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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HONORABLE ANDREW J. GUILFORD, JUDGE PRESIDING

HSINGCHING HSU,)	
)	
)	
)	
Plaintiff,)	
)	
)	
)	
Vs.)	No. SACV15-0865-AG
)	
)	
PUMA BIOTECHNOLOGY, ET AL,)	
)	
)	
)	
Defendants.)	
)	
)	

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL, DAY 1

OPENING STATEMENTS

SANTA ANA, CALIFORNIA

TUESDAY, JANUARY 15, 2019

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A P P E A R A N C E S

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IN BEHALF OF THE PLAINTIFF,
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ALSO PRESENT: ALEX YOUNGER
ALAN AUERBACH

1 SANTA ANA, CALIFORNIA; TUESDAY, JANUARY 15, 2019; 2:40 P.M.

2 ---

3 (Open court - jury present)

4 THE COURT: Welcome, ladies and gentlemen of the
5 jury. What a fine-looking jury. I've come to appreciate a
6 little bit about you, hearing from you, from our World Trade
7 Center person to our Trojan to lots of folks out there.

8 So, I said that I was going to begin by reading
9 jury instructions, but I think on the first day you should
10 hear both sides' opening statements. Therefore, I'm going to
11 read the jury instructions tomorrow when we start at 8:00.
12 We're going to conclude today all the way until 4:30 or a
13 little bit after 4:30 hearing the opening statement from each
14 side.

15 Now, in the jury instructions I'll say that you're
16 to rely on evidence, and attorneys' statements are not
17 evidence. They're there to help you through the evidence,
18 but don't consider attorneys' statements evidence. That will
19 be the instructions tomorrow. But for now Ms. Bredahl, has
20 some work to do.

21 THE CLERK: Please stand and raise your right hand.

22 (Jury sworn)

23 THE COURT: Anyone have any problem with that oath?
24 Okay. I see none, so we're ready to go. Again, jury
25 instructions tomorrow. We'll go until a little after 4:30

1 today and start with jury instructions tomorrow at 8:00.

2 So we'll turn to the plaintiff. Who will we hear
3 from? All right. Please step forward. As you like.

4 MR. FORGE: Thank you, Your Honor.

5 THE COURT: Proceed.

6 Opening statement.

7 MR. FORGE: July 22nd, 2014, was a
8 character-defining day for Alan Auerbach, because that was
9 the day he had to choose between integrity and easy money.
10 We are all here, ladies and gentlemen, because Mr. Auerbach
11 chose easy money.

12 THE COURT: Be a little careful on argument.

13 Go ahead.

14 MR. FORGE: July 22nd, ladies and gentlemen, was
15 the day Mr. Auerbach announced the results of a study of an
16 experimental cancer treatment called neratinib. He chose
17 easy money that day by telling investors, doctors, everyone,
18 that neratinib was twice as good and half as bad as it really
19 was.

20 The reason why neratinib was so important, as you
21 will learn, ladies and gentlemen, is because the company that
22 Mr. Auerbach founded and his codefendant in this case, Puma
23 Biotech, a company in which Mr. Auerbach was the single
24 largest individual shareholder, had only one product --
25 neratinib.

1 Neratinib was doubly important to Mr. Auerbach and
2 Puma Biotech because they didn't create it. Mr. Auerbach has
3 never created a cancer treatment; neither has Puma Biotech.

4 Mr. Auerbach is a former Wall Street analyst who
5 raised money from investors to license the rights to
6 neratinib from Pfizer. So neratinib was not only Puma's lone
7 product. They had no capability of developing a different
8 product. So Mr. Auerbach and Puma were betting on neratinib
9 to be a blockbuster drug.

10 But as you will learn, ladies and gentlemen, by mid
11 July 2014 Mr. Auerbach knew that neratinib was not a
12 blockbuster. You will see throughout this trial, ladies and
13 gentlemen, actual e-mails, the actual results that
14 Mr. Auerbach received, e-mails such as this one -- and I know
15 that monitor is a little blurry, ladies and gentlemen, but
16 you have monitors on both sides of the jury box also.

17 This is a July 15th e-mail from a man named Alvin
18 Wong, who is a co-worker at Puma Biotech. He will testify
19 for you. He's telling Mr. Auerbach the results are coming
20 tomorrow. You can see in here there's a reference in this
21 e-mail to safety analysis. And one of the terms you're going
22 to hear in this case, safety analysis, safety is kind of a
23 euphemism for side effects.

24 I'm going to talk to you about various terms as I
25 go over this preview of evidence, and I want to give you

1 those terms in context so it's easier to understand and sink
2 in. So on July 15th, Alvin Wong is basically telling
3 Mr. Auerbach, get ready, the top-line analysis is coming
4 tomorrow. And you can see in here there's a reference to
5 efficacy.

6 Okay. Efficacy is another kind of fancy term for
7 the effectiveness, the benefits of the drug. And you'll see
8 sure enough, just as he said he would, on July 16th, 2014,
9 Mr. Wong e-mailed Mr. Auerbach all of the top-line efficacy
10 analysis, all of the information about how good this drug is.

11 On July 17th, after Mr. Auerbach told him to send
12 the results to a wider audience, that's exactly what Mr. Wong
13 did. He sent the same efficacy or benefits results to
14 additional people at Puma. You are going to see those actual
15 results, ladies and gentlemen. You are going to get the
16 opportunity to contrast them with what Mr. Auerbach wound up
17 telling people on July 22nd.

18 On July 18th, as Mr. Wong had also promised, he
19 sent Mr. Auerbach the top-line safety results -- again, the
20 side effects. Now, you're going to hear a lot about benefits
21 and side effects. It's easy to keep track of those being how
22 good the drug is, how much bad the drug does. You'll see
23 those actual side effects.

24 So what the evidence is going to show here, ladies
25 and gentlemen, is a stark contrast between what Mr. Auerbach

1 knew and what he said on July 22nd. That was the
2 character-defining day to which I'm referring. And make no
3 mistake, ladies and gentlemen. This was not a casual,
4 water-cooler kind of encounter. This was a call with
5 financial analysts, a call that Mr. Auerbach chose to have,
6 chose to host for the purpose essentially of promoting Puma
7 Biotech by virtue of releasing these results.

8 So, those results. What the evidence will show --
9 and this is not by inference. This is by direct documents,
10 by direct eyewitness testimony -- is that Mr. Auerbach knew
11 that neratinib delivered only a marginal benefit,
12 2.3 percent. That 2.3 percent figure, ladies and gentlemen,
13 is going to be referred to as the absolute benefit, absolute
14 difference. What it represents is the percentage of patients
15 who take neratinib who had actually derived a benefit from
16 it -- 2.3 percent.

17 Another way of looking at it, ladies and gentlemen,
18 is the difference in patients who take neratinib versus
19 patients who take a placebo. Let's talk about placebo right
20 now. Remember, July 22nd was the day Mr. Auerbach was
21 announcing the results of a study.

22 That study is known as the ExteNET study. It's a
23 multi-year study involving dozens of countries and literally
24 thousands of patients. There are two groups of patients in
25 this study. One is the neratinib group, the group of

1 patients who actually receive the drug being tested. The
2 other is referred to as the placebo group. That's the group
3 of patients who receive a sugar pill.

4 So what the study does is it tracks the progress of
5 these patients. And this acronym here, DFS, as in DFS rates,
6 stands for disease-free survival. So what this study is
7 measuring is what percentage of people went through a
8 one-year period of time on neratinib and then another year on
9 top of that. At the end of those two years, what percentage
10 of those patients did not have a recurrence of cancer?

11 It's important to keep in mind that even though DFS
12 stands for disease-free survival, it's not a life-or-death
13 statistic. It is a measure of whether anyone had a
14 recurrence of cancer.

15 So what Mr. Auerbach knew and what you will see in
16 black and white is that the difference in the DFS rates
17 between the placebo group and the neratinib group was
18 2.3 percent. However, you will hear the actual analyst call.
19 You will see the transcript. And you will hear and see that
20 Mr. Auerbach led people to believe that the actual absolute
21 benefit was four to five percent, twice as good, with DFS
22 rates of 86 percent for the placebo group, 90 to 91 percent
23 for the neratinib group.

24 Here's a clip of that audio which you'll hear in
25 this case.

1 (Audiotape recording played)

2 MR. FORGE: Okay. So that's a placeholder for you,
3 ladies and gentlemen. I would be comfortable with that
4 number. You could hear it. You can see it. The last number
5 given was 86 percent. So we've got that locked in. The
6 control arm is also another term used for the placebo group.
7 So we've got 86 percent locked in for the placebo group.

8 Then this analyst inquires further.

9 (Audiotape recording played)

10 MR. FORGE: So the question of what you had to
11 show, that's a reference to the neratinib group. So what
12 he's saying is, so 86 percent in the placebo group. And you
13 had to show 90 -- you must have shown 90 or 91 percent in the
14 neratinib group.

15 Now, this 33 percent improvement figure, let me
16 give you a little context for that. That is a figure that
17 Mr. Auerbach and Puma announced in a press release. This
18 number, this 33 percent, is known as a relative risk
19 reduction. I emphasized that word relative because it's very
20 important to keep it in mind.

21 Let me give you an example to fully understand why
22 it's important to keep that relativity in mind. Imagine if I
23 was selling a lead helmet for \$5,000, and I told you: Ladies
24 and gentlemen, step right up. This lead helmet will reduce
25 your risk of being killed by lightning by 33 percent.

1 Well, a 33 percent reduction in the risk of being
2 killed by lighting, that relative risk is 33 percent, but the
3 actual benefit you get from this lead helmet which would
4 carry with it side effects like back problems and neck
5 problems is so marginal that people probably wouldn't step
6 right up and buy my \$5,000 lead helmet.

7 So this 33 percent risk reduction, relative risk
8 reduction, is critical to understand in the context of these
9 numbers that Mr. Auerbach was agreeing to in providing that
10 day, because -- I know we have an accountant here, so
11 everyone will be able to appreciate when you start off with
12 being comfortable with that number of 86 percent with a
13 placebo group -- remember, that's 86 percent who did not have
14 a recurrence -- that means there are 14 percent that did have
15 a recurrence.

16 So that's the risk that's being reduced, and that's
17 why this analyst is able to do the math, because -- and
18 that's why Mr. Auerbach confirms the math. So if you do a
19 33 percent reduction in that 14 percent figure, okay,
20 33 percent of 14 percent is just under five percent. It's
21 between four and five percent.

22 So that's why all he did was add the four to
23 five percent to the 86 percent, and Mr. Auerbach confirmed
24 that, yes, I think you can do a 33 percent improvement in DFS
25 and come up with that calculation, given the numbers we gave.

1 That's all a long way of demonstrating that Mr. Auerbach led
2 investors to believe that neratinib was delivering an
3 absolute benefit of four to five percent instead of
4 2.3 percent.

5 Now, the evidence will show that Mr. Auerbach also
6 knew that the absolute benefit was not improving at the very
7 end of that two-year period. These little squiggly lines
8 here, ladies and gentlemen, are called KM curves. That
9 stands for Kaplan-Meier curves. Basically these are curves
10 that just track the disease-free survival in both groups over
11 time.

12 So obviously if they want neratinib to be a
13 blockbuster, they want that benefit to be widening over time.
14 As you will see, those curves ended at two years, technically
15 two years and 28 days, but I'm going to shorthand it and call
16 it two years. Those curves ended at two years, and they're
17 not separating at the end of two years. The absolute benefit
18 is not improving at the end of two years.

19 This exhibit, this Exhibit 123, that is a graph
20 you're going to see in this case, ladies and gentlemen. But
21 despite seeing this graph and knowing this information, on
22 July 22nd Mr. Auerbach led investors to believe that the
23 absolute benefit was getting better at the end of two years
24 and that those curves were continuing to separate at and
25 after two years.

1 (Audiotape recording played)

2 MR. FORGE: Ladies and gentlemen, the one thing
3 Mr. Auerbach is not going to be accused of in this case, and
4 that is being dumb. He's very smart. He's a former analyst,
5 and he knows how to push the right buttons. So he uses words
6 like we're seeing preliminary trends and couches his
7 statements with that type of language. But the message is
8 crystal clear. The curves appear to be continuing to
9 separate as you go out year over year. We're seeing the same
10 preliminary trend.

11 The trend he just referred to was six percent at
12 two years, seven percent at three years, eight percent at
13 four years. As you will see, ladies and gentlemen, that
14 simply was not true. Now, that's the good. That's what I
15 mean when I say twice as good as it really was.

16 Let's talk about the bad, the side effects. The
17 evidence will show that Mr. Auerbach knew that the
18 grade-three diarrhea rate for neratinib users was
19 39.9 percent. Let me talk to you about that particular type
20 of diarrhea. This is -- a grade-three diarrhea is a
21 debilitating diarrhea. It means seven bowel movements per
22 day over a baseline. It can include incontinence, possible
23 hospitalization.

24 It is a very significant side effect. It does not
25 mean it happened throughout the full year of treatment, but

1 it is a huge factor for patients or potential patients,
2 because, remember, this is an experimental drug to consider.
3 It is also a factor to consider regarding the market
4 potential of this drug, and that's something that you need to
5 keep in mind throughout this case, ladies and gentlemen.

6 There's nothing wrong with Puma Biotech trying to
7 make a profit off of selling cancer treatment, but at the end
8 of the day that is what the purpose is. It's to sell as much
9 of this drug as possible.

10 Now, this rate was 39.9 percent, which means
11 40 percent of the people in the neratinib group suffered
12 grade-three diarrhea at some point during their year of
13 treatment. Now, Mr. Auerbach said -- and I'll show you a
14 video of him saying it -- he admitted that he had gone over
15 the safety results with a fine-tooth comb.

16 This is a clip from a deposition taken in this
17 case. You can see this is the actual document that he
18 received from Alvin Wong on July 18th showing quite clearly
19 the grade-three diarrhea rate was 39.9 percent. This was the
20 data and the results to which Mr. Auerbach was referring when
21 he provided this admission.

22 (Videotape recording played)

23 MR. FORGE: So he went through it with a fine-tooth
24 comb on July 18th. On July 22nd this is how he answered
25 questions regarding grade-three diarrhea. He said, first of

1 all, that Puma had not even seen the safety results from the
2 ExteNET trial.

3 (Audiotape recording played)

4 MR. FORGE: Later he said that they anticipated
5 that the rate of grade-three diarrhea would be 29 to
6 30 percent. Again, this is a smart person. He's trying to
7 couch things with saying anticipated. But as you will see,
8 throughout this case, deception comes in many forms. Telling
9 someone something is anticipated when he knows it not to be
10 true is deceptive.

11 (Audiotape recording played)

12 MR. FORGE: You can see the contrast, ladies and
13 gentlemen. You can hear for yourself, and you will hear
14 throughout this trial.

15 Now, the last of these four categories of results
16 and the second of the how-bad-is-it category, the evidence
17 will show that Mr. Auerbach knew that 16 percent of the
18 neratinib users, the people in the neratinib group,
19 discontinued the drug due to the diarrhea side effect alone
20 and that 27.6 percent discontinued due to all AEs. AE is
21 another acronym. Stands for adverse event. It's another
22 fancier way of saying side effects.

23 So he knew unequivocally because he received this
24 information, went through it with a fine-tooth comb, and the
25 varied tables that he received showed that 16.8 percent of

1 the neratinib group discontinued treatment due to diarrhea
2 alone and 27.6 percent due to all side effects.

3 Here's what he told analysts: That he anticipated
4 -- again, anticipated -- the dropout rate in the neratinib
5 arm due to adverse events would be in the 5 to 10 percent
6 range.

7 (Audiotape recording played)

8 MR. FORGE: Anticipate 5 to 10 percent. He knew it
9 was 27.6 percent.

10 So as we've discussed, from July 16th through 18th,
11 2014, Mr. Auerbach and the ExteNET team were poring over
12 those results. On July 22nd, 2014, Mr. Auerbach had that
13 conference call and he knew that neratinib was not a
14 blockbuster, but he led investors to believe that it was.

15 The very next day, on July 23rd, the price of Puma
16 stock skyrocketed from \$59 per share prior to these
17 announcements to \$233 per share by the close of trading on
18 July 23rd, 2014.

19 So what Mr. Auerbach knew was that neratinib was
20 not a blockbuster drug. He knew it had marginal benefits
21 with major side effects, only a 2.3 benefit that, remember,
22 was not a lifesaving benefit. In fact, four neratinib
23 patients died versus two placebo patients.

24 There was an offhand remark earlier about neratinib
25 curing breast cancer. That is simply not true. Forty

1 percent of patients suffered debilitating diarrhea. I went
2 over that earlier. Almost all grade-three diarrhea. There
3 was one instance of grade-four. That's seven bowel movements
4 per day over an average. Potential incontinence. Potential
5 hospitalization. 27 percent discontinued due to side
6 effects; 16.8 percent due to diarrhea alone. 46 percent
7 suffered vomiting. They were hoping to eventually sell all
8 of this for \$10,000 per month per patient.

9 So the contrast between what Mr. Auerbach knew and
10 what he said could not be more stark. We've been over these
11 figures. The last one on here, those Kaplan-Meier curves,
12 again you will see all this evidence. You don't have to take
13 my word for it. You will see for yourselves.

14 What Mr. Auerbach knew was laid out in
15 black and white and what he said is laid out in
16 black and white and on audio.

17 Now, the evidence will show that the primary goal
18 for doing this was a \$218 million stock offering that
19 Mr. Auerbach and Puma started pursuing immediately. As you
20 might imagine, a biotech company whose only product is an
21 experimental drug, there's no revenues coming in. So Puma
22 had to raise money to continue studying this drug. They
23 needed more money.

24 It's a lot easier to raise money when prospective
25 investors think they're raising money to develop a

1 blockbuster drug versus raising money to develop a marginal
2 drug with major side effects. But this doesn't happen
3 overnight. A stock offering takes time because the
4 underwriters, banks, conduct marketing for the offering.
5 They go out and solicit their clients and try to interest
6 them in the company and its loan product. And they conduct
7 due diligence.

8 Now, just because neratinib wasn't a blockbuster
9 didn't mean Puma and Mr. Auerbach weren't going to try to
10 treat it as if it was a blockbuster. You will see that in
11 July -- I'm sorry -- in August of 2014 Puma pursued what's
12 called a breakthrough therapy designation with the FDA.

13 You'll see that breakthrough therapies have two
14 basic requirements. First, they must treat a serious or
15 life-threatening disease or condition. Clearly neratinib
16 satisfied that criterion.

17 Second, and this is directly from the FDA's
18 definition, second, preliminary clinical evidence must
19 indicate that the drug may demonstrate substantial
20 improvement over existing therapies. The clinical evidence
21 just has to show the potential to be a substantial
22 improvement over existing therapies.

23 So in August of 2014, Puma submitted a preliminary
24 request for breakthrough designation to the FDA. The next
25 month, on September 23rd, 2014, Mr. Auerbach and several

1 other Puma employees had a telephonic meeting with the FDA.
2 During that meeting the FDA told them that 2.3 percent
3 absolute benefit was not sufficient for a breakthrough
4 designation. We know that because one of the employees at
5 this meeting took handwritten notes there.

6 You'll see those handwritten notes in this trial,
7 ladies and gentlemen, and you'll see the date at the top, the
8 attendees. Alan's name is the second one. And at the very
9 bottom of that page, 2.3 percent improvement in DFS not
10 enough for breakthrough.

11 So the FDA told Puma essentially that these results
12 don't even show a potential for a substantial improvement
13 over existing therapies. Puma didn't even disagree. The
14 very next day Puma employee Christine Woods wrote the FDA and
15 said: We appreciate you sharing your recommendations, and we
16 will follow them. We do not intend to submit a formal
17 breakthrough therapy designation for this neratinib
18 indication. No dispute.

19 Now, just because neratinib was not going to be a
20 blockbuster didn't mean the process with the FDA grinds to a
21 halt. There are many mediocre drugs in the world. So
22 there's -- the process continued, and you will learn that
23 part of that process involves submitting information to the
24 FDA and meeting with the FDA.

25 And after the next meeting with the FDA, after Puma

1 had submitted certain results to the FDA, the FDA generated
2 the official minutes of that meeting. The meeting took place
3 on November 25th, 2014. On December 15th, 2015, the FDA sent
4 Puma the official minutes of that meeting. You'll see those
5 actual minutes. You'll see that that very same day,
6 Mr. Auerbach received his copy of those official minutes
7 which were electronically signed by two FDA employees, same
8 day, December 15th, 2014, same FDA cover letter, same
9 reference to these being the official minutes of this
10 government entity.

11 The evidence will show, ladies and gentlemen, that
12 these official minutes posed a due diligence problem for
13 Mr. Auerbach because those FDA minutes reflected the true
14 absolute benefit from the ExteNET study, because those
15 official minutes showed the actual DFS rates, the very same
16 DFS rates Mr. Auerbach had misled people about on July 22nd.

17 The reason why that posed a due diligence dilemma
18 is because one of the things that the banks, the underwriters
19 for this offering, want to see as part of due diligence are
20 any material or important communications with the FDA. That
21 includes FDA meeting minutes, official FDA meeting minutes.

22 Now, you will see as part of that due diligence
23 process, the lawyer for the underwriters, a man named William
24 Hicks, Bill Hicks, signed a nondisclosure agreement. He
25 signed that nondisclosure agreement on November 10th, 2014.

1 That assured Mr. Auerbach and Puma they could rely on
2 Mr. Hicks to keep in confidence any of the information that
3 they provided to him.

4 You will also learn that Mr. Hicks had done deals
5 with them before, so there was absolutely no reason for them
6 not to trust Mr. Hicks with the true information. You will
7 see these official meeting minutes. You will see in them the
8 references to DFS rates.

9 What you will also see, ladies and gentlemen, is
10 that Mr. Auerbach solved his due diligence dilemma by
11 creating phony FDA minutes. You will see that on
12 January 6th, 2015, at 11:15 at night Mr. Auerbach created a
13 phony set of the FDA minutes. Some of you may have heard the
14 term metadata before. You will see in this trial metadata,
15 which is basically like a digital fingerprint for an
16 electronic file.

17 The metadata for these phony FDA minutes show that
18 Mr. Auerbach created them at 11:15 at night, lists him as the
19 author, and the creation time and date as 11:15 at night on
20 January 6th, 2015. Here you can see on the left-hand side
21 the original. It reported that the placebo group had a DFS
22 rate of 8.4 percent. He deleted that sentence right in the
23 middle of the paragraph and then the rest of the paragraph
24 also. The one on the right is the phony document.

25 You will see the actual DFS chart, the efficacy

1 chart that he had received on July 16th and July 17th. No
2 question about the accuracy of these figures. Those 93.9
3 percent and 91.6 percent figures, they reveal that marginal
4 2.3 percent benefit. He deleted the entire table. So he
5 made all these revisions to the official FDA meeting minutes,
6 and he did it without leaving a trace -- re page-numbered
7 them, kept the electronic signatures on them.

8 You're going to see the phonies, and you're going
9 to see the real ones. And I can assure you that you're not
10 going to be able to tell from the phony ones that anybody had
11 monkeyed around with them. That's how good of a job he did
12 at 11:15 at night on January 6, 2015.

13 He even changed a no answer from the FDA to a yes
14 answer to one of the questions. So you'll see that he
15 deleted and rewrote entire sections of the FDA minutes to
16 remove all information that revealed the actual absolute
17 benefit from neratinib. That was January 6th, 2015, 11:15 at
18 night.

19 The next day, ladies and gentlemen, Mr. Auerbach
20 sent those phony FDA minutes to Bill Hicks, William Hicks,
21 who is the counsel for the underwriters. He wrote: Hi,
22 Bill. Happy New Year and best wishes to you and your family
23 for a happy and healthy new year. Please find attached the
24 minutes from our recent meeting with FDA for neratinib which
25 is being provided to you for regulatory diligence.

1 He even pointed out this information -- it's a
2 typo -- is being provided to you under the CDA. That's
3 nondisclosure agreement, the confidential disclosure
4 agreement dated November 10th, 2014. Gave Mr. Hicks
5 absolutely no reason to doubt that he was receiving the real
6 official FDA minutes.

7 Then Mr. Auerbach faced another dilemma because
8 Mr. Hicks thanked Mr. Auerbach for providing those minutes,
9 but he asked him: Is there any other material, FDA
10 correspondence like this, since the deal we did in February
11 2014? Well, remember, material correspondence means
12 important communications.

13 Just a few months earlier the FDA had told Puma
14 that 2.3 percent absolute benefit was not enough for
15 breakthrough therapy designation, was not enough to
16 demonstrate even the potential for a substantial improvement
17 over existing therapies. And Puma communicated directly to
18 the FDA that it was following the FDA's recommendation and
19 was not going to submit neratinib for breakthrough therapy
20 designation.

21 So Bill Hicks asked him for any other important FDA
22 communications. Another dilemma. What to do about this? If
23 he reveals this information, that could enable people to
24 connect the dots and see that the real absolute benefit was
25 2.3 percent, about half of what he had represented of four to

1 five percent.

2 You will see that Mr. Auerbach solved this dilemma
3 by simply telling Mr. Hicks: Hi, Bill. No, there is no
4 other material correspondence since the February 2014 deal.
5 So he didn't alter this correspondence. He simply denied
6 that it existed.

7 The evidence will show, ladies and gentlemen, that
8 Mr. Auerbach consistently hid the actual absolute benefit
9 from neratinib. You have seen the highlights, the phony FDA
10 minutes, concealed correspondence with the FDA, and, of
11 course, the July 22nd conference call.

12 The evidence will show it worked. You will see
13 that the underwriters for this offering marketed it as a
14 blockbuster market opportunity in oncology. Remember, one
15 product, neratinib. They were marketing it to people as a
16 blockbuster opportunity. Why? Because Mr. Auerbach had not
17 revealed that he had told people that it was twice as good
18 and half as bad as it really was.

19 So the offering went through. This is the easy
20 money I was referring to. On January 27, 2015, the offering
21 closed. Puma sold 1.15 million shares for \$218 million at
22 \$190 a share. Remember what I said to you before. No one is
23 going to accuse Mr. Auerbach of being dumb.

24 This money obviously didn't go directly into his
25 pocket, but as the largest individual shareholder of Puma, it

1 clearly offered a substantial benefit to him. The evidence
2 will show that this worked for Puma employees also. Between
3 July 22nd and April 13th, 2015, while people outside of Puma
4 believed that neratinib was twice as good and half as bad as
5 it really was, these various Puma employees sold millions of
6 dollars' worth of stock.

7 You'll hear from them during this trial, and you
8 will see that they all had access to the truth. So a recap.
9 July 16th to 18th in 2014, Mr. Auerbach learns, pores through
10 with a fine-tooth comb the ExteNET results. The stock price
11 on July 22nd closed at \$59.

12 On July 22nd, 2014, he had the conference call in
13 which he represented it to be twice as good and half as bad
14 as it really was, and the stock price shot up to \$233. On
15 January 27th, they had the \$218 million stock offering. And
16 in the meantime Puma employees sold millions of dollars'
17 worth of stock.

18 Now, from Mr. Auerbach's perspective, fraud is
19 complete. They got the -- they got the offering. He knew
20 the truth was always going to be revealed. That was for
21 sure. But the money stays with Puma, that \$218 million. And
22 sure enough, the truth was revealed. It was revealed at a
23 medical conference. The acronym ASCO -- you might be able to
24 see the small writing -- stands for the American Society of
25 Clinical Oncology. It is a very large and significant

1 medical seminar.

2 As you will learn, it's a natural part of the
3 process of developing a drug to present the results at a
4 medical conference. Now, at that time it's not Mr. Auerbach
5 revealing the results. It's an academic steering committee.
6 It's people he can't completely control. And the truth has
7 to come out anyhow.

8 So as you'll see, the prelude to an actual
9 presentation at ASCO is what's called an abstract, which is
10 another fancy word for summary. The abstract revealed some
11 of the truth that Mr. Auerbach had previously misrepresented.
12 It revealed the true absolute benefit to be 2.3 percent
13 because it revealed those -- you can see -- those actual DFS
14 rates.

15 It also revealed that four percent of neratinib
16 users suffered grade-three diarrhea. That's on May 13th.
17 The very next day Puma's stock price dropped \$40 per share.
18 I probably don't have to point it out to you, but I will --
19 obviously an opposite reaction to the way people reacted to
20 what he said on July 22nd.

21 But remember, the abstract is just a prelude to the
22 actual presentation, and more truth was revealed at the
23 actual presentation. The actual KM curves were not
24 separating. So in other words, the benefit was not getting
25 greater at the end of the two years, and they ended at two

1 years.

2 Also, the higher rate of discontinuation, not the
3 anticipated supposedly 5 to 10 percent but from diarrhea
4 alone of 16.8 percent. And then it was revealed that
5 39 percent of the people discontinued treatment, not
6 necessarily connected to side effects but discontinued
7 treatment, because after the presentation there's a
8 question-and-answer session with doctors.

9 You will hear the actual audio of that
10 question-and-answer session. Here's a clip and a transcript
11 from it.

12 (Audiotape recording played)

13 MR. FORGE: Dr. Chan, Dr. Arlene Chan, the person
14 to whom Dr. Bogel is directing that question, was the
15 principal investigator for this study. She was the one
16 making the presentation.

17 (Audiotape clip played)

18 MR. FORGE: So with only 61 percent completing
19 therapy, that obviously leaves 39 percent who did not
20 complete the therapy. So the ASCO conference reveals that
21 the KM curves were not separating, that they ended at two
22 years, and the higher discontinuation rate.

23 Then on June 1st and June 2nd, Puma's stock price
24 dropped another \$48 per share. All of this brings us back to
25 why we are here, ladies and gentlemen. When Mr. Auerbach led

1 people to believe that neratinib was twice as good and half
2 as bad as it really was, the stock price shot up to \$233.
3 When the truth was revealed, the stock price settled at the
4 end of June 2nd at \$146.

5 Now, as you might guess, stocks do go up and down.
6 You'll see there was even some movement within this stock
7 price during that May to June period. Well, we'll have an
8 expert explain to you how he can clearly trace \$87 per share
9 of stock drop to this fraud, \$87 to the statements that were
10 made on July 22nd and then corrected in May and June.

11 But you don't need an expert just to see the
12 difference in these share prices. On July 23rd after
13 Mr. Auerbach made those statements, \$233. On June 2nd after
14 the truth was revealed, \$146. The difference, \$87 per share.

15 Ladies and gentlemen, you also don't need an expert
16 to see that this is a case about integrity. That's why it is
17 so fitting that Judge Guilford appointed a pension fund from
18 a modest county in England to represent all of the investors.

19 THE COURT: Well, now, let's be a little careful
20 about vouching. It's not really relevant whether I appointed
21 them or not, and it certainly doesn't indicate anything about
22 the strength of plaintiffs' case.

23 Continue.

24 MR. FORGE: And I apologize, ladies and gentlemen,
25 if I gave you that impression. My point was to emphasize

1 that it was a pension fund from England that Judge Guilford
2 appointed in this case.

3 The reason why I say that is so fitting is because
4 we want investors all around the world to be able to trust
5 and rely on the integrity of our stock markets, even a modest
6 pension fund in Norfolk County, England, which protects the
7 pensions and provides the pensions for caregivers and road
8 workers and teachers' assistants.

9 Ladies and gentlemen, when Mr. Auerbach had to
10 choose between integrity and easy money, he made the wrong
11 choice. At the end of this trial, you and only you will have
12 the opportunity to choose integrity. You can choose
13 integrity by taking back that easy money and by holding
14 Mr. Auerbach and Puma accountable for their lack of
15 integrity.

16 Thank you.

17 THE COURT: All right. Thank you, counsel.

18 What would the defense like to do at this moment?

19 MR. CLUBOK: Your Honor, we'd like to respond if we
20 can have a few minutes to --

21 THE COURT: I'm asking how much time do you want.

22 MR. CLUBOK: Just about a little over an hour.

23 THE COURT: No. How much time do you want before
24 you respond?

25 MR. CLUBOK: We only need a few minutes.

1 THE COURT: A few minutes isn't clear to me, so
2 I'll take it on my own. You may stand and stretch if you
3 want as defendant prepares.

4 (Pause in proceedings)

5 THE COURT: I have a question for counsel. Is it
6 correct in this case that the plaintiffs' counsel asked me to
7 approve of class counsel and I did so?

8 MR. CLUBOK: Yes, Your Honor.

9 THE COURT: I believe that's what happened,
10 correct?

11 MR. CLUBOK: Yes.

12 THE COURT: Okay. That's my understanding of what
13 occurred.

14 Go ahead.

15 Defense opening statement.

16 MR. CLUBOK: Thank you.

17 Well, you've all heard the old saying there's two
18 sides to every story. You just heard quite a story from the
19 plaintiffs' lawyer, but the judge asked you at the beginning
20 of today to keep an open mind. What you're going to see over
21 the course of this trial is not stories but facts and
22 evidence.

23 You're going to see witnesses come here and talk to
24 you directly about what actually happened. You're going to
25 be able to see the documents and not just clips from part of

1 a story but the actual documents themselves. And over the
2 course of this trial, you are going to be able to decide what
3 those facts show. You don't have to rely on the stories of
4 lawyers.

5 I do want to preview the facts of this case for
6 you, and I want to preview what you're going to be seeing
7 over the course of the trial. You know, you heard a blizzard
8 of statistics in that last hour. You heard two percent,
9 eight percent, 30 percent, a bunch of different numbers. I'm
10 not sure if it all registers because some of this is somewhat
11 complicated.

12 But there's one fact that you're going to hear over
13 the course of this case that no matter what story you hear,
14 that fact is not going to change, and that's going to be the
15 fact that the neratinib clinical trial was successful.

16 What's a clinical trial? A clinical trial in this
17 case was a phase-three trial after phase-one and phase-two
18 trials had already been met. The neratinib clinical trial
19 had 2,800 women with breast cancer enrolled. With those
20 2,800 women, half of them got placebos and the lucky half got
21 neratinib.

22 And what was the results of that trial? For the
23 women who had HER2-positive breast cancer -- that's the worst
24 kind of breast cancer -- for those women who had already had
25 every other treatment that was then available, they had

1 surgery, they had chemotherapy, they had this drug called
2 Herceptin which you heard a little about. That was all that
3 there was available for those women. And for those women who
4 had all the other treatments, many of them still had the
5 disease come back.

6 And for those women for whom nothing else worked,
7 neratinib saved at least 33 percent whose cancer would have
8 otherwise come back within two years. But just stop right
9 there, because that's the most important fact in this case.
10 If there were nine women who would have otherwise had
11 HER2-positive breast cancer return within two years without
12 taking neratinib, a third of them now are saved.

13 You know, I'm not going to respond to every word
14 that plaintiffs' lawyer said, but he said, look, we're just
15 talking about -- he said something like we're just talking
16 about the return of breast cancer. It's not like it's a
17 life-or-death statistic. Those are the words he used.

18 Actually with HER2-positive breast cancer, it is a
19 life-or-death statistic. If that disease returns, if you do
20 not remain disease free and if it comes back within two
21 years, it's virtually all the time you'll hear from the
22 doctors a death sentence. Women who have that happen to them
23 die within five years almost always.

24 So return of the disease. If you -- in other
25 words, if you do not remain disease free and instead the

1 disease comes back, it is essentially a death sentence. That
2 is a life-or-death statistic. And this clinical trial that
3 neratinib was involved in for 2,800 women showed 33 percent
4 of those who otherwise would not have been disease free -- in
5 other words, the cancer would have come back within two
6 years -- they remained disease free.

7 That's the neratinib clinical trial. What's this
8 trial about? Okay. This trial is not about the women who
9 were -- who got neratinib. There's no women who got
10 neratinib who are here suing Puma. This is not about the
11 doctors who participated in this trial. There's no doctors
12 here suing.

13 This trial is about Alan Auerbach. You've heard a
14 little bit about him. You sure haven't heard the whole story
15 about him. You're going to learn about Mr. Auerbach and what
16 motivates him and why he has devoted his life to fighting
17 cancer. It's not about money. He'll tell you himself the
18 personal reasons why he's devoted his life to this mission.

19 You're going to hear about the company he founded.
20 It's actually the second company he founded to fight cancer
21 called Puma Biotechnology company. You'll hear what that
22 means and what it means to be not one of these big
23 pharmaceutical companies that makes lots of money and has
24 tens of billions of dollars. It's a company that in the
25 early stage trying to develop a new cure.

1 But you'll hear about that because those are the
2 folks that the plaintiffs have sued. Those are our clients.

3 I'm Andy Clubok. With my partner Michele Johnson
4 who you met before and Colleen Smith and Sarah Tomkowiak, we
5 are all here proud to be defending Alan Auerbach and Puma
6 Biotechnology.

7 Who are we defending them from? We're defending
8 them from the plaintiff in this case which you didn't hear
9 too much about -- Norfolk Pension Fun. You heard at the end
10 it's this modest pension fund from England who chose to come
11 here and defend the rights of investors all over the world.
12 And they're just a modest fund, and that's why they sued us.

13 The fact of the matter is this case is all about
14 the fact that Norfolk Pension Fund made a bet on Puma early
15 on, and they bailed out of that bet and lost money. As a
16 result, they would like you to award money to them to
17 compensate for those investment losses. That's what this
18 trial is all about, whether or not Norfolk Pension Fund that
19 invested in Puma and that lost money should get paid back for
20 those losses.

21 Now, who is Norfolk Pension Fund? You heard it
22 described as a modest pension fund from England. You will
23 meet the representative, Mr. Younger. He's sitting here.
24 You'll meet him. Norfolk Pension Fund has over \$4 billion in
25 assets. It holds these assets, investments that are managed

1 by some of the top investment professionals in the world. --
2 Goldman Sachs, Fidelity, Wellington, Standard Life. These
3 are some of the I think more than a dozen professional
4 financial managers who manage the billions of dollars and
5 make investments all over the world.

6 In this -- in the year that they invested in Puma,
7 I think they made something like \$300 million in investments.
8 They lost a little bit, like .025 percent of their total
9 value or something, on the investment they made on Puma.
10 They did lose money on that particular bet based on when they
11 bought and when they sold.

12 But they made 300 million in other investments, and
13 they have four billion dollars. That's the modest little
14 pension fund from England that sued and asked to be the
15 representative.

16 Now, they didn't do this on their own. You know,
17 you were sort of -- Mr. Forge gave this idea about why some
18 London pension fund would be suing us. Well, the fact of the
19 matter is the London pension fund has all of these investment
20 advisors like Goldman and Fidelity and others. They manage
21 their investments.

22 And for the most part, the folks back in England,
23 they certainly don't know what investments are being made at
24 any particular time. They get reports on I think a quarterly
25 basis or an annual basis. But what they do is they hire

1 professionals to make the decision, and they do something
2 called give them discretion. So they have discretionary
3 managers who make investment decisions and make decisions
4 about when to buy and sell stock in companies.

5 In this particular case you're going to hear about
6 a woman named Skye Drynan. I don't think Ms. Drynan's name
7 came up at all when the plaintiffs' were telling you their
8 story, but Skye Drynan is important because she is a woman
9 for 20 years who has been an analyst in the biotechnology
10 sector.

11 What she does for a living is she analyzes
12 companies and she makes recommendations for her company,
13 Capital, who make decisions to buy and sell stocks on behalf
14 of modest investors like Norfolk that have billions of
15 dollars in assets.

16 Skye Drynan you will learn made the decision to
17 invest in Puma. She did so after researching the company,
18 after digging under the hood, after looking at all of the
19 data. She looked at the data before and she looked at the
20 data after the results were announced for this clinical
21 trial, and she looked at all the information as it came out.
22 And more information came out over months and months.

23 She looked at all that. She made her investments.
24 She made the bets for Norfolk into Puma, and it turns out,
25 like it happens in the stock market, they didn't make money

1 on that particular investment. But years later we deposed
2 her, and we got to ask her under oath what happened here.
3 Were you defrauded? Were you misled? Did Mr. Auerbach have
4 some character deficiency where he hid information?

5 Here's what she said under oath:

6 "Question: Do you believe Mr. Auerbach ever lied
7 to you?"

8 Remember, this is years later.

9 "Answer: I do not believe he ever lied to me.

10 "Question: Do you believe he ever misled you in
11 any way?

12 "Answer: I do not believe he misled me in any way.

13 "Question: Do you believe he ever defrauded you in
14 any way?

15 "Answer: No."

16 That is the woman who actually made the decision on
17 behalf of Norfolk to buy Puma after hearing all of the
18 information, not 30 seconds of a conference call, which we'll
19 talk about, but after seeing all the information the company
20 put out about neratinib or about how excited it was about
21 neratinib and after she saw all the information that the
22 plaintiffs today, that the folks in England are now saying
23 supposedly revealed fraud, Ms. Drynan saw all that and she
24 says, nope, I wasn't defrauded.

25 So what are the keys to the case? Frankly you

1 could stop right there, but there are four main keys to this
2 case that you will learn about as you learn all the facts and
3 not just the story that you're being told.

4 First of all, you're going to learn that Puma
5 developed an effective and safe breast cancer treatment.
6 Again, I heard it being said it wasn't a cure for -- you'll
7 hear for thousands of women with the worst kind of breast
8 cancer. HER2-positive, it's a cure. It's a cure that never
9 was available until neratinib came along.

10 Second of all, you'll hear that Puma told the truth
11 about the development work it did. They were proud to tell
12 the truth. They were happy to tell the truth because it was
13 terrific news. It's a great additional step in the fight
14 against cancer.

15 You'll hear that Mr. Auerbach had no motive to
16 commit fraud. Mr. Auerbach hasn't sold a single share of
17 stock in his company. Okay? Mr. Auerbach has raised money
18 to develop lifesaving drugs and has plowed all that money
19 into R&D. Mr. Auerbach has never sold a single share of
20 stock.

21 So why did Norfolk -- why did the folks in this
22 pension fund happen to lose money on this investment? Well,
23 there are other reasons, and you will see the other reasons.
24 It may be, as one potential juror said today, just because
25 it's the lottery of investing in biotech. You'll see it's

1 also because of lots of other reasons. That's what happens.
2 Sometimes investments pan out. Sometimes they don't.

3 In this case the plaintiffs want insurance for an
4 investment, a bet they made, hoping that Puma would make a
5 lot of money off of treating cancer patients. When they
6 didn't make money, they sued.

7 So let's talk about each of those four. First,
8 Puma developed an effective and safe breast cancer treatment.
9 Who is Puma? Okay. Puma, we talked about this a little bit.
10 It's actually not Puma, the sneaker company, for those who
11 remember that company. It's Puma Biotechnology.

12 What's a biotechnology company? It's a development
13 stage company that is dedicated to developing new breast
14 cancer treatments. It's based right here in Southern
15 California. What it basically means -- that's a bunch of
16 fancy words for a new company. They don't have products.
17 They're working to develop it. And by the way, you heard
18 some criticism that, well, it wasn't Mr. Auerbach who had the
19 original idea for the drug. No, that's not what Mr. Auerbach
20 does.

21 What he does is he identifies other drugs that
22 companies are not properly developing that they've basically
23 put on the shelf. Maybe they think they're not going to make
24 enough money off it. Maybe they don't realize what great
25 potential is. Mr. Auerbach has specialized in identifying

1 those opportunities so that he can develop a drug that will
2 actually drug cancer.

3 He started Puma in 2011. Now, what was he doing
4 before that and who is he? Mr. Auerbach is the founder of
5 Puma. He's the CEO. He's chairman of the board of
6 directors. He has a master's degree. He is a Trojan. Some
7 people will be happy. Some Bruins maybe won't be. But he
8 has a master's degree in biomedical engineering.

9 What that means is it's a specialty where you
10 identify how drugs will impact certain kinds of diseases. He
11 has 20 years of experience. Yeah, he spent some time as an
12 analyst analyzing these kinds of companies for other
13 investors like Norfolk. At some point he said, hey, I'm
14 pretty good at analyzing which drug companies have good
15 drugs. I have -- and you'll hear -- sort of a life-changing
16 moment, and I'm going to now devote my life to actually
17 developing the drugs as opposed to just analyzing and talking
18 about it.

19 So what did he do? He developed a company -- he
20 started, I should say, a company called Cougar. Now, the
21 number-one cancer killer for men is prostate cancer, and
22 Cougar was a company he developed because he saw a drug that
23 fought prostate cancer that a big pharmaceutical company,
24 Johnson & Johnson, basically had on the shelf, wasn't
25 developing.

1 Mr. Auerbach said, hey, give me a chance to develop
2 this drug. I can help get trials going, and eventually I
3 think this drug will be a success in helping fight prostate
4 cancer. Sure enough, it was. I think Zytiga is now one of
5 the leading components of the standard of care for fighting
6 prostate cancer. It saved thousands and thousands of men
7 throughout the country. There's all kinds of -- you'll hear
8 Mr. Auerbach happily talk to you about the success of Cougar
9 in developing this drug called Zytiga to help men fight
10 prostate cancer.

11 But that wasn't enough for him. Okay. What he did
12 then was he said, all right. We helped in the fight against
13 prostate cancer. I'm now going to move on to the number one
14 killer of cancer among women, and that of course is breast
15 cancer.

16 He took the money he made from Cougar and he took
17 all of his energy and he worked seven days a week. Except
18 when he's here in court, he's otherwise at the office working
19 developing new drugs. And he started Puma to focus on breast
20 cancer. So what kind of breast cancer? We probably all know
21 breast cancer, as I said, is one of the worst kinds of
22 cancers. It is responsible for about 400,000 deaths per
23 year.

24 The good news is we have lots of treatment for
25 breast cancer. Okay. Breast cancer itself thankfully is no

1 longer a death sentence. There is a lot of treatment
2 particularly if you catch it early. There is surgery.
3 There's chemotherapy. There's this drug called Herceptin
4 which has been a great drug. Those were the ways you would
5 treat breast cancer.

6 For a lot of breast cancers that worked
7 terrifically, and that's great. For some of the worst kind
8 of breast cancer, at the time called HER2-positive, it's a
9 breast cancer that has a gene mutation that makes it more
10 aggressive even than normally bad aggressive cancer. For
11 that, neratinib. Neratinib can come along and now can
12 prevent HER2-positive breast cancer from recurring for
13 thousands of women.

14 So what happened before neratinib if you had
15 HER2-positive breast cancer? If you or someone you knew had
16 it, you pretty much there's a standard of care, and everyone
17 knew what it was and everyone knew that that was really your
18 only hope. You had to have surgery.

19 You had to have something called adjuvant care.
20 Adjuvant is a fancy word for additional. So after the
21 surgery, for an additional year adjuvant, you take
22 chemotherapy. You take Herceptin. You can see you take it
23 with an IV. And these are drugs that all in, all combined
24 actually did a lot to really cure breast cancer for many
25 women, in fact for most women.

1 For about 86 to 92 percent of women, that treatment
2 that was the only treatment available before neratinib was
3 success in keeping women disease free. That's the focus,
4 disease-free survivability for five years. That's
5 effectively in the cancer world a cure. If you can keep the
6 disease from coming back for five years, you got a good shot
7 at basically having beaten it.

8 That treatment was great, but for approximately 8
9 to 14 percent of women, they had the disease return. Okay.
10 I know there's a blurry of statistics. What you have to
11 realize is we're not talking about getting hit by lightning.
12 We're not talking about lead hats or some analogy I didn't
13 completely understand.

14 We're talking about 8 to 14 percent of women who
15 have HER2-positive breast cancer, even when they used
16 everything else available known to science back in 2014,
17 still 8 to 14 percent got the disease back in two years.
18 Then it's effectively a death sentence certainly for most
19 women if not for all.

20 So what about that? What about those women?
21 Should we just say, well, you know, it's only a few. It's
22 only 8,000 out of -- 8 percent out of 400,000, so let's not
23 do anything about it. It's not worth doing. No. But we did
24 was ExteNET. ExteNET is the clinical trial that had those
25 2,800 women, half of whom got neratinib. Half of whom got

1 placebo.

2 It was a trial that was originally started by
3 another drug company. It was actually started by a company
4 called Wyeth. They designed the study. They started it.
5 And long story, but eventually they were bought by Pfizer.
6 Eventually the drug study was basically abandoned.

7 That's when Mr. Auerbach and Puma came along and
8 said, hey, I think there's something here. I want to see
9 this study completed, and I want to see if this can actually
10 be a cure. And sure enough, that's what they found.

11 The evidence they're going to show, that neratinib
12 was a success as demonstrated in this massive clinical
13 phase-three trial. And it's not just Alan Auerbach's word
14 you have to take for it, and certainly don't take my word to
15 for it because you'll hear him testify.

16 But you'll also hear Arlene Chan. You heard a
17 little snippet of her, and I'm not sure you caught who she
18 is. She's a researcher who supervised the presentation of
19 the data and was overall looking at the study. She is not
20 paid by Puma. She never has been. She never will be.

21 She runs a breast cancer study research center down
22 in Australia. She's a breast cancer doctor. She has no
23 financial incentive. She doesn't have any stock in Puma.
24 All she cares about is fighting breast cancer, and she's the
25 one who presented the results of this study declaring it to

1 be a great success because it is a great success.

2 Notwithstanding what Norfolk, the investors from
3 back in 2014, think, for doctors, patients, women who have
4 this disease, this is a success. But it's not just her that
5 you'll hear from. You'll hear from Alvin Wong, who is the
6 director of clinical and pharmacology at Puma. You'll hear
7 from Claire Sherman who is the head biostatistician at the
8 time of the study.

9 You'll hear from Troy Wilson who is another -- who
10 is on the board of directors. You'll hear his story about
11 why he has devoted his life to fighting cancer. Again, it's
12 not about profit. He hasn't sold a single share of stock.
13 You'll hear from Dr. Richard Bryce, who is the chief medical
14 officer.

15 You'll hear from -- if my clicker works, you might
16 hear from other folks. Judy Segal, who is the current head
17 of biostats, and most importantly perhaps you'll hear from
18 Dr. Richard Schwab, a practicing breast cancer specialist who
19 practiced here in Southern California with real women,
20 treating real patients. You'll hear what he says about these
21 results and about the effectiveness of the drug.

22 So once you hear all this, you will decide for
23 yourselves whether Puma developed an effective and safe
24 breast cancer treatment. Full stop. Okay. That's where the
25 case really should end.

1 But the next key to the case, the next thing that
2 you'll be asked to consider is whether Puma told the truth
3 about it, whether Mr. Auerbach told the truth when he had
4 these exciting results and he released them and he announced
5 them and talked about it. Somehow in this three- or
6 four-minute telephone call exchange -- I think it's actually
7 shorter than that -- did he somehow intentionally commit
8 securities fraud to try to defraud this modest pension fund
9 in England, or was he trying to just talk about the drug
10 because he was excited and telling truthful information the
11 best he could about this exciting new drug?

12 So first of all, what you also didn't hear about
13 and you won't hear about in this case is any complaint over
14 something called a press release. This press release, you
15 heard a lot about this telephone call, the telephone calls
16 where Mr. Auerbach got on and did some -- tried to do some
17 Q&A with investors.

18 What you didn't hear was that before he ever did
19 that, he put out a press release. Puma put out a press
20 release. The press release on July -- and it's just this one
21 page. This is literally it, so it's not buried in some --
22 you know, this is the kind of thing where if it had been a
23 stack of documents, folks would say, oh, gee, you buried the
24 news. If it's one page, maybe they say it's too little.

25 If investors lose money, you get sued either way.

1 But in this case this press release said something very clear
2 and very simple in the headline. It says: Puma
3 Biotechnology announces positive top-line results from phase
4 three PB272 in adjuvant breast cancer ExteNET trial.
5 Neratinib achieves statistically significant improvement in
6 disease-free survival.

7 That is what was put on the press release. That is
8 true. No witness here, no expert, no even lawyer's story
9 will tell you that this was not true in this case.

10 What else did the press release say? It said
11 simply the trial was successful. It said that there's a 33
12 percent improvement in disease-free survival for the entire
13 population of the study. It said that Puma is going to be
14 seeking FDA approval, and it said that the full trial results
15 will be presented later at a medical conference.

16 All four of those things are said in this press
17 release. All four of them exactly true. And this is what
18 goes out to the world.

19 Now, it -- Mr. Auerbach and Puma did not disclose
20 the mountain of data that was behind these results. You'll
21 find out that some of it was not validated yet. Some of it
22 they were still making sure it was accurate. They knew the
23 top-line results, but some of the details they were still
24 working through. What they said, though, was all of those
25 details are going to be presented at a medical conference.

1 Okay. So we're going -- we're telling you the
2 truth. For all the details, come to the medical conference
3 and you'll get all the rest of the details. Why did they do
4 that? Why didn't they just in the press release, you know,
5 put -- make it a 50-page press release and put all the
6 details?

7 The reason is because of how lifesaving drugs get
8 to patients in this country at least. Okay. I don't know
9 how it's done in England, but in this country the way it
10 works is you have to go through a phase-three trial where you
11 get clinical results. If they're bad results, you stop. You
12 don't go and present them usually at a medical conference.
13 Or maybe, you know, you just show it for a moment to show how
14 something bad happened.

15 But if you have good results, what you do is you go
16 try to present them at a medical conference, and you submit
17 those results. And if the -- and there's about, I think,
18 three or four major medical conferences around the country.
19 They're spaced out over the course of the year.

20 If your results are good enough, the major medical
21 conferences will accept you. And then what happens is at
22 these conferences there are thousands of doctors, sometimes
23 tens of thousands of attendees. That's how doctors find out
24 about drugs. That's how drugs get to patients. That's an
25 important step of the process.

1 You will hear testimony about how this is key.
2 What you'll also hear is that if you don't present at the
3 conference, if for whatever reason you're not allowed to
4 present at the conference, doctors don't find out about the
5 drug. Ultimately, even if it's a great drug, not enough
6 doctors find out about it and women don't get the cures they
7 need.

8 Now, again, you don't have to take my word for
9 this. You will see facts in evidence that will show that
10 what I'm saying is accurate. Investors, the people like Skye
11 Drynan, the people who are doing the work and the research,
12 who were deciding to bet on Puma, they knew that all of the
13 results weren't going to be coming out until a medical
14 conference.

15 It wasn't some big surprise to them that it was
16 being saved. It was in the press release. Plus, they knew
17 it and they knew why. Remember Skye Drynan? Again, she's
18 the woman who made the decision to invest, and she did it
19 knowing full well that all of the little details were going
20 to be presented at the medical conference. And she said,
21 well, yeah, that's what you have to do, because if you're a
22 biopharmaceutical company, you have a press release with the
23 top-line data but you can't actually give the full data out
24 in the press release or you will not be able to present the
25 data at the medical meeting.

1 That's what Skye Drynan admitted in her deposition
2 when we asked her under oath, you know, why it is that the
3 results were saved. It's not just her. There's another
4 person you'll hear testimony from, someone named Eric Schmidt
5 who also -- he may say he's unhappy about the way the
6 investment went, but even he admits if companies give away
7 too many details in advance, they're not accepted for
8 presentation at the conference.

9 This is a picture of the 2015 ASCO annual meeting.
10 It doesn't do it justice. This is the gold standard
11 conference. It's the largest one I believe in the world or
12 certainly in this country. There's 30,000 attendees in a
13 large convection center in Chicago. This is where
14 Mr. Auerbach and Puma and Dr. Chan, who doesn't even work for
15 Puma, presented the results of the neratinib study, just like
16 Mr. Auerbach promised, just like he tried because he was so
17 excited and because ASCO agreed.

18 By the way, ASCO gets something like 6,000
19 submissions a year. They only take a tiny fraction, only the
20 ones that have the most important results. They accepted
21 Puma to present at this conference because of the importance
22 of the results from the clinical study.

23 So we go back in time to this July 22, 2014,
24 conference call. Remember, that's what the -- that's what
25 this lawsuit is about. The lawsuit is whether he said

1 something in that few-second exchange that was intentional
2 securities fraud. Well, that call was available to the
3 public. It was -- it was sophisticated analysts and
4 investors were listening to it. It was an opportunity to ask
5 questions. And most importantly, the questions aren't
6 provided in advance.

7 So Mr. Auerbach puts out the press release. He
8 gets on the call. It lasts about a half hour. That exchange
9 that the plaintiffs are complaining about are a few minutes
10 at most or a few seconds out of this call, and they say the
11 answers he gave there, because they weren't perfect, that's
12 securities fraud and we should get our money back for the
13 investment we made when we thought that the drug would be --
14 would have even bigger sales than it does.

15 So what are the basic misrepresentations they
16 claim? Let's boil it down because you're going to hear a lot
17 of things where they're going to quibble over, look, every
18 single statement that Mr. Auerbach makes in an e-mail or in a
19 phone call or in any context for ten months, you'll hear
20 quibbles with him not getting the words exactly right.

21 But at the end of the day, or actually at the
22 beginning of this case when the judge told you what the case
23 was going to be about, it's about the statements that were
24 made on this conference call, statements that relate to the
25 absolute DFS rates, the Kaplan-Meier curves, and safety data.

1 That's basically what the supposed false statements
2 were. You all are going to see what was actually said and
3 decide for yourself whether Mr. Auerbach was intending to
4 commit securities fraud when he tried to answer these
5 questions.

6 First of all, absolute DFS rates. What was he
7 asked and what did he say? On the conference call he was
8 asked -- this is the -- this is a doctor who also happens to
9 be an analyst working for one of these investment analyst
10 firms. He says -- the doctor says, congrats on this
11 fantastically in many ways unexpected data. So I have a ton
12 of questions. Maybe I'll just take two if you don't mind.

13 One is, and he starts with, give us a little bit of
14 a sense what was the DFS on the control arm. That's his
15 question, give us a little bit of a sense. Why does he say
16 that? This is Dr. Werber, Yaron Werber. You'll hear I think
17 a video deposition from him.

18 He knows he can't get all the details. Puma said
19 we're not going to give all the details. He knows that Alan
20 Auerbach is not going to tell him the precise numbers. But,
21 you know, he's doing his job. No blame to him. He's trying
22 to get a little bit of a sense of what he can get.

23 What Mr. Auerbach responds is, so in terms of the
24 DFS of the placebo arm of the trial, it was in line with
25 other reported trials. So it's in line with the Herceptin

1 adjuvant studies.

2 Anybody know what any of that means? Probably not.
3 But Dr. Werber knew exactly what that meant, in line with the
4 Herceptin adjuvant studies -- or at least he should have
5 known. What does that mean?

6 Remember the drug Herceptin? Herceptin was the
7 standard of care before neratinib came along and it still is
8 for the first year after surgery. What happens is neratinib
9 is the second year after surgery. So neratinib is extended
10 adjuvant additional therapy after Herceptin.

11 Well, these were the four prior Herceptin studies,
12 and the comparable DFS rates -- and I know this is all a blur
13 of stuff, but these are people who are talking together.
14 They're all doctors. They all know what these words mean.
15 The comparable DFS rates for the four prior Herceptin studies
16 from 2005, it went from 85.8, to 2011, 86.7; 2011, 88, all
17 the way up to 2013, 92 percent.

18 What does that mean? That means if you just
19 take -- if you get surgery, you get chemo, and you get
20 Herceptin. Remember, this is Herceptin trying to demonstrate
21 that it's successful. The good news is that as of 2013, the
22 disease-free survivability rate had gotten up to about
23 92 percent. And you can see it's kind of increasing over
24 time. There's no change in the treatment. It's just that
25 doctors get more familiar with how to give Herceptin, as they

1 figure out how to --

2 THE COURT: You need to slow down a bit.

3 MR. CLUBOK: I appreciate that. Thank you.

4 As doctors figure out how to adjust the dosage, and
5 sometimes they will discontinue some of the dose or decrease
6 the dose over the course of a woman's treatment. As they
7 figure out how to do that over the years, you can see that
8 the DFS rates are increasing such that by 2013 about
9 92 percent of women were disease-free survival after two
10 years just with Herceptin. That's terrific. Okay?

11 But it still leaves eight percent, and it still is
12 a serious problem for eight percent out of 400,000 a year.
13 That's a lot of women. So remember, what Alan Auerbach has
14 said is, well, this is -- what we saw is in line with these
15 studies. So what did they see? For ExteNET, 91.6. You can
16 decide for yourself.

17 You don't have to -- as Mr. Forge would say, you
18 don't need an expert to tell you. Is 91.6 in line with these
19 other comparable DFS rates? When Mr. Auerbach says, yeah,
20 it's in line with the prior studies, and you could see it's
21 almost exactly like the most recent study and certainly in
22 line with the others, is he committing securities fraud? You
23 are the ones who are going to decide that.

24 So that's the first question. Was it in line with
25 the prior studies? You'll decide. Then there's this

1 exchange that's even more complicated, and I apologize, but
2 this is the accusation, that in the complicated question and
3 answer, Mr. Auerbach committed securities fraud. So the next
4 series of questions: Is Dr. Werber still trying to get a
5 little more information? And he says you're thinking that if
6 I'm correct, the DFS is probably around mid to high 80s, mid
7 to high 80s, around 86 percent or so.

8 Mr. Auerbach says he would be comfortable.
9 Mr. Werber says you can imagine one probably had to show 90
10 or 91. Is that reasonable? Mr. Auerbach says, yes. I think
11 you can do a 33 percent improvement in DFS and come up with
12 that calculation given of the numbers we give.

13 Again, probably incomprehensible to people who are
14 not experts in this field and analysts and doctors. But
15 let's break that down. What was he asked and what is he
16 saying? Yaron Werber is estimating.

17 THE COURT: Hold on. Especially when you're
18 reading, you're going a bit too fast. You would be more
19 effective and the court reporter would be more relieved if
20 you went a little slower.

21 MR. CLUBOK: I appreciate that. Thank you, Your
22 Honor.

23 You can see, ladies and gentlemen, that Mr. Werber
24 is saying the placebo estimate, he guessed it was mid to high
25 80s. Now, mid to high 80s, I think folks would agree without

1 an expert is about 85 to 89. That's mid to high 80s. Then
2 he says, well, if that were true, then the treatment would be
3 90 to 91. So he's asked this question, and Mr. Auerbach has
4 to quickly in his head do the math. What's the math show?
5 89 to 90? That's a one percent difference. You're basically
6 trying to figure out what is the absolute difference between
7 the women who had the placebo, the sugar pill, versus the
8 women in the study who got neratinib.

9 What's the absolute difference? If, for example,
10 89 percent with the placebo were disease free, that's great.
11 If it goes up to 90 percent with neratinib, that's very good.
12 It's not as good as you would like, but it's still one
13 percent, which translates to lots of women.

14 On the other hand, if the placebo arm was 85, and
15 therefore the treatment arm was 91, that would be a six
16 percent difference. He's basically speculating that the
17 absolute difference is somewhere between 1 to 6.

18 What were the ExteNET results? Well, and again
19 we're not talking about percentage improvement, which is that
20 other stat. We're talking about the absolute numbers which
21 they complain about. For every single woman in the study at
22 the exact end point, 2.3 percent. So right there in that
23 range of 1 to 6.

24 But even more importantly, for women in the study
25 who had centrally confirmed HER2-positive, that means that,

1 you know, sometimes people in these studies just want to be
2 in the studies. They might not actually have the really bad
3 kind of breast cancer. They might have had not
4 HER2-positive. But there's a central lab that tests to see
5 whether or not they really have the HER2-positive, and
6 there's a lot of what they call subgroup data where they look
7 at women who have the worst of the worst kind of breast
8 cancer.

9 For those women who are centrally confirmed, it was
10 a 4.1 percent difference, a 4.1 percent absolute improvement.
11 All of these statistics get released at the medical
12 conference months later. None of them can be released now or
13 they won't be invited to present to the medical conference.

14 But when Yaron Werber says, hey, give me a little
15 sense of what's going on here, and then he gives this range
16 that translates to 1 to 6, Mr. Auerbach says, yeah, I would
17 be comfortable with that, that's what he's referring to. And
18 that is one of the three big things they claim is securities
19 fraud when he says that in that two-second moment.

20 That's what this case is about. You will decide
21 whether that's securities fraud.

22 The second thing they quibble with is the
23 Kaplan-Meier curves. Kaplan-Meier curves are just pictures
24 that show these same numbers. So what's a Kaplan-Meier
25 curve? On the conference call a different doctor, Dr. Liang,

1 said again can you give us a sense as to whether the
2 separation is widening over time? He says, give us a sense
3 of that. So Mr. Auerbach says -- it's a long answer. We'll
4 play the whole thing. We'll happily play it two or three or
5 four times. You can take the transcript. You can read it
6 yourself.

7 He says, if we look at the curves going out beyond,
8 it looks like the curves are continuing to separate. He also
9 talks about it being a preliminary trend because the data is
10 not all in. They have the data for two years, but there's
11 lots of women who started taking this drug more than two
12 years ago and they are starting to get post two-year data.

13 They had some three-year data at the time, the
14 evidence will show, and eventually they're going to get four-
15 or five-year data. So going out beyond two years he talks
16 about it being a preliminary trend.

17 Well, what do the curves again actually show? He's
18 not going to -- everyone knows they're not putting the curves
19 in the press release. You know this is the curve. This is
20 what the curves look like. So folks know they don't have the
21 curves. Dr. Liang is, like, hey, can you give us a little
22 sense of what they look like? Are they continuing to
23 separate?

24 What does that mean? The curve just shows here,
25 this is all the women who started in this trial. At the

1 beginning they're all at the same place. What happens is
2 over time, this is months. As months go by, the women who
3 took the placebo, the number who remain disease free goes
4 down and down. That's the problem. Okay? As time goes on,
5 some of them have cancer return, so disease-free survival
6 rate goes down.

7 For the women who got neratinib in the trial, you
8 can see the curves are separating and they continue to
9 separate throughout. What that means is there's a big
10 difference at every point in time between the lucky women who
11 got the neratinib in the trial versus the women who did not.

12 At year one it was a 2.2 percent difference. At
13 year two it is a 2.3 percent difference. That means -- that
14 is what continuing to separate means. It means it's not --
15 if the curves came back together, if after a couple years it
16 just ended up being you're in the same place whether you took
17 the drug or not, that would be a problem. But when the
18 curves stay separated, when it shows that even after two
19 years it's not just holding steady but in fact continuing to
20 separate, that's a good drug.

21 And by the way, for those centrally confirmed
22 women, the ones who actually were confirmed to have the
23 HER2-positive, it's even better. At year one it's
24 3.2 percent difference. At year two it's 4.1 percent
25 difference. That's the data he had in mind when he said the

1 curves are continuing to separate. You all will decide
2 whether that's securities fraud.

3 By the way, we will bring an expert here. They may
4 not want you to hear from experts, but there's an expert in
5 statistics. They will bring one, and their expert will try
6 to say that our statistics are wrong. We have hired one of
7 the best experts in the world. Went to the University of
8 Nottingham. He's now a professor in residence at the
9 University of California San Francisco.

10 He will show you statistically even if you couldn't
11 see it with your own eyes that the curves were not narrowing.
12 In fact, the curves are continuing to separate.

13 So finally, safety data. This is -- essentially
14 it's diarrhea rates. Okay? It's grade three -- as the judge
15 said at the beginning of the case, it's whether or not
16 Mr. Auerbach committed securities fraud when he tried to
17 describe generally the grade-three diarrhea rates in this
18 study.

19 So what did he say? First of all, he said, hey,
20 listen. The safety data, that is, the diarrhea rates, that
21 has not yet been validated. Okay. They had validated the
22 what's called efficacy results, the results about how it
23 actually worked on women. As of July 22nd you will see the
24 safety data had not yet been validated. And he says this
25 several times.

1 He says the data is still being validated. He says
2 that -- he refers to previous studies where grade-three or
3 higher diarrhea was seen in approximately 30 percent or more.
4 And in response to questions, he talks about it not being
5 validated, not being validated.

6 The plaintiffs are going to get up here and say
7 that was a big lie because he had a team of folks helping him
8 and of course it would have been validated. Remember, he's
9 anal, by his own words, so he would have of course had
10 validated data.

11 You'll see what the facts show. The facts are the
12 safety data had not been completely validated. It had been
13 clinically validated, and that's what Alvin Wong will testify
14 to. So it was good enough that you could tell basically
15 where it was going to come out, but it had not been
16 statistically validated at that time.

17 You will hear from the chief biostatistician,
18 Claire Sherman, who will just tell you we hadn't finished the
19 statistical validation to make sure it was right. And you'll
20 hear from Judy Segal explaining that that validation process
21 takes months. By the way, it does get validated by January,
22 and the data comes in just fine.

23 THE COURT: Okay.

24 MR. CLUBOK: Again, I apologize. I appreciate it.

25 THE COURT: I think the record is going to be

1 unclear, and I think you lose effectiveness.

2 MR. CLUBOK: Thank you. Thank you, Your Honor.

3 What's most important for you to know and what's
4 most important really about this whole grade-three diarrhea
5 rate is whether the grade-three diarrhea rate was 20 percent,
6 30 percent, or 40 percent in this study, it was not a
7 material fact for investors to care about.

8 Now, you're sitting there saying, well, why
9 wouldn't they care about it? If I was taking a drug, I might
10 care if it's a 20 or if it's a 30 or 40 percent diarrhea
11 rate. But the fact of the matter is that the study which,
12 remember, was designed by Wyeth, did not allow for something
13 called loperamide prophylaxis to be used for the women who
14 were in the study.

15 For whatever reason when they designed the study,
16 they thought that maybe it would, I don't know, affect the
17 results. So they did not allow loperamide prophylaxis to be
18 used. What does that mean? It's a fancy term for Imodium.

19 All you have to do is prescribe Imodium when you
20 start taking this drug. And by the way, you take this drug
21 by a pill. It's not an IV. You just take pills. But if
22 doctors prescribe Imodium at the outset prophylactically,
23 which means preventatively -- and by the way, loperamide is
24 just the drug name for Imodium. It's loperamide.

25 If you do that, the studies showed -- by the way,

1 when the data came in and when they presented the data at the
2 big medical conference, the grade-three diarrhea rate dropped
3 to 0 to 17 percent. That's what it drops to when you
4 actually take this, 0 to 17. And by the way, it lasts for a
5 median time of about two days.

6 So the question you folks will have is do you take
7 a drug that's going to improve your chances of remaining
8 disease free if you have the worst kind of breast cancer by
9 33 percent. Balance that against the chance of getting
10 grade-three diarrhea, which by and large is manageable.

11 And you'll hear from Dr. Schwab who treats women in
12 the real world, and in the real world other cancer drugs, the
13 adverse effects that they cause like cardiomyopathy, like
14 tumor -- cause other cancers, cause all kinds of internal
15 organ damage, all those terrible side effects that the FDA
16 would put a big black box around if you were prescribed those
17 drugs? None of that stuff is here.

18 We're talking about grade-three diarrhea which,
19 whether it's 30 or 40 percent, is not good. But with Imodium
20 when it drops to 0 to 17 percent, it becomes pretty much
21 immaterial. Again, you don't have to take my word for it.
22 This is what the investors said at the time.

23 When the actual exact number came out, that it was
24 39.9 percent, what was the reaction? The reaction of every
25 analyst that looked at this was pretty much. No big deal.

1 In terms of tolerability, the rate of grade-three diarrhea
2 was 40 percent, which is slightly higher than what has been
3 reported, but it was described as manageable. Recall the
4 Imodium prophylaxis was not instituted in this trial.

5 Another investor from RBC Capital told its
6 investors when high-dose loperamide prophylaxis is used, the
7 incidence of grade-three diarrhea declined significantly.
8 Oncologists we spoke with view it as very manageable.

9 So Puma told the truth.

10 Well, why are we here? We're here because the
11 plaintiffs, the modest pension fund, says that securities
12 fraud was committed. But to have a fraud like that, you
13 would have to have a motive. You will see Mr. Auerbach had
14 absolutely no motive to commit securities fraud. He had no
15 reason to lie because he was excited, rightly so, about his
16 new and effective breast cancer treatment. And you'll hear
17 all of these other doctors say the same thing.

18 Also, by the way, he spent the next ten months
19 working to present all of the details at the largest medical
20 conference in the world. What kind of a securities fraud
21 case is that where for a few months you -- you know, you say
22 things that you know all the details are going to be released
23 later?

24 Well, most importantly you find out that he had no
25 personal financial motive to lie. How much did he profit

1 from the stock increase? I kind of gave this away at the
2 beginning because you know he hasn't sold a single share of
3 stock. The fact of the matter is he made zero dollars. He's
4 never sold a stock. He's never exercised an option. He is
5 not in it for some temporary boost in the stock price, which
6 is the whole theory of the case. The stock jumped up for a
7 couple months, and that was his intentional securities fraud.

8 Why would he do it? Now, they say, well, it's
9 because of a stock offering. They say, oh, he had to do it
10 to get this stock offering. Well, what they didn't tell you
11 is that stock offerings happen all the time for developmental
12 stage biopharmaceutical companies.

13 In fact, Mr. Auerbach had done two of them in over
14 roughly a year and a half period where he raised 270 million.
15 This is what happened back in 2012 and even earlier in the
16 year 2014. You can see when the stock price was down at \$16
17 a share, they were able to raise \$138 million in stock
18 offering. And when the stock goes up to \$122 a share, they
19 were able to raise \$138 million in stock offering.

20 Trying to claim that you need to boost the stock
21 price to raise money at a stock offering just is misleading,
22 I would say, about what a stock offering is all about and how
23 they occur.

24 By the way, what happened to this money? On this
25 one at least you heard a little bit. The money doesn't go to

1 line Mr. Auerbach's pockets. The money goes to Puma's
2 ongoing cancer trials and research. In fact, they had many,
3 many ongoing trials. They still do. In 2014 you know how
4 much they spent? 122 million developing drugs. Yeah, they
5 weren't selling a single drug at that point. At that point
6 they weren't charging a single patient. They had no
7 revenues.

8 They were just spending money, including money that
9 Mr. Auerbach had originally invested, to develop the drug.
10 You know what they did in 2015? They spent \$208 million.
11 That's what they did with the proceeds of this stock
12 offering. They put it into research and development to
13 develop a breast cancer treatment.

14 By the way, the stock offering process, it involves
15 lots of people. That's one that you probably will find maybe
16 not the most exciting part of this case when you hear about
17 the stock offering process. You'll hear about underwriters.
18 That's bankers who work on that. You'll hear from someone
19 named Brad Wolff from Citigroup who is one of the lead
20 bankers.

21 You will hear that lawyers get involved. You heard
22 about William or Bill Hicks. He'll testify about his role.
23 You'll also hear about the board of directors and their role.
24 Sorry. Troy Wilson you'll hear from. He'll talk to you
25 about how there was a board of directors supervising to make

1 sure all the information came out and was appropriate in the
2 stock offering.

3 You'll also hear that in that stock offering, they
4 sold stock to lots of really sophisticated investors in this
5 country like Fidelity, T. Rowe Price, Franklin Templeton.
6 Interestingly, not a single share of stock to Norfolk in this
7 stock offering.

8 Okay. Now, you'll hear from all these folks on the
9 left. You'll hear from bankers and lawyers and the board who
10 are involved in stock offering. What you won't hear from in
11 this case is a single investor in that stock offering who
12 will come in here and say they were defrauded. Okay.

13 Remember, Norfolk wasn't in that stock offering.
14 Norfolk is complaining about that conference call that
15 happened six months before this. They just want to talk
16 about the stock offering and claim there was some problem
17 there. Yet not a single person involved in that stock
18 offering is here to complain there was fraud.

19 This FDA minutes thing, I guarantee you you will
20 hear -- there will be more minutes spent in this trial on
21 this subject than the FDA ever spent on the FDA minutes. You
22 will hear that Mr. Auerbach sent the wrong document to
23 Mr. Hicks during this course of what's called due diligence.

24 You can hear how it happened. You can hear what we
25 know about it. What you'll also hear, though, is that it was

1 only sent to Mr. Hicks. Mr. Hicks is the lawyer for the
2 bankers who were involved in the process. You'll hear that
3 it was six months after this conference call, so it doesn't
4 really have anything to do with why you're here. It's really
5 a sideshow.

6 And you'll hear that the clinical data that is what
7 matters in this case, that was all shared separately with
8 Mr. Hicks. You'll also learn that those minutes were never
9 sent to Norfolk or Capital, so they never relied on them.
10 They had nothing to do with them.

11 You'll learn that it wasn't made public. It's
12 certainly not like they were trying to trick the public by
13 sending accidentally the wrong minutes. Of course, you won't
14 see anything in that conference call about FDA minutes or
15 anything like that.

16 What you will learn is that the three things that
17 this case is actually about, that is, the absolute
18 disease-free survival rates, that information, the absolute
19 DFS rates, that was shared with Mr. Hicks in a simple
20 PowerPoint presentation that -- I know it's a little hard to
21 read here, but Mr. Hicks and Mr. Auerbach sat in a room.
22 They looked at -- they went through these slides. They
23 looked at this data. Mr. Hicks got to see all the data.

24 So this data that was supposedly hidden was shown
25 to Mr. Hicks. Yes, there was a confidentiality agreement

1 because at the time -- this is in January of 2015 -- this is
2 still five months or six months before the medical
3 conference. So Mr. Auerbach can't make these -- this data
4 public, and everyone knows he can't. But he does show it to
5 Mr. Hicks, so Mr. Hicks is comfortable going forward with the
6 offering.

7 And that's the absolute DFS rates. That's the
8 curves, the Kaplan-Meier curves. And on the next page that's
9 the safety data, the 39.9 percent. All of that information
10 is showed to Mr. Hicks, the stuff that this case is
11 supposedly about Mr. Auerbach hiding.

12 Mr. Hicks sees all that before he signs off on that
13 stock offering which doesn't even involve Norfolk.

14 So finally, why does the stock drop? If everything
15 that I'm talking about turns out to be true, if you see these
16 facts and you see that neratinib was a successful drug, if
17 you see that Mr. Auerbach did tell the truth as best he could
18 in that short phone call, if you see that he had no motive to
19 lie or commit securities fraud, you say, well, why did this
20 pension fund lose a little bit of money out of their \$4
21 billion fund on this investment?

22 What you'll see is that the stock dropped for other
23 reasons. And by the way, we may never know the exact reason.
24 You all know the stock market goes up and down a lot every
25 day. Who knows why? There's all kinds of reasons. But what

1 we will see is that the plaintiffs will not be able to meet
2 their burden of proof to show that it was somehow due to
3 something Puma did.

4 Remember, the theory is that conference call
5 launched some massive fraud that lasted ten months. That's
6 the whole theory of the case, that when he gave those quick
7 answers off the cuff, he was committing securities fraud.

8 And what they say is that then, something like ten
9 months later when the ASCO, is the meeting, and right before
10 you go to the meeting you publish something called an
11 abstract where you basically write up all the details, on May
12 13th the abstract is released. That's when ASCO says --

13 THE COURT: Okay.

14 MR. CLUBOK: I appreciate it, Your Honor. I'm
15 really trying.

16 THE COURT: Okay. Well, you need to try more.

17 MR. CLUBOK: I will try even more.

18 THE COURT: Let me ask this. I'm just giving a
19 pause in the proceedings here. How much more time do you
20 think you need?

21 MR. CLUBOK: Less than ten minutes.

22 THE COURT: All right. Proceed.

23 MR. CLUBOK: Thank you, Your Honor.

24 In May of 2015 the abstract is released. It has
25 got some additional details, and this is where plaintiffs

1 claim that it reveals fraud from that conference call that
2 happened ten months before. And the abstract releases some
3 details like, first of all, the 33 percent improvement and
4 disease-free survival. That hasn't changed. Just like
5 Mr. Auerbach said back in July, the data still shows that
6 there is a 33 percent improvement in disease-free survival
7 for women who took this drug compared to the women who took
8 the placebo. That hasn't changed a bit.

9 The abstract does -- technology is only so good.
10 The abstract does show the 2.3 percent difference. This is
11 what the plaintiffs say, well, that's revealed some kind of
12 fraud. Now, that 2.3 percent difference again is for
13 everyone in the study. We know that when you really dig in
14 the details, it's much better for the centrally confirmed.
15 But that's what it says in the abstract. By the way, the
16 abstract is also pretty short.

17 But the abstract also says some really good news.
18 It shows a 48 percent improvement in disease-free survival
19 for centrally confirmed HER2-positive. That's the great
20 news. Not just 33, but for those women who were centrally
21 confirmed to actually have HER2-positive breast cancer, a
22 48 percent improvement.

23 And it shows the 39.9 percent grade-three diarrhea,
24 but it also makes it clear that that diarrhea is manageable
25 if you simply take Imodium. So do the stock price movements

1 show fraud? Again you were told a couple times you don't
2 need an expert to tell you what happened here. Just use your
3 own eyes. I'll tell you or I'll ask you at least to do the
4 same thing.

5 Look at the stock. We start back in July 22nd,
6 2014. Right before the press release, right before the
7 clinical trial is released, the stock is trading at about \$59
8 a share. And then this press release comes out that has all
9 truthful information about the success of the trial, and sure
10 enough the stock drop goes way up because everyone gets
11 excited about it.

12 After a couple days, it kind of settles down,
13 right, on July 28th at about \$198 a share. That's what
14 happens when stock -- news comes out about a company.
15 Everybody jumps in, gets excited. Maybe after a couple days
16 it settles. It settled at \$198.

17 For the next ten months, what happens to Puma's
18 stock. Well, Puma's stock basically goes on a journey. As
19 you can see if you follow the bouncing ball, this is what the
20 stock does for the next ten months. It's up \$20 one day.
21 It's down \$30 another day. It's up 41 one day, down 50
22 another day -- ten months of the stock being what's called
23 volatile, nothing to do with any fraud.

24 There's no claim that there's any fraud that's
25 affecting the stock price from going up and down, up and

1 down. That's just people making bets one day that it's going
2 to be great. Maybe another day they bet that the FDA won't
3 approve it. Another day a competitor announces some results
4 so they say it's not going to be good. The next day a
5 competitor says they didn't do well. That's what happens to
6 stock price.

7 All of those fluctuations, none of those are fraud.
8 But what the plaintiffs want to say is, well, on May 13th
9 when the abstract gets published and the stock is \$209 a
10 share, at that point the stock does drop, and it drops just
11 about \$39 a share. The plaintiffs say, ah-hah, when the
12 abstract came out, that must show fraud.

13 Forget about the fact that just like a couple weeks
14 earlier the stock dropped \$40 a share over a few days for
15 non-fraud reasons. They want you to believe that this
16 particular drop was all because of fraud. Well, the problem
17 is we have how people reacted at the time, and you all will
18 learn about that.

19 And how did they react at the time? After the
20 abstract analysts continued to believe in neratinib --
21 remember Yaron Werber? He was the guy who asked those
22 questions to Mr. Auerbach. He's the guy who back ten months
23 before was supposedly defrauded. What does he say after he
24 sees the results? Data is actually robust in HER2-positive
25 women -- he works for Citibank. He recommends buy the stock.

1 He doesn't say there's fraud. He puts out a public
2 research report telling people the data is good. Buy. RBC,
3 another analyst, said the same thing. Trial succeeded. Drug
4 works. Says the stock is going to outperform its
5 competitors. UBS said that they're maintaining a buy rating
6 into ASCO -- that means until we get to the medical
7 conference. Bank of America, ExteNET still supports FDA
8 approval. They recommend buy.

9 This is what all of these analysts said. But what
10 does the most important person say for purposes of Norfolk?
11 Norfolk's investment advisor, Skye Drynan, she says, after
12 looking at all the data, the house is not on fire. Buy. She
13 thinks the company is undervalued, as you'll hear her
14 testify. And sure enough, Norfolk bought. They bought 2,200
15 shares.

16 Now, Mr. Younger here at the time probably had no
17 idea that Skye Drynan was buying on his behalf because she
18 had been given discretion by Norfolk to just do that whenever
19 she thought it was appropriate. And after she saw this
20 abstract which supposedly revealed some big fraud, she
21 decides to buy more stock for Norfolk.

22 This is part of the damages they say that they are
23 entitled to be paid for when they end up not making as much
24 money or losing some money on these shares. They want Puma
25 to now pay them back for it.

1 So the stock fluctuates again. You don't need an
2 expert to see this was not fraud, but guess what happens the
3 next few days. The stock goes right back up to \$200 a share.
4 After all of these folks like Skye Drynan and Yaron Werber
5 and everybody else looks at this information, compares it
6 after a couple days of thinking about it to what Mr. Auerbach
7 said, looks at the subgroup data, looks under the hood, the
8 stock ends up basically, you know what, after all of this,
9 after the conference call, it had settled at 198. After the
10 abstract it settled at 200.

11 That's basically the same place, and this is what
12 plaintiffs want you to believe shows fraud. You don't have
13 to believe an expert. You can use your own eyes.

14 So -- but then what happens?

15 THE COURT: Now, okay. But then what happened? I
16 think it's about time to be wrapping up.

17 MR. CLUBOK: Okay, Your Honor.

18 THE COURT: How much longer do you think, because
19 ten minutes ago you said ten minutes.

20 MR. CLUBOK: I now think less than five minutes.
21 Hope springs eternal. I'm trying my best.

22 THE COURT: In all fairness let's bring it to a
23 close.

24 MR. CLUBOK: Okay.

25 When the results get presented at ASCO, what

1 happens? All of these details are released and all of these
2 additional details are released at ASCO, and the stock does
3 go down. The plaintiffs again say, well, that must be fraud.
4 Now, you got thousands of doctors at ASCO. They say if you
5 have three doctors in a room, you're going to get five
6 opinions. When you have thousands of doctors, you're going
7 to get tens of thousands of opinions.

8 Some doctors did not think the drug was that good
9 from what they saw, and so that's what caused the stock to go
10 down. But you know what? The plaintiffs say the new
11 information that is revealed that supposedly ties back to
12 that conference call? That is -- you can barely even see it.
13 It's this curve right here and it's this data point right
14 here.

15 They say those two data points out of all this
16 information that gets presented at ASCO somehow causes the
17 stock to drop. Well, again, you'll hear from experts who
18 will say this is not true. You'll hear from experts
19 including Paul Gompers who is a professor at Harvard business
20 school who has looked at all the analyst reports.

21 You guys can do it for yourselves. You'll see that
22 the reaction to this ASCO was positive. Investors reacted
23 positively. Again, all of these analysts at the time were
24 like, hey, this data is great.

25 We believe the Kaplan-Meier curves, they did

1 separate. The ExteNET curves separate. Subgroup data is
2 robust. Taking a look at the curves, we see the difference
3 is maintained. We view this as new key takeaway from
4 witnessing the curves. Everybody is seeing now what Alan
5 knew at the time. The curves are separating. It's great
6 news, not bad news.

7 And, yes, 16 percent required dose discontinuation,
8 not dropout but dose discontinuation. But the reports say
9 it's no big deal because Imodium prophylaxis can be effective
10 in managing the disease.

11 Safety is in line with previous trials. That is
12 what the analysts report at the time. And guess what Norfolk
13 does. They get this data, and the very next day they run out
14 through Skye Drynan and buy even more stock. The very next
15 day they buy more stock after hearing this information that
16 they now want you to believe is fraud.

17 Again, Norfolk didn't do it. The person they
18 hired, Skye Drynan, who they trusted, she did it because it
19 made sense. So that's what this case is about. That's the
20 evidence that you're going to see.

21 By the way, you'll also see that, of course, Puma
22 had always warned investors about the risk. Puma told
23 everyone it only had one drug it was working on. Puma told
24 everyone over and over again in warnings after warnings after
25 warning that it was a risky company, that they weren't then

1 selling any drugs, that they were spending all their money on
2 R&D.

3 They warned everybody. There's warnings -- there's
4 more warnings in this press release than there are those four
5 information points, but all of this they said if you want to
6 invest in us, you're risking it. We're happy to have you
7 risk with us, but it's a risk.

8 The investors at the end of the day were told the
9 truth about this drug. They were told it was a developmental
10 stage company, and they were told there was a risky
11 investment. All of that is true. No fraud.

12 Again, finally, what does Skye Drynan say? When
13 all of the evidence is in and she's being deposed, she was
14 asked if she still trusts Mr. Auerbach. Yes.

15 THE COURT: We already did this; didn't we?

16 MR. CLUBOK: These are different statements.

17 THE COURT: All right.

18 MR. CLUBOK: The final statement: To the best of
19 your knowledge, do you believe he ever lied to Puma
20 investors? To the best of my knowledge, no. Do you believe
21 he ever lied to you? I do not believe he ever lied to me.

22 I told you the four keys of the case. You're going
23 to hear about all four of those.

24 I'll end where I began. I'm sorry it took a little
25 longer, but there's a lot of things we had to respond to here

1 so that you get the full story. And the full story --

2 THE COURT: I'm sorry. Opening statement is not a
3 response. Opening statement -- I don't understand that
4 statement. Go ahead. Opening statement is your statement,
5 not a response. I'll note that the plaintiff doesn't get a
6 chance to rebut. That's because opening statement isn't
7 about a response. Otherwise shall I give him a chance to
8 rebut? He didn't get any chance to respond.

9 Continue.

10 MR. CLUBOK: I appreciate that, Your Honor.

11 You'll see the facts in the evidence for yourself.
12 You don't have to take my word for it or the word of the
13 plaintiffs' lawyer. You'll see that what Puma did, what Alan
14 Auerbach did, is develop a lifesaving drug called neratinib.
15 You will decide whether or not in the course of that, there
16 was some kind of securities fraud.

17 Thanks.

18 THE COURT: All right, folks, thank you. We'll see
19 you tomorrow, and we'll start at 8:00. Ms. Bredahl, will you
20 be talking to them about that?

21 (Court and clerk conferring)

22 THE CLERK: All rise.

23 THE COURT: Anything else for the jury before we
24 leave? Okay. We'll see you tomorrow at 8:00. Thank you.

25 (Open court - jury not present)

1 THE COURT: The jury is gone. Be seated for just a
2 moment.

3 Gosh, there was a lot of argument in both opening
4 statements. I hope the trial will proceed with some focus.

5 Two quick points. We have this projector here. I
6 do use a button that turns off the screen to the jury at
7 times when we need to discuss an exhibit, and we're going to
8 need someone either able to turn off the projector with a
9 flip or able to put a notepad in front of it or something so
10 that we can proceed with that being blocked when I hit the
11 blackout screen for the jury.

12 Also, there's a few folks in the audience chewing
13 gum. It's not a good idea to chew gum during the trial. I
14 think it's disrespectful of the process. So please cease on
15 that.

16 Is there anything else to decide or talk about now
17 before we meet at 8:00 tomorrow?

18 MR. FORGE: Your Honor, one brief matter, because
19 it does implicate the witness who is testifying tomorrow
20 morning.

21 THE COURT: All right. Now, go ahead.

22 MR. FORGE: Your Honor gave a very clear in=limine
23 ruling with in limine number four. I'll just read it:
24 Plaintiffs' motion in limine four to exclude evidence of
25 post-class period events, results, or outcomes is granted.

1 That is a hard cutoff of evidence. That means both sides
2 don't get to put in some stuff that they would like to, but
3 it's a hard cutoff.

4 THE COURT: Please get to your point.

5 MR. FORGE: The point is defendants have already
6 talked today about --

7 THE COURT: You're not getting to the point. What
8 would you like me to do now?

9 MR. FORGE: I would like Your Honor to simply
10 confirm --

11 THE COURT: No. I'm not going to confirm. Let me
12 state the obvious. My motions in limine are my motions in
13 limine. If you want to argue with them about it afterwards
14 and confirm for yourself that I mean what I said, you may.

15 If you need me to say I mean what I said, I don't
16 need to confirm that, because I do. If they go beyond that,
17 make an objection and I'll make a response.

18 MR. FORGE: I didn't want to say anything in front
19 of the jury, but there were references to --

20 THE COURT: What are we doing now? Are you asking
21 me to say something more?

22 MR. FORGE: No, Your Honor.

23 THE COURT: What do you want me to do now?

24 MR. FORGE: I can give you specific examples of
25 violation --

1 THE COURT: No. You can make an objection when
2 they go beyond.

3 MR. FORGE: Okay.

4 THE COURT: Anything else? Okay. Yes.

5 MS. JOHNSON: No, Your Honor.

6 THE COURT: Okay. We'll see you at 8:00 tomorrow.

7 Thanks.

8 (Proceedings adjourned at 4:51 p.m.)

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