know where -- where that would be. Q. Okay. But it wouldn't be destroyed; those -- those records would be kept, correct? A. I don't know the answer to that. I don't know what the retention policy is for Bank of America. Q. Okay. Do you know if BAML ever received a favorable opinion from Mintz Levin pursuant to Section 5D of this agreement? A. Yes. That would have been typical, as well. Q. Okay. Would -- do you know if the deal would have went forward if the underwriters had not received that favorable opinion from Mintz Levin? A. The deal would -- would not have gone forward without giving that opinion. Q. Okay. And what about the officer's certificate pursuant to Section 5E? Do you know if BAML received that from PUMA? A. We would also have received that.”)).</p> <ul style="list-style-type: none">• Murphy Decl. Ex. 4 (JPM 30(b)(6) (Bleharski) Tr. 34:3-15 (“Q. Subsection D provides for the receipt of also, a favorable opinion from Mintz Levin. Do you see that? A. Yes. Q. Who is Mintz Levin? A. Underwriter's counsel. Q. So they represented J.P. Morgan in connection with

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	this offering? A. That’s right. Q. And did you receive that favorable opinion from Mintz Levin? A. Again, I don’t know specifically, but I would assume, given the transaction went forward.”)).
85. On February 12, 2015, Alan Auerbach gave a presentation on the ExteNET trial at the Leerink Global Healthcare Conference, which was transcribed.	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 210 (Leerink Global Healthcare Conference Transcript (PUMA00001301-06)).
86. On February 12, 2015, Puma stock opened at \$196.00 and closed at \$202.51.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 163 (Yahoo! Finance historical stock price chart, PBYI).
87. On February 13, 2015, Puma stock opened at \$202.51 and closed at \$205.26.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 163 (Yahoo! Finance historical stock price chart, PBYI).
88. On February 25, 2015, Alan Auerbach gave a presentation on the ExteNET trial at the RBC Capital Markets Global Healthcare Conference, which was transcribed.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 111 (RBC Capital Markets Global Healthcare Conference Transcript (PUMA00001314-20)).
89. On February 25, 2015, Puma stock opened at \$201.25 and closed at \$204.45.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 163 (Yahoo! Finance historical stock price chart, PBYI).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
90. On February 26, 2015, Puma stock opened at \$204.24 and closed at \$205.96.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 163 (Yahoo! Finance historical stock price chart, PBYI).
91. The ExteNET trial’s Academic Steering Committee (“ASC”) was made up of independent medical oncologists specialized in the treatment of breast cancer, none of whom is a Puma employee.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 49 (Academic Steering Committee Charter: Protocol Number: 3144A2-3004-WW (PUMA00113246 at - 250)). • Murphy Decl. Ex. 47 (3004 Former Academic Steering Committee List (PUMA00024520)).
92. The ASC oversaw and developed the protocol for the ExteNET trial.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 49 (Academic Steering Committee Charter: Protocol Number: 3144A2-3004-WW (PUMA00113246 at - 250)). • Murphy Decl. Ex. 6 (Chan Tr. 64:24-65:16 (“As a steering committee, we recognized that when we developed the protocol . . .”)).
93. In December 2014, the ASC met at the San Antonio Breast Cancer Symposium.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 68 (Dec. 31, 2014 email re: Extenet study and Puma Scientific Advisory Board (PUMA00025808-811)). • Murphy Decl. Ex. 6 (Chan Tr. 20:15-25 (“Q: And do you recall the circumstances under which you learned that information? A: At the academic steering committee that was held at San Antonio. Q: You said at San Antonio? A: Correct. Q: And was that at the

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	San Antonio breast cancer symposium that year? A: Correct. Q: Meaning in 2014? A: Correct.”)).
94. Dr. Arlene Chan became the chair of the ASC in December 2014 / January 2015, when the ASC reconvened.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 68 (Dec. 29, 2014 email from R. Bryce to J. Baselga, A. Auerbach (PUMA00025808)). • Murphy Decl. Ex. 70 (ExteNet Advisory Committee Meeting Agenda, Jan. 30, 2015 (PUMA00027661)). • Murphy Decl. Ex. 6 (Chan Tr. 10:13-16 (“I’m the study chair of the academic steering committee for the [ExteNET] trial.”)).
95. At the San Antonio Breast Cancer Symposium in December 2014, the ASC decided to submit the ExteNET data to ASCO to consider for presentation at ASCO’s 2015 annual conference.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 2 (Auerbach Tr. (Jan. 28, 2018) 360:12-361:11 (“So they made the decision just to meet at the San Antonio Breast Cancer Meeting in December in which case we would have – we presented it to [the ASC] there. And at that point, they made the decision to present the data at ASCO. And the ASCO deadline was late January of 2015, so we had a meeting in Los Angeles at LAX where we went through the data and drafted the abstract.”)). • Murphy Decl. Ex. 6 (Chan Tr. 50:24-52:12 (“Q: We talked earlier about a meeting of the academic steering committee that was held at

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>the San Antonio breast cancer symposium in December 2014, do you remember that? A: I do. Q: And I believe you said it was at that meeting that you learned additional details about the ExteNET trial data? A: Correct. [] Q: Did you decide at that meeting whether to present the data at a medical conference? A: We did. Q: And what did you decide? A: As a group, we believed that, given the positive results, it should be presented at a major medical oncology meeting and given the time interval, the ASCO annual conference appeared to be the most appropriate meeting to present the data. Q: Okay. Other than the timing, were there any other factors that you considered in deciding to submit the data for a presentation at ASCO? A: It was important information that should be presented at a major medical oncology meeting, and that was the most appropriate one. Q: Did you believe that the data was practice changing? A: The short answer, yes. Q: Were there any other viable options for presenting the data, given the timing that would be needed to put together the submission? A: I don't believe so.”)).</p>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>96. ASCO’s abstract submission guidelines impose a 2,000 character limit.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 93 (Abstract Submission/Modification Form (HsuvPumaASCO_00000023-40) at -23).
<p>97. On February 3, 2015, Puma submitted the ExteNET abstract to ASCO.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 84 (Abstract Submission, Abstract ID #149972 (HsuvPumaASCO_00000018)). • Murphy Decl. Ex. 73 (February 4, 2015 email from L. Miller to ASC (“ExteNET abstract for ASCO: submitted”) (PUMA00169904)).
<p>98. Dr. Chan was the lead author of Puma’s ExteNET abstract and Puma’s ExteNET presentation at ASCO.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 5 (Bryce Tr. 103:5-16 (“Q: And [Dr. Chan] is the lead author of the ExteNET abstract that was submitted to ASCO; is that right? A: That’s correct. Q: And she also did the oral presentation of those results at the conference; is that right? A: That’s correct.”)). • Murphy Decl. Ex. 6 (Chan Tr. 11:9-12 (“Q: You authored the abstract that was presented at ASCO, A-S-C-O, in 2015? A: Correct.”)). • Murphy Decl. Ex. 40 (Abstract #508 (Dep. Ex. 503)). • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>99. On March 26, 2015, ASCO notified Puma that ASCO had accepted Puma’s submission for oral presentation at its 2015 annual medical conference.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 100 (March 26, 2015 email from ASCO to Dr. Arlene Chan regarding Abstract ID #149972 (HsuvPumaASCO_000000243-44)).
<p>100. Various analysts issued reports in April and May 2015 stating that they expected the ExteNET trial DFS rates to be disclosed in connection with or at ASCO.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 112 (<i>Alert: SVP Of Operations & BD Leaves PUMA</i>, Citi (May 5, 2015) (CGMI001133-39) at -133 (“We continue to anticipate that Puma’s neratinib ExteNET data in extended adjuvant breast cancer that will be released on Monday, June 1st, during the oral breast cancer presentation will be good and will show a 3%-4% DFS benefit at 2 years equating to a HR=0.67 (p=0.0046).”)). • Auerbach Decl. Ex. 199 (<i>PBYI ExteNET Data Confirmed for ASCO</i>, Cowen (April 20, 2015) (PUMA00002195-99) at -195 (“Full data from this trial are expected to be presented on June 1, at the 2015 ASCO meeting. In our view, investors will likely be keenly interested in (1) the absolute magnitude of the drug’s DFS benefit (primary endpoint); (2) neratinib’s impact on subgroups and secondary endpoints; (3) Grade 3 diarrhea rates with the understanding that Imodium prophylaxis was

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>not employed; and (4) the incidence of adverse events and secondary cancers.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 113 (<i>PBYI Downgrade: Major Stock Upside Increasingly Dependent On M&A</i>, Cowen (May 5, 2015) (Dep. Ex. 313) (CW000001-9) at -1 (“Full 2-year ExteNET data will be showcased during an oral presentation on June 1 (10:24-10:36 am CT) at ASCO, and published concomitantly in a leading medical journal. We expect the primary endpoint data to be as advertised (HR=0.67, p=0.0046) with no surprises. In terms of additional details, investors will likely be keenly interested in . . . neratinib’s absolute DFS benefit at 2 years relative to placebo.”)). • Auerbach Decl. Ex. 201 (<i>PBYI - Sweet Home Chicago</i>, RBC (May 11, 2015) (PUMA00002747-56) (Dep. Ex. 139) at -747 (“We continue to expect the ExteNET data in Chicago to show the 3+% difference between the two arms that investors and oncologists have been benchmarking as the minimum to achieve meaningful clinical significance... We expect the ExteNET data to confirm the topline p-value and hazard

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>ratio and result in a low-to-mid single digit % difference between the two arms.”)).</p> <ul style="list-style-type: none"> • Auerbach Decl. Ex. 200 (<i>PBYI: Q1 Results Uneventful - Near-Term Focus Is on ExteNET at ASCO</i>, Citi (May 11, 2015) (PUMA00002730-739) (Dep. Ex. 138) at -730 (“We note that conversations with [Key Opinion Leaders] suggest an absolute DFS gain of greater than 3% would be a viewed as a clear win, with opinions mixed below this level. We would view a 4% DFS benefit to be a very good outcome.”)).
<p>101. After market close on May 13, 2015, ASCO publicly released the abstracts for the clinical trial data that would be presented at its 2015 annual medical conference, including Puma’s ExteNET abstract (“Abstract #508”).</p>	<ul style="list-style-type: none"> • AC ¶ 12 (Dkt. No. 138). • Murphy Decl. Ex. 40 (Abstract #508 (Dep. Ex. 503)).
<p>102. After Abstract #508 was released, some analysts and journalists commented that neratinib’s commercial potential remained strong, and anticipated their understanding of the data to be fully realized at ASCO.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 202 (<i>Puma Biotechnology Why We’re Buyers on the ExteNET ASCO Abstract</i>, UBS (May 13, 2015) (PUMA00002780-785) (Dep. Ex. 140) at -780 (“The ExteNET data are good; commercial potential unchanged”; “[U]ltimately we think neratinib’s \$4bn+

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>commercial potential is unchanged’’)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 125 (<i>Biotech: Asco Giveth, Asco Taketh Away</i>, Barron’s (May 14, 2015) (PUMA00001430-31) (Dep. Ex. 125) at -431 (“Our conviction in neratinib and Puma remains unchanged, and we anticipate investor/medical community understanding of the data to be fully realized at ASCO’’) (quoting RBC’s Simos Simeonidis)). • Auerbach Decl. Ex. 204 (<i>ASCO Presentation Expected to Clarify Neratinib ExteNET Data</i>, RBC Capital Markets (May 27, 2015) (PUMA00002939-952) (Dep. Ex. 142) at -939 (“We reiterate our view that neratinib’s Phase III ExteNET data were positive and misread by many in the market following release of the ASCO abstracts ...’’)).
<p>103. Many analysts, including an analyst for Plaintiff’s investment advisor, Capital International, recommended buying Puma stock after Abstract #508 was released.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 101 (<i>Puma: The house is NOT on fire - - BUY</i>, Skye Drynan (May 14, 2015) (CII – 00390-92) (Dep. Ex. 34)). • Auerbach Decl. Ex. 202 (<i>Puma Biotechnology Why We’re Buyers on the ExteNET ASCO Abstract</i>, UBS (May 13, 2015) (PUMA00002780-785) (Dep. Ex. 140)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 204 (<i>ASCO Presentation Expected to Clarify Neratinib ExteNET Data</i>, RBC Capital Markets (May 27, 2015) (Rating: Outperform) (PUMA00002939-952) (Dep. Ex. 142)).
<p>104. After Abstract #508 was released, some analysts and journalists believed that they would get a better understanding of the ExteNET data at the ASCO annual conference.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 202 (<i>Puma Biotechnology Why We're Buyers on the ExteNET ASCO Abstract</i>, UBS (May 13, 2015) (PUMA00002780-785) (Dep. Ex. 140)). • Murphy Decl. Ex. 125 (<i>Biotech: Asco Giveth, Asco Taketh Away</i>, Barron's (May 14, 2015) (PUMA00001430-431) (Dep. Ex. 125)). • Auerbach Decl. Ex. 204 (<i>ASCO Presentation Expected to Clarify Neratinib ExteNET Data</i>, RBC Capital Markets (May 27, 2015) (PUMA00002939-952)).
<p>105. On May 14, 2015, Puma's stock opened at \$209.72 and closed at \$170.76 (down 18.6% or -\$39.05 per share).</p>	<ul style="list-style-type: none"> • AC ¶ 12 (Dkt. No. 138).
<p>106. On May 27, 2015, Puma's stock closed at \$200.21.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 163 (Yahoo! Finance historical stock price chart, PBYI).
<p>107. On June 1, 2015, Dr. Chan gave a presentation on the</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
ExteNET trial at ASCO’s annual conference in Chicago, Illinois.	
108. The ExteNET ASCO presentation began at 11:24 a.m. EST on June 1, 2015.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 95 (2015 ASCO Annual Meeting, “Annual Meeting Program,” May 29-June 2, 2015 (RBCCM0017908-8223, at - 8113)).
109. Trading in Puma’s stock was halted from 11:23 a.m. EST to 12:29 p.m. EST on June 1, 2015.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 162 (06/01/2015 TICK data (GOMPERS00002829)).
110. The ExteNET ASCO presentation included data showing that the two-year DFS rate of the ExteNET trial was 93.9% for the treatment arm and 91.6% for the control arm, resulting in an absolute difference in DFS of 2.3% at two years.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. 176) at 10).
111. ExteNET ASCO presentation included data showing that 39.9% of patients in the treatment arm experienced grade 3 or higher diarrhea.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176) at 16).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>112. The ExteNET ASCO presentation consisted of twenty slides regarding the ExteNET trial, discussing changes to the study protocol, patients demographics, additional efficacy and subgroup results beyond those disclosed in Abstract #508, and additional analyses of adverse events.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176)).
<p>113. The ExteNET ASCO presentation included two-year Kaplan-Meier curves for the ExteNET trial.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176) at 16). • AC ¶ 71 (Dkt. No. 138).
<p>114. The Kaplan-Meier curves for the ExteNET trial presented by Dr. Chan at ASCO showed separation in DFS rates between the treatment and control arms for the full trial population between years one and two.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176) at 10).
<p>115. The Kaplan-Meier curves for the ExteNET trial presented by Dr. Chan at ASCO showed separation in DFS rates between the treatment and control arms for the hormone receptor positive</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176) at 14-15).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
and centrally confirmed subgroups between years one and two.	
116. The ExteNET ASCO presentation disclosed that the absolute difference in DFS for the centrally confirmed HER2+ subgroup was 3.2% at year one, and 4.1% at year two.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176) at 15).
117. The ExteNET ASCO presentation disclosed that there was not a statistically significant difference in DFS rates between the treatment and placebo arms for the node-negative (patients who do not have cancer in their lymph nodes) subgroup.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176) at 12).
118. The ExteNET ASCO presentation disclosed that 16.8% of trial participants discontinued treatment because of diarrhea.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 41 (ASCO Presentation (Dep. Ex. 176) at 17).
119. At ASCO’s annual conference on June 1, 2015, discussant and independent oncologist Dr. Shanu Modi spoke about Dr. Chan’s	<ul style="list-style-type: none"> • Murphy Decl. Ex. 95 (<i>2015 ASCO Annual Meeting</i>, “Annual Meeting Program,” May 29-June 2, 2015 (RBCCM0017908-8223, at - 8113)). • Murphy Decl. Ex. 77 (ASCO Discussant

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>ExteNET presentation (and five others) from approximately 11:36 a.m. EST to 11:48 a.m. EST.</p>	<p>Presentation (PUMA00467216.00001-00027)).</p>
<p>120. Dr. Modi noted that overall survival data was not yet available from ExteNET and predicted that doctors and the FDA would need longer-term follow-up data.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 77 (ASCO Discussant Presentation (PUMA00467216.00001-00027) at -25-26 (“We await longer follow-up (and FDA deliberations) to determine how/whether to offer neratinib extended therapy as an option for our early stage patients”)).
<p>121. A Q&A session followed Dr. Chan’s and Dr. Modi’s presentations from 11:48 a.m. EST to 12:01 p.m. EST.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 42 (ASCO Q&A Audio Transcription (PUMA00236647) at 1-11).
<p>122. During the Q&A session, Dr. Steven Vogl commented negatively on neratinib.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 42 (ASCO Q&A Audio Transcription (PUMA00236647) at 6:15-18 (“Dr. Chan, this Neratinib sounds like a terrible drug. How many people were still taking it after six months and how many actually finished a year of the stuff?”)).
<p>123. During the Q&A session, Dr. Richard Gelber commented negatively on neratinib.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 42 (ASCO Q&A Audio Transcription (PUMA00236647) at 2:21-3:4 (“You mentioned a limitation from the ExteNET trial in the short follow-up. And I would hypothesize that it’s actually a fatal limitation for the results we saw today. I

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>would consider the results nonactionable. In fact, the early results of ALTTO done at about that time showed an even larger advantage than we saw here today. Similar pathway. And I would propose that the longer-term follow-up would likely prove a negative result.”)).</p>
<p>124. In reports and articles published after the ExteNET ASCO presentation, analysts and reporters cited Dr. Vogl’s and Dr. Gelber’s comments, and stated their (analysts’) concern that there was a risk to the FDA approval of neratinib and that the FDA might not approve neratinib without seeing more data.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 206 (<i>Puma Biotechnology ExteNET Reaction Mixed, but 8.6%pt Delta is Nice</i>, UBS (June 1, 2015) (PUMA00008909-8914) at -09 (“However, Q&A was clearly mixed with both positive and negative comments, with the negative focused on the short follow up making the data ‘non-actionable.’”)). • Auerbach Decl. Ex. 209 (<i>In Case You Missed it at ASCO...Tons of Tidbits</i>, UBS (June 3, 2015) (“In our opinion, the thing that hurt the stock at ASCO was the question from “Vogl, New York.” Although the Q&A was mixed, the sound-bite of ‘this looks like a terrible drug’ went viral.”) (PUMA00003014-23, at -17)). • Murphy Decl. Ex. 127 (Susan London, <i>ASCO: Adjuvant neratinib has payoff in HER2-positive breast cancer</i>, MDedge (June

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>2, 2015) (GOMPERS00002413-18) (“Session attendee Richard Gelber, Ph.D., of the Dana-Farber Cancer Institute, Boston, agreed with Dr. Chan that the trial’s short follow-up is a limitation. ‘I would hypothesize that it’s actually a fatal limitation for the results we saw today. I would consider the results non-actionable...’ Dr. Steven Vogl, an oncologist in the Bronx, New York, didn’t mince words about the observed toxicity, saying, ‘This neratinib sounds like a terrible drug. How many people were still taking it after 6 months and how many actually finished a year of the stuff?’”).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 126 (<i>Puma Bio Breast Cancer Drug Given Rough Treatment at ASCO ’15</i>, TheStreet (June 1, 2015) (FEINSTEIN0000270-73) (“During a Q&A session at the end of the ASCO presentation, an audience member said ‘neratinib seems like a terrible drug,’ referring to the high rate of diarrhea. Another ASCO attendee called the ExteNET results presented ‘unactionable’ and criticized the study’s short follow up.”)). • Murphy Decl. Ex. 76 (June 1, 2015 email from C. Gordon to A. Auerbach (PUMA00041389-95, at -89) (“I can attest

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	that bears are going back to the approvability question. We were all good until the Vogl comment”).
<p>125. Following the ExteNET ASCO presentation, analysts indicated that they wanted to see more data than what was presented by Puma on June 1 to better understand the risk that the FDA would not approve neratinib or would need to see more data before approving it.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 115 (<i>Puma Biotechnology ExteNET as Advertised, But Questions Remain on FDA Strategy and Market Oppy</i>, Cowen and Co. (June 1, 2015) (CW000035) (Dep. Ex. 326) (“The results were in line with expectations, with no major surprises. However, the presentation may fuel debate on the need for longer term follow up and the size of the patient population that might derive a favorable risk benefit from the drug.”)). • Auerbach Decl. Ex. 205 (<i>ExteNET Curves separate, subgroup data are robust</i>, RBC Capital Markets, June 1, 2015 (PUMA000002975-80) at -75 (“Many mentioned that these data would have to be validated with longer follow up.”)). • Auerbach Decl. Ex. 207 (<i>First Read: Puma Biotechnology Investigators Supportive at Investor Meeting</i>, UBS, June 2, 2015 (PUMA00003008-13, at -08) (explaining the “debate” regarding neratinib approvability following ASCO and the forthcoming three-

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>year analysis)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 75 (June 1, 2015 email re: “PBYI thoughts from Eric...” (PUMA00041368-69) at -68 (“Bottom line is that post full Extenet data at ASCO, the path to approval seems longer and filled with more pitfalls than investors realized ... there is risk the effect wanes overtime and may not look as efficacious as after 2 years, raising more ?’s on approvability.”)). • Auerbach Decl. Ex. 208 (<i>Puma Biotechnology, Inc. No Surprises in ExteNET Presentation – 3-Year Follow-Up Likely Closely Watched</i>, Leerink (June 2, 2015) (PUMA00002988-94, at -88) (“The discussant for ExteNET presentation at ASCO appeared to want to see longer follow-up and the results of FDA deliberations to determine how and whether to use neratinib in this setting...”)).
<p>126. Following the ExteNET ASCO presentation, some analysts predicted that there may be a smaller commercial market for neratinib than they anticipated prior to the ASCO</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 115 (<i>Puma Biotechnology ExteNET as Advertised, But Questions Remain on FDA Strategy and Market Oppy</i>, Cowen and Co. (June 1, 2015) (CW000035) (Dep. Ex. 326) (“The results were in line with expectations, with no major

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>presentation, based on the results for the node-negative subgroup.</p>	<p>surprises. However, the presentation may fuel debate on the need for longer term follow up and the size of the patient population that might derive a favorable risk benefit from the drug.”)).</p> <ul style="list-style-type: none"> • Auerbach Decl. Ex. 206 (<i>Puma Biotechnology ExteNET Reaction Mixed, but 8.6%pt Delta is Nice</i>, UBS (June 1, 2015) (PUMA00008909-14, at -09) (discussing commercial opportunity as “high penetration in high risk, low use in low-risk” (node negative) populations)). • Auerbach Decl. Ex. 209 (<i>In Case You Missed it at ASCO... Tons of Tidbits</i>, UBS (June 3, 2015) (PUMA00003014-23, at -14) (describing market for neratinib, if approved, as “niche”)).
<p>127. An analyst reported that as many as 70-80% of HER2+ breast cancer patients in the U.S. could be node-negative.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 115 (<i>Puma Biotechnology ExteNET as Advertised, But Questions Remain on FDA Strategy and Market Oppy</i>, Cowen and Co. (June 1, 2015) (CW000035) (Dep. Ex. 326) (estimating that “70-80% of the U.S. population is at low risk for recurrence (node negative disease)”)).
<p>128. Four analysts mentioned the Kaplan-Meier curves or</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 205 (<i>ExteNET Curves separate, subgroup data are robust</i>, RBC

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>16.8% discontinuation rate due to diarrhea rate in their reports on the ExteNET ASCO presentation.</p>	<p>Capital Markets (June 1, 2015) (PUMA00002975-76, at -75) (“ExteNET curves separate”).</p> <ul style="list-style-type: none"> • Auerbach Decl. Ex. 206 (<i>Puma Biotechnology ExteNET Reaction Mixed, but 8.6%pt Delta is Nice</i>, UBS (June 1, 2015) (PUMA00008909-10, at -09) (“Curve separation impressive”). • Auerbach Decl. Ex. 208 (<i>Puma Biotechnology, Inc. No Surprises in ExteNET Presentation – 3-Year Follow-Up Likely Closely Watched</i>, Leerink (June 2, 2015) (PUMA00002988-94, at -88) (reporting on “clearly separated disease-free survival (DFS) curves that persisted to widened somewhat from 1 to 2 years”). • Murphy Decl. Ex. 115 (<i>Puma Biotechnology ExteNET as Advertised, But Questions Remain on FDA Strategy and Market Oppy</i>, Cowen and Co. (June 1, 2015) (CW000035) (Dep. Ex. 326) (noting that “16.8% [of patients] required dose discontinuations”).
<p>129. On June 1, 2015 Puma’s stock opened at \$191.95 and closed at \$169.97 (down 11.5% or -\$21.98)</p>	<ul style="list-style-type: none"> • AC ¶ 75 (Dkt. No. 138).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>130. On June 2, 2015 Puma’s stock opened at \$169.97 to \$146.65 (down 13.7% or - \$23.32).</p>	<ul style="list-style-type: none"> • AC ¶ 75 (Dkt. No. 138).
<p>131. Plaintiff’s Investment Advisor, Capital International, purchased additional Puma stock on Plaintiff’s behalf after Abstract #508 was released on May 13, 2015.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 103 (Trade Blotter, Capital International (CII – 00001) (purchasing 2200 shares of Puma on May 14, 2015)).
<p>132. Plaintiff’s Investment Advisor, Capital International, purchased additional stock on Plaintiff’s behalf after the ExteNET ASCO presentation on June 1, 2015.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 105 (Trade Blotter, Norfolk Pension Fund (NORF0000991-92, at-91) (purchasing 1100 shares of Puma on June 1, 2015)). • Murphy Decl. Ex. 30 (Younger Tr. 33:21-35:8 (Q: Okay. So Norfolk has full discretionary authority over the purchase and sale of stock for its investors? A: No, it does not...Definitively, it does not have discretionary authority over the purchase and sale of individual lines of security. And I think you were referring to individual lines of stock. But to individual lines of stock, that fiduciary purchase and sales decision is what is outsourced to those investment managers, which in the case of Puma Bio is Capital’s discretion to have purchased or sold any

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>individual line of stock in their portfolio during the Puma Bio class period and, indeed, any other period going back to the inception of the fund in 1974...Q: So Norfolk itself does not make any decisions with regard to buying or selling securities? A: Individual lines of securities, no.”)).</p> <ul style="list-style-type: none"> • Murphy Decl. Ex. 85 (Investment Management Agreement Between Norfolk County Council as administering authority for Norfolk Pension Fund and Capital International Limited (NORF0000919-972)).
<p>133. After the ExteNET ASCO presentation on June 1, 2015, Skye Drynan, an analyst from Plaintiff’s investment advisor, Capital International, viewed Puma stock as a “strong buying opportunity.”</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 102 (CII WAC June 2, 2015 Call Summary (CII-00563-64, at -63) (“[Puma] [s]tock down 13% on June 1, 2015; [Skye Drynan] views as strong buying opportunity”)). • Murphy Decl. Ex. 8 (Drynan Tr. 139:1-4 (“Q. And the notes from the call suggest that the stock was down 13 percent on June 1st, but you still viewed this as a strong buying opportunity? A. Correct.”)).
<p>134. Skye Drynan, an analyst from Plaintiff’s investment advisor, Capital International, who recommended purchasing</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 8 (Drynan Tr. 39:4-12 (“Q: Do you believe Mr. Auerbach ever lied to you? A: I do not believe he ever lied to me. Q: Do you believe he ever misled you in any

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>Puma stock on Plaintiff’s behalf, testified that she does not believe she was misled, lied to, or defrauded by Mr. Auerbach.</p>	<p>way? A: I do not believe he ever misled me in any way. Q: Do you believe that he defrauded you in any way? A: No.”)).</p>
<p>135. On July 21, 2016, Puma announced that it had submitted its New Drug Application (“NDA”) for neratinib to the FDA.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 190 (8-K attaching press release titled, “Puma Biotechnology Submits New Drug Application for PB272 (Neratinib) to U.S. FDA for Extended Adjuvant Treatment of HER2-Positive Early Stage Breast Cancer” (July 21, 2016)).
<p>136. The NDA for neratinib was based primarily on the efficacy and safety data from the primary two-year analysis (Part A) of the ExteNET trial.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 39 (Walling Report ¶¶ 8, 53 (opining that Puma’s NDA and the FDA’s approval decision were based primarily on the efficacy and safety data from the primary analysis (Part A) of the ExteNET trial)). • Murphy Decl. Ex. 79 (Sponsor (Puma) Briefing Document for Oncologic Drugs Advisory Committee (PUMA00453097-248) (“The New Drug Application (NDA) for neratinib is supported by data from 31 clinical studies, including the pivotal ExteNET Trial, also referred to as Study 3004.”)). • Murphy Decl. Ex. 81 (FDA Briefing Document for Oncologic Drugs Advisory Committee (PUMA00281785 at -88) (“The efficacy of neratinib in support of this

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>indication is based on the results of Study 3004, a multicenter, randomized, double-blind, placebo-controlled trial of one year of neratinib versus placebo in women with early stage HER2-positive breast cancer after adjuvant treatment with trastuzumab.”)).</p>
<p>137. On May 24, 2017, the FDA’s Oncologic Drugs Advisory Committee (“ODAC”) voted to recommend approval of neratinib.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 80 (Oncologic Drugs Advisory Committee Meeting Transcript, Morning Session, May 24, 2017 (PUMA00281441-646 at -630-32, -634-37, -642)). • Auerbach Decl. Ex. 194 (Puma Form 8-K attaching press release entitled, “Puma Biotechnology Receives FDA Advisory Committee Support for Neratinib” (May 24, 2017) (“ODAC voted 12-4 to recommend approval of PB272 (neratinib) for the extended adjuvant treatment of HER2-positive early stage breast cancer based on finding that the risk-benefit profile of neratinib is favorable.”)).
<p>138. On July 17, 2017, the FDA approved neratinib (brand name Nerlynx®) for the extended adjuvant treatment of HER2+ breast cancer in all patient</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 195 (Puma Form 8-K (July 19, 2017)).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
subgroups, to follow adjuvant trastuzumab (brand name Herceptin®)-based therapy.	
139. As of April 30, 2018, physicians had ordered more than 2,400 new patient prescriptions for Nerlynx in the United States.	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 211 (Puma Biotechnology, Earnings Call Commercial Update (May 9, 2018)) at 6.
140. On June 29, 2018, the European Committee for Medicinal Products for Human Use (“CHMP”) adopted a positive opinion recommending market authorization for NERLYNX.	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 197 (Puma Form 8-K (June 29, 2018) (“Puma Biotechnology, Inc. (the ‘Company’) announced that the Committee for Medicinal Products for Human Use (‘CHMP’) of the European Medicines Agency (‘EMA’) adopted a positive opinion recommending marketing authorization for the medicinal product NERLYNX® (neratinib) for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab based therapy”).
141. Charles Eyler was not aware of the non-public ExteNET results as reflected in	<ul style="list-style-type: none"> • Murphy Decl. Ex. 9 (Eyler Tr. 193:11-13 (“To my recollection, I did not receive or

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
the July 22, 2014 press release and Abstract #508 until they were publicly released.	know of this information till the abstracts were released.”)).
142. Alan Auerbach did not sell any Puma common stock between July 22, 2014 and June 2, 2015.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 3 (Auerbach Tr. (Jan. 29, 2018) 882:21-24 (“Q: And at any point in time have you ever reported any loss due to a sale or holding of Puma stock? A: No. I’ve never sold.”)). • Auerbach Decl., ¶ 7.
143. Charles Eyler did not sell any Puma’s common stock between July 22, 2014 and June 2, 2015.	<ul style="list-style-type: none"> • Declaration of Charles Eyler, ¶ 3.
144. Mr. Auerbach’s compensation package was comprised of a salary, bonus, and stock options.	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 188 (Puma Form DEF14A (April 30, 2015) at 22). • Murphy Decl. Ex. 67 (Minutes of the Meeting of the Compensation Committee of the Board of Directors of Puma Biotechnology, Inc., December 15, 2014 (PUMA00000082) at -85-86).
145. Of Mr. Auerbach’s total compensation package in 2014, his salary represented approximately 3.4%, bonus, approximately 1.7%, and stock options, approximately 94.8%.	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 188 (Puma Form DEF14A (April 30, 2015) at 22. <ul style="list-style-type: none"> ○ Total 2014 compensation: \$17,797,606 ○ 2014 Salary: \$610,000 ○ 2014 Bonus: \$300,000 ○ 2014 Option Award: \$16,876,576

UNCONTROVERTED FACT	EVIDENCE
	<ul style="list-style-type: none"> ○ 2014 All Other Compensation: \$11,030) ● Murphy Decl. Ex. 67 (Minutes of the Meeting of the Compensation Committee of the Board of Directors of Puma Biotechnology, Inc., December 15, 2014 (PUMA00000082) at -85-86, -88).
<p>146. On December 15, 2014, Mr. Auerbach was granted options to purchase 150,000 shares of Puma stock that, once vested, he could exercise at a price of \$195.33 per share.</p>	<ul style="list-style-type: none"> ● Auerbach Decl. Ex. 188 (Puma Form DEF14A (April 30, 2015) at 23). ● Murphy Decl. Ex. 67 (Minutes of the Meeting of the Compensation Committee of the Board of Directors of Puma Biotechnology, Inc., December 15, 2014 (PUMA00000082) at -88).
<p>147. Of Mr. Auerbach’s stock options granted on December 15, 2014, one-third vested on September 1, 2015, and one-thirty-sixth vested on a monthly basis thereafter.</p>	<ul style="list-style-type: none"> ● Auerbach Decl. Ex. 188 (Puma Schedule 14A (April 30, 2015) at 25, note 5 (“One-third of the option vests on the first anniversary of the vesting commencement date of September 1, 2014 and then one thirty-sixth monthly thereafter, subject to continued service.”)). ● Murphy Decl. Ex. 67 (Minutes of the Meeting of the Compensation Committee of the Board of Directors of Puma Biotechnology, Inc., December 15, 2014 (PUMA00000082) at -88).
<p>148. Of Mr. Eyler’s total compensation package in 2014,</p>	<ul style="list-style-type: none"> ● Auerbach Decl. Ex. 188 (Puma Form DEF14A (April 30, 2015) at 22.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>his salary represented approximately 6.8%, bonus, approximately 2.6%, and stock options, approximately 90.3%.</p>	<ul style="list-style-type: none"> ○ Total 2014 compensation: \$4,499,559 ○ 2014 Salary: \$304,336 ○ 2014 Bonus: \$117,610 ○ 2014 Option Award: \$4,061,879 ○ 2014 All Other Compensation: \$15,734) <ul style="list-style-type: none"> ● Murphy Decl. Ex. 65 (Unanimous Written Consent of the Compensation Committee of the Board of Directors of Puma Biotechnology, Inc., November 19, 2014 (PUMA00000162) at -62-65, -69).
<p>149. On November 19, 2014, Mr. Eyler was granted options to purchase 31,500 shares of Puma stock that, once vested, he could exercise at a price of \$223.32 per share.</p>	<ul style="list-style-type: none"> ● Auerbach Decl. Ex. 188 (Puma Form DEF14A (April 30, 2015) at 23). ● Murphy Decl. Ex. 65 (Unanimous Written Consent of the Compensation Committee of the Board of Directors of Puma Biotechnology, Inc., November 19, 2014 (PUMA00000162) at -62-63, -69).
<p>150. Of Mr. Eyler’s options that were granted on November 19, 2014, one-third vested on September 1, 2015, and one-thirty-sixth vested on a monthly basis thereafter.</p>	<ul style="list-style-type: none"> ● Auerbach Decl. Ex. 188 (Puma Form DEF14A (April 30, 2015) at 25, note 9). ● Murphy Decl. Ex. 65 (Unanimous Written Consent of the Compensation Committee of the Board of Directors of Puma Biotechnology, Inc., November 19, 2014 (PUMA00000162) at -69).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>151. On June 1, 2015, Puma’s stock price closed at \$169.97, below the exercise price of the stock options that were awarded to Mr. Auerbach on December 15, 2014, and to Mr. Eyler on November 19, 2014. Since that date, Puma’s stock price has not risen above the exercise price of their stock options.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 163 (Yahoo! Finance historical stock price chart, PBYI).
<p>152. For Puma’s fiscal year 2014, the Compensation Committee of Puma’s Board of Directors had the sole discretion to determine the bonus and equity compensation of Puma’s executive officers, including Mr. Auerbach.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 192 (Compensation Committee Charter, http://www.pumabiotechnology.com/docs/062013_Compensation_Committee_Charter.pdf.)
<p>153. Mr. Auerbach’s and Mr. Eyler’s compensation packages were not tied to Puma’s stock price or the results of the ExteNET trial.</p>	<ul style="list-style-type: none"> • Auerbach Decl. Ex. 188 (Puma Form DEF14A (April 30, 2015) at 19-20). • Murphy Decl. Ex. 15 (Malley Tr. 204:9-18 (“Q. And what do you understand is meant by “performance highlights”? A. For me it would be did the company execute on the plan that Alan would have given to us at the beginning of the year. In this document, it references a stock price, but the stock price

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>was not a consideration of the board committee. Q. Why not? A. Because stocks go up and down.”); 204:19-205:16 (“Q. And next one, the board refers in July 2014, we announce positive top-line results from the Phase III clinical trial. Do you see that? A. Yes. Q. Is that something that was considered by the compensation committee? A. It was considered but -- and certainly was a positive, but at the beginning of the year, that wasn’t one of the requirements. The requirement was to execute on the trial and do a good job of running the trial, but as I mentioned, the best guess with an unknown situation was that the trial would continue. And so if the trial had continued but we determined that the company was doing a good job, this is speculation, but I believe the board would have still awarded Alan his whole bonus and his normal stock option grant, if the trial had not been successful but was just continuing ongoing. So in the end, I believe that the fact that the trial was successful and stopped and a press release was announced did not change the compensation that he received that year.”)).</p>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
<p>154. Puma has received interest from potential acquirers before, during, and after the class period.</p>	<p>• Murphy Decl. Ex. 3 (Auerbach Tr. (Jan. 29, 2018) 793:11-794:1 (“Q. Between July 22nd, 2014, and the ASCO conference in June of 2015, did you engage any conversations with anyone about potentially selling Puma? A. We always had interest in larger companies talking to us. There was not anyone who would say, ‘Yes, we are definitely interested in this acquiring the company.’ There were always preliminary indications that people were interested, but we never put anybody under a CDA, we never hired a bank. Conversations always occur between large companies and small companies, and they can be people interested in the buying company, they could be people interested in partnering with the company, or it could morph into other things.”); 796:10-16 (“Q. And as you sit here today, can you identify for us the name of any company that you told the board had made an overture to potentially acquire Puma? A. Oh, I don't remember which ones we had back 2000 -- 2014 or ‘15, but over the years, there's been many of them.”); 800:12-16 (“Q. Would that have been after the full ExteNET data was presented? A. The data would have been presented in May of -- June</p>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	<p>of 2015. But meetings continued after that.”); 811:13-16 (“Q. And between June 1st, 2015, and today, has Puma entered into a CDA with any company with regard to a potential acquisition or partnership? A. Yes, we have.); 811:20-812:1 (Q. Were they interested in acquisitions of Puma? A. Their intent was not fully stated. Their intent has been partnerships. Their intent has been acquisitions. We have also entered into CDAs with roughly ten companies on partnerships as well.”).</p>
<p>155. Analyst commentary is a critical component of the loss causation analysis.</p>	<ul style="list-style-type: none"> • Murphy Decl. Ex. 33 (Feinstein Report ¶¶ 34, 37 (citing and relying on analyst reports)). • Murphy Decl. Ex. 36 (Gompers Report ¶ 44 (“To establish loss causation with respect to Facts 3 and 4, a sound analysis should demonstrate that the public release of Facts 3 and 4 generated concerns among market participants or among groups of people whose opinion matters to market participants that were significant enough to trigger a stock price adjustment.”)). • Murphy Decl. Ex. 11 (Gompers Tr. 102:3-10 (“A: Again, in terms of understanding how

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNCONTROVERTED FACT	EVIDENCE
	the market’s expectations for neratinib were changing, the critical documents to look at are the analyst reports around the alleged corrective disclosure date...”).
156. Puma’s stock traded in an efficient market during the Class Period.	<ul style="list-style-type: none"> • Murphy Decl. Ex. 33 (Feinstein Report ¶ 1 (“I concluded that Puma Biotechnology, Inc. [] common stock traded in an efficient market”)). • Murphy Decl. Ex. 31 (Feinstein Class Certification Report ¶ 29 (“An efficient market . . . is a market in which available information is rapidly incorporated into the price of a security”)).

1 **II. CONCLUSIONS OF LAW**

2 1. To avoid summary judgment, Plaintiff must adduce evidence from
3 which a rational trier of fact could find in its favor on each element of its claims.
4 *Celotex Corp. v. Catrett*, 477 U.S. 317, 325-28 (1986).

5 2. To prevail on each claim asserted under Section 10(b) and Rule 10b-5,
6 Plaintiff must establish a misstatement or material omission, made with scienter,
7 that caused its alleged losses. *Provenz v. Miller*, 95 F.3d 1376, 1382 (9th Cir.
8 1996). Each of Plaintiff’s alleged claims fails as a matter of law.

9 3. Defendants’ statements that the ExteNET trial met its primary
10 endpoint by demonstrating a “33% improvement in DFS” were neither false nor
11 materially misleading by omission. *See Omnicare, Inc. v. Laborers Dist. Council*
12 *Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1329 (2016) (explaining that in order
13 to render an otherwise true statement misleading, the omitted fact must “conflict
14 with what a reasonable investor would take from the statement itself”); *Matrixx*
15 *Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 30 (2011) (stating that the federal
16 securities laws “do not create an affirmative duty to disclose any and all material
17 information”); *Kleinman v. Elan Corp.*, 706 F.3d 145 (2d Cir. 2013) (holding that
18 defendants’ statements regarding clinical trial results were not false or misleading
19 simply because statements did not also disclose additional data urged by plaintiff).

20 4. Mr. Auerbach’s statement on Puma’s July 22, 2014 conference call
21 that he was comfortable with the ranges of DFS rates posed by analyst Yaron
22 Werber was neither false nor materially misleading by omission. *Pompano Beach*
23 *Police & Firefighters’ Ret. Sys. v. Las Vegas Sands Corp.*, 2018 WL 2015510, at
24 *2 (9th Cir. May 1, 2018) (to be misleading, statement must have “affirmatively
25 create[d] an impression of a state of affairs that differ[ed] in a material way from
26 the one that actually exist[ed]”) (quoting *Brody v. Transitional Hosps. Corp.*, 280
27 F.3d 997, 1006 (9th Cir. 2002)).

28

1 5. Mr. Auerbach’s statement about a preliminary trend of continuing
2 separation of the Kaplan-Meier (“KM”) curves was neither false nor materially
3 misleading by omission. *See McGonigle v. Combs*, 968 F.2d 810, 817-19 (9th Cir.
4 1992) (affirming grant of summary judgment where statements contained “specific
5 disclaimers” and were “openly hypothetical [in] nature”).

6 6. Mr. Auerbach’s statements that the grade 3+ diarrhea rate was 29%-
7 30% and that the dropout rate due to adverse events was 5%-10% were neither
8 false nor materially misleading by omission. *See Vaughn v. Teledyne, Inc.*, 628
9 F.2d 1214 (9th Cir. 1980) (granting summary judgment for defendants as
10 projections made without reasonable certainty should not be released to the
11 public).

12 7. Defendants did not act with scienter—the “intent to deceive,
13 manipulate, or defraud”—when they announced the top-line study results from the
14 ExteNET trial on July 22, 2014, and then reiterated the top-line study results
15 thereafter. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 & n.12 (1976). Mr.
16 Auerbach did not act with scienter when he made the challenged statements on the
17 July 22, 2014 conference call. *Id.*

18 8. Plaintiff cannot recover losses associated with the stock price drop on
19 May 14, 2015 because they have not presented sufficient evidence from which a
20 rational trier of fact could find that statements regarding the DFS rates or safety
21 data disclosed in Abstract #508 were materially false or misleading, or made with
22 scienter. 15 U.S.C. § 78j; 17 C.F.R. § 240.10b-5. Plaintiff likewise cannot recover
23 losses associated with the stock price drop on June 1, 2015 because they have not
24 presented sufficient evidence from which a rational trier of fact could find that
25 statements regarding the KM curves or discontinuation rates disclosed at ASCO
26 were materially false or misleading, or made with scienter. 15 U.S.C. § 78j; 17
27 C.F.R. § 240.10b-5.

28

1 9. The allegedly “corrective” information (the KM curves and 16.8%
2 diarrhea discontinuation rate) disclosed at the American Society of Clinical
3 Oncologists (ASCO) annual conference did not cause Puma’s stock price decline
4 on June 1 or 2, 2015. *See Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345-46
5 (2005) (quoting 15 U.S.C. § 78u-4(b)(4)); *Mineworkers’ Pension Scheme v. First*
6 *Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018) (per curiam); *In re Merck & Co., Inc.*
7 *Sec. Litig.*, 432 F.3d 261, 269-71 (3d Cir. 2005) (public information is absorbed
8 into a stock price “in the period immediately following disclosure”).

9 10. Defendants are not liable as “control persons” under Section 20(a)
10 because Plaintiff cannot prove a primary violation of Section 10(b). *See* 15 U.S.C.
11 § 78t(a).

12
13 Dated: July 10, 2018

LATHAM & WATKINS LLP

14 By: /s/ Michele D. Johnson

15 Michele D. Johnson
16 Andrew Clubok
17 Colleen C. Smith
18 Sarah A. Tomkowiak
19 Kristin N. Murphy

20 COOLEY LLP
21 Michael A. Attanasio (Bar No. 151529)
22 Koji F. Fukumura (Bar No. 189719)
23 Ryan E. Blair (Bar No. 246724)
24 Mary Kathryn Kelley (Bar No. 170259)
25 Craig E. TenBroek (Bar No. 287848)
26 440 Eastgate Mall
27 San Diego, CA 92121
28 Tel: (858) 550-6000
Fax: (858) 550-6420
mattanasio@cooley.com
kfukumura@cooley.com
rblair@cooley.com
mkkelley@cooley.com
ctenbroeck@cooley.com

*Attorneys for Defendants Puma Biotechnology,
Inc., Alan H. Auerbach, and Charles R. Eyler*