UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. AVEO PHARMACEUTICALS, INC., TUAN HA-NGOC, DAVID JOHNSTON, and WILLIAM SLICHENMYER, Defendants.	)	Case No. **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff United States Securities and Exchange Commission ("the Commission") alleges:

SUMMARY

1. In 2012 and 2013, AVEO Pharmaceuticals, Inc. ("AVEO"), its chief executive officer, Tuan Ha-Ngoc ("Ha-Ngoc"), chief financial officer, David Johnston ("Johnston"), and chief medical officer, William Slichenmyer ("Slichenmyer") (collectively, "defendants") made materially misleading statements to investors about communications with staff of the Food and Drug Administration ("FDA") about AVEO's flagship drug candidate, tivozanib ("Tivo"). In these statements, the defendants noted that FDA staff had expressed concerns about survival rates for patients receiving Tivo, and told investors that AVEO would be addressing those concerns by doing "additional analyses." In so doing, the defendants concealed the critical fact that FDA staff had recommended that AVEO conduct an additional clinical trial, an expensive and time-consuming proposition.

2. AVEO was involved in developing Tivo as a potential treatment for renal cell

carcinoma, an extraordinarily deadly form of kidney cancer.

3. Beginning in 2010, AVEO conducted a large-scale, randomized clinical trial of Tivo, known as TIVO-1. That clinical trial generated promising results concerning Tivo's effectiveness in limiting tumor growth.

4. On May 11, 2012, AVEO officials met with FDA staff to discuss the results of the clinical trial and to discuss the anticipated filing of a New Drug Application ("NDA") for Tivo.

5. NDAs are the formal mechanism through which drug companies propose that the FDA approve a new pharmaceutical for sale and marketing. Drug companies typically meet with FDA staff at a formal "pre-NDA" meeting before filing an NDA to discuss the adequacy of their scientific data and address concerns raised by FDA staff. Accordingly, the investment community expects that an NDA will respond to concerns raised by FDA staff during the pre-NDA period.

6. At the May 11, 2012 pre-NDA meeting, FDA staff told AVEO they were concerned about results from TIVO-1 that showed that, while Tivo seemed to be slowing the progression of the disease, patients taking Tivo were dying sooner than patients taking the other study drug. The FDA staff recommended that AVEO conduct a second large, randomized clinical trial to address these concerns. Conducting a clinical trial for an experimental drug such as Tivo is expensive and time-consuming. AVEO estimated the cost of such an additional trial at more than $80 million, and estimated that it would take approximately three years. AVEO had already invested a similar amount of time and money in TIVO-1.

7. Ha-Ngoc, Johnston and Slichenmyer each were aware that the FDA staff had recommended conducting a second clinical trial. They were also aware that ignoring such a recommendation could affect Tivo's chances of being approved.

8. AVEO began designing a second clinical trial, to be called TIVO-2, shortly after the pre-NDA meeting. Despite having designed, and re-designed, a second trial, and having discussed those trial designs with the FDA staff, AVEO never began a second clinical trial.

9. For more than eleven months, from May 11, 2012 to April 30, 2013, the defendants concealed from investors that the FDA staff had recommended a second clinical trial.

10. Although AVEO informed investors that FDA staff had raised concerns about death rates for patients taking Tivo, defendants concealed from investors the depths of the FDA staff's concerns and, in particular, the fact that FDA staff had recommended a second full clinical trial to address those concerns. AVEO adhered to a corporate communications strategy that emphasized AVEO's data analysis efforts, while downplaying the possibility of further, pre-approval trials. For example:

- On August 2, 2012, AVEO issued a press release that referenced the FDA's "concern regarding the [overall survival] trend" from TIVO-1. The press release stated that AVEO would be doing "additional analyses" to address the FDA's concerns, but omitted any reference to the FDA staff's recommendation to conduct another trial or AVEO's ongoing work designing TIVO-2.
- In a conference call with investors the same day, consistent with AVEO's communications strategy, Slichenmyer falsely stated that he could not "speculate" on what the FDA might want in the future as far as additional studies. Slichenmyer did not need to "speculate" because he knew that FDA staff had recommended an additional clinical trial and that failure to complete such a clinical trial could jeopardize Tivo's approval prospects.

11. In September 2012, AVEO filed an NDA for Tivo. The NDA was filed without data from any second clinical trial and without any agreement from the FDA staff about whether or when such a trial might be needed, or about its design.

12. Investors and analysts generally understand the filing of an NDA to be a final step in the approval process for a new drug. Despite the FDA staff's recommendation that AVEO conduct an additional clinical trial, the Tivo NDA did not mention that FDA staff had recommended an additional clinical trial, nor that such a trial had neither been approved by the FDA, nor started by AVEO. AVEO did not publicize this when it publicized the filing of its NDA.

13. Following its NDA filing, which AVEO announced publicly on September 28, 2012, AVEO raised approximately $53 million in a public offering of securities in January 2013.

14. On or about April 30, 2013, in advance of a meeting of an advisory panel of outside experts convened by the FDA to consider AVEO's NDA, FDA staff released a pre-meeting summary. That summary included the FDA staff's prior recommendation to AVEO to conduct a second trial. That day, AVEO's stock price closed down 31%, with analyst attention focused squarely on the unexpected news about a recommended second trial and the negative implications such a recommendation had for Tivo's approval prospects.

15. On May 2, 2013, the advisory panel voted resoundingly against approving Tivo, citing various flaws in TIVO-1. On June 10, 2013, the FDA followed suit and refused to approve the drug.

16. By knowingly or recklessly engaging in the conduct described in this Complaint, each of the Defendants violated Section 17(a) of the Securities Act of 1933 ("Securities Act") and Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5

thereunder. In addition, Johnston and Ha-Ngoc violated Exchange Act Rule 13a-14, and AVEO violated Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder.

JURISDICTION AND VENUE

17. The Commission seeks a permanent injunction and disgorgement pursuant to Section 20(b) of the Securities Act [15 U.S.C. §77t(b)], and Section 21(d)(1) of the Exchange Act [15 U.S.C. §78u(d)(1)]. The Commission seeks the imposition of a civil penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. §77t(d)], and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)].

18. The Court has jurisdiction over this action pursuant to Sections 20(d) and 22(a) of the Securities Act [15 U.S.C. §§77t(d), 77v(a)], and Sections 21(d), 21(e) and 27 of the Exchange Act [15 U.S.C. §§78u(d), 78u(e), 78aa].

19. Venue is proper in this District because, at all relevant times, AVEO maintained offices in Massachusetts and conducted business in Massachusetts, and Ha-Ngoc, Johnston and Slichenmyer lived in Massachusetts. A substantial part of the actions that give rise to the Commission's claims also occurred in Massachusetts.

20. In connection with the acts described in this Complaint, defendants directly or indirectly made use of the mails or the means or instruments of transportation or communication in interstate commerce.

21. Defendants' conduct involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements, and resulted in substantial loss, or significant risk of substantial loss, to other persons.

DEFENDANTS

22. **AVEO Pharmaceuticals, Inc.**, ("AVEO"), a Delaware corporation, is a small biopharmaceutical company whose principal place of business is in Cambridge, Massachusetts. AVEO's common stock is registered under Section 12(g) of the Exchange Act and trades on the NASDAQ stock exchange under the symbol "AVEO." AVEO does not have any drugs that have been approved by the FDA for sale to the public.

23. **Tuan Ha-Ngoc ("Ha-Ngoc")**, age 64, served as chief executive officer of AVEO from 2002 to 2015. Ha-Ngoc was AVEO's chairman of the board of directors from January 6, 2015 until November 6, 2015. Before joining AVEO, Ha-Ngoc worked in various positions at a number of biotechnology companies, as well as serving as a director for two other biotechnology companies. Ha-Ngoc is a resident of Lexington, Massachusetts.

24. **David Johnston ("Johnston")**, age 60, served as AVEO's chief financial officer from 2007 through 2013. Johnston left AVEO to join another small biotechnology company as its chief financial officer. From 1998 until 2007, Johnston worked in various finance-related positions at another biotechnology company. Johnston is a resident of Marblehead, Massachusetts.

25. **William Slichenmyer ("Slichenmyer")**, age 58, was AVEO's chief medical officer from 2009 to 2014. Since leaving AVEO, he has been working as a consultant to the biopharmaceutical industry. Before AVEO, he worked at various other biotechnology companies, including as the chief medical officer. Slichenmyer is a resident of Sherborn, Massachusetts.

STATEMENT OF FACTS

The FDA Approval Process

26. Before a drug can be sold in the United States, a drug company must obtain approval from the FDA. The FDA will only approve a drug if there is "substantial evidence" consisting of "adequate and well-controlled" trials demonstrating that the drug is safe and effective for its intended use in humans.

27. To demonstrate the safety and efficacy of a drug, drug companies conduct human clinical trials in three phases. Phase I focuses on dosing and side effects; Phase II determines whether there is adequate evidence of efficacy and safety to justify further development; and Phase III trials are supposed to provide evidence of efficacy and safety to enable the FDA to evaluate the overall risk-benefit relationship of the drug.

28. Safety is particularly important for cancer drugs, like Tivo, because they are generally toxic even if effective in stopping the progression of a disease. Consequently, cancer drugs often are assessed based on progression-free survival ("PFS") (the length of time from the start of treatment to the disease's "progressing") and overall survival ("OS") (the length of time from the start of treatment to patient death).

29. After completing the Phase III trial(s), a drug company may seek approval to market and sell its drug to the public. It does so by submitting an NDA to the FDA.

30. Within 60 days of receiving an NDA, the FDA staff must either accept the NDA as sufficiently complete to permit a substantive review or issue a Refusal to File ("RTF") letter. A RTF letter is typically reserved for circumstances when there is facial error in the application, and the non-issuance of such a letter is not a substantive determination on the merits of the NDA. If the FDA staff does not issue a RTF letter, then the FDA staff's next correspondence with the

drug company comes in the form of a "74 day letter," which details any significant review deficiencies the FDA staff identifies during its preliminary review of the NDA and gives the drug company the opportunity to respond to any FDA staff concerns by amending the NDA.

31. In circumstances where the FDA staff wants additional technical advice, or an opportunity to discuss controversial issues, before the FDA's official vote on a particular drug, it convenes an advisory panel of outside experts to opine as to the drug's safety and efficacy. The FDA staff poses one or more questions to the panel, which responds in the form of a non-binding vote. For cancer drugs, this panel is called an Oncologic Drugs Advisory Committee ("ODAC"). Both the drug company and the FDA staff submit briefing documents to the ODAC. These documents contain background information on the drug being considered, including detailed clinical data, prior regulatory interactions, the competitive landscape, and an ultimate question for a non-binding up or down vote. A few days before the meeting, the FDA staff and the drug company release these documents to the public.

32. After the ODAC votes, the FDA holds its official vote on whether to approve the drug unconditionally, approve the drug assuming certain conditions are met, or deny approval.

Tivozanib and Its Significance to AVEO

33. AVEO is a biopharmaceutical company focused on discovering, developing, and commercializing cancer drugs. One such drug candidate was Tivo. Tivo was developed for the treatment of advanced renal cell carcinoma ("RCC"), a particularly deadly form of kidney cancer. Since AVEO was formed, Tivo is the drug AVEO has advanced farthest in the FDA approval process. Tivo's development, hoped-for approval by the FDA, and ultimate success were material to AVEO because the company had yet to have a drug approved for sale to the public. As a result, at all relevant times, investors valued AVEO's business prospects based

primarily on the estimated likelihood of Tivo's success. As AVEO itself acknowledged in public filings with the Commission in 2012 and 2013, the company was "dependent on the success of [its] lead drug candidate, tivozanib."

34. In February 2011, AVEO signed an agreement with Astellas Pharma, Inc., a Japanese biopharmaceutical company with subsidiaries in the United States, to share the development and commercial costs and profits for Tivo in exchange for an initial cash payment of $125 million and various potential milestone payments totaling $1.3 billion from Astellas. Under the agreement, AVEO was responsible for commercializing Tivo in North America and Astellas was responsible for commercializing Tivo in Europe.

35. AVEO initiated its large-scale, randomized Phase III study for Tivo, known as TIVO-1, in 2010. TIVO-1 tested the performance of Tivo against a drug already on the market, sorafenib (trade name Nexavar). Without formal agreement from FDA staff, AVEO permitted study participants assigned to receive sorafenib to take Tivo once their disease had progressed. Patients initially assigned to take Tivo did not have the complementary option of later taking sorafenib. This design was described as a "one-way crossover." TIVO-1 was conducted predominantly in Central and Eastern Europe, where RCC treatment options are severely limited. Because there were few treatment options outside the study, the one-way crossover design meant that patients assigned to take sorafenib were more likely to have received two consecutive therapies, while those assigned to the Tivo arm of the study received only one therapy.

36. In January 2012, AVEO announced that TIVO-1 had achieved its primary endpoint by demonstrating a statistically significant increase in PFS for Tivo relative to sorafenib. The OS results were less positive. In its preliminary review of OS data, AVEO

observed a decrease in OS for patients taking Tivo, meaning patients assigned to take Tivo were dying earlier than patients taking sorafenib.

AVEO's Regulatory Interactions

37. Representatives from AVEO and Astellas met with FDA staff in Maryland on May 11, 2012 to discuss the data from TIVO-1 and the anticipated filing of the Tivo NDA (the "pre-NDA meeting").

38. The official, FDA-generated minutes of that meeting, which were created by the FDA staff and AVEO ("the sponsor") during the meeting, summarized the parties' main discussion points. These minutes were provided to AVEO at the conclusion of the meeting. They stated, in relevant part,

> The Agency expressed concern about the adverse trend in overall survival. Further discussion of these findings will be required at the time of filing and if the application is filed they will be a review issue that could affect approvability. FDA recommended that the sponsor conduct a second adequately powered randomized trial in a population comparable to that in the US. FDA also recommended that the sponsor conduct the final analysis of overall survival in the current trial. The Sponsor noted they plan to submit exploratory analyses in the NDA.

39. According to FDA staff, TIVO-1's one-way crossover design and Central/Eastern European patient population made it difficult to determine if patients taking Tivo were dying earlier because Tivo was toxic or because -- as AVEO posited during the meeting -- they were only receiving one therapy instead of two.

40. Slichenmyer attended the pre-NDA meeting. After leaving the meeting, beginning on his flight back to Boston, Slichenmyer prepared a PowerPoint presentation summarizing the pre-NDA meeting and laying out options for AVEO to consider. AVEO's

Executive Committee met the next day (a Saturday) and saw the PowerPoint presentation. Johnston attended the meeting, and Ha-Ngoc, who was out of town, participated by telephone. Thus, both Johnston and Ha-Ngoc learned by May 12 of the FDA staff's OS concerns and its recommendation to conduct a second trial. One slide in the presentation included the FDA staff's feedback quoted above. Another laid out three options for AVEO going forward, as well as the benefits and risks for each. The first option, "staying the course" (i.e. filing the NDA without data from an additional trial), included a "con" of "high risk for RTF or Non-approval." Both of the other two options involved delaying the filing of the NDA until the second clinical trial was complete. The "pro" for those options was "Reduces Risk," either in the United States or world-wide. Under "con," the slide noted, "Lose 3 years of US revenue," and "Lose 3 years of WW [worldwide] revenue." The slide appeared as follows:

Tradeoffs

Approach	Pro	Con
Stay the course, start an additional OS trial	Maintains potential for on-time launch	High Risk of RTF or Non-approval
Proceed in EU, Delay in US until 2nd OS trial complete	Reduces Risk in US	Lose 3 years of US revenue
Delay WW until 2nd trial complete	Reduces Risk WW	Lose 3 years of WW revenue

41. On or about May 12, 2012, Slichenmyer received a PowerPoint presentation from another AVEO employee who had been at the pre-NDA meeting. This presentation contained additional FDA staff feedback from the pre-NDA meeting and included the statement, "The FDA did not seem moved by the analysis of the differential use of crossover as an explanation for OS results."

42. On or about May 30, 2012, the defendants received another PowerPoint presentation intended for AVEO's Board of Directors that included additional feedback received from FDA staff at the pre-NDA meeting. According to this presentation, at the pre-NDA meeting, FDA staff told AVEO that "when one randomized trial is used to support registration, all endpoints must be consistent," that it is "[p]roblematic for FDA to approve a drug if OS trends in the wrong direction, despite positive PFS[,] even if there is a good reason for the OS trend," that it would be "in the sponsor's best interest to start another randomized trial, in a population relevant to the US," and that "[o]verall survival is a key safety endpoint." Ha-Ngoc reviewed this slide, and Johnston was involved in discussions of all of these points.

43. Less than a month after the pre-NDA meeting, AVEO began running additional analyses of the existing OS data in an effort to show that the OS results were a product of some patients' having taken one drug, while others took two. AVEO also began designing a second large-scale, randomized trial, to be called TIVO-2. These efforts included drafting a study protocol and gaining approval from the Board of Directors on a budget for the study. TIVO-2 was projected to cost at least $83 million and take approximately three years.

44. In July 2012, AVEO requested a meeting with the FDA staff. The purpose of this proposed meeting was to discuss two issues from the pre-NDA meeting in May: the second trial that FDA staff had recommended, and the additional analyses of OS data that AVEO had volunteered. In its meeting request to the FDA staff, AVEO stated it "will conduct an additional randomized study (AV-951-13-302; TIVO-2) as recommended by the Agency at the pre-NDA meeting" and included a draft study protocol for TIVO-2. AVEO proposed that TIVO-2 be initiated "by the first quarter 2013" and queried, "Does the Agency agree that the timing and design of the study... are consistent with the Agency's thoughts regarding an additional RCC

study mentioned in the pre-NDA meeting?"

45. On or about August 29, 2012, FDA staff responded in writing to AVEO's request for a meeting. In response to AVEO's question about the timing and design of the study, FDA staff wrote, in pertinent part, "No. The FDA has significant concerns regarding the trial design described in your meeting package . . .[.]" The FDA staff criticized the proposed TIVO-2 design for not adequately measuring OS, given that "the primary concern of the current proposed NDA submission is the negative trend in [overall] survival."

46. On or about August 31, 2012, AVEO cancelled the meeting it had requested, writing to the FDA staff that, "[u]pon thorough review, AVEO believes it is not necessary to proceed with this meeting."

47. That same day, Astellas wrote to AVEO to express its disagreement with AVEO's decision to cancel the meeting. In an email from its head of medical oncology to Slichenmyer, Johnston, and others, Astellas wrote:

> The FDA did not provide a direct response on the question of timing for this study. [...] This raises the possibility that this [additional] trial might be required before approval. These issues are directly relevant to the timing and probability for approval of the RCC indication and therefore necessitate discussion and deeper understanding with the FDA as soon as possible.
> [. . .]
> [W]e find it highly unusual for a sponsor to cancel a scheduled Type A meeting with the FDA when the preliminary responses from the FDA indicate lack of agreement with the strategies proposed and 'significant concerns' with a Phase 3 study design. The approach taken by AVEO may decrease [sic] the risk of an acceptance for filing by the FDA which could also impact the probability of successful applications in other regions such as Europe.

48. On or about September 28, 2012, AVEO filed the Tivo NDA with the FDA. The NDA included the final OS results, which had worsened slightly for Tivo since the pre-NDA

meeting. The NDA also included additional analyses of the OS data, which were aimed at showing that the OS results were a product of some patients' having taken one drug, while others took two. The submission did not include data from any second trial, as no second trial had even been started. Nor did the NDA include any timetable or design for such a trial. The FDA accepted the NDA for review. In the 74-day letter, issued in December 2012, FDA staff cautioned that the OS results remained "a significant safety concern" to be discussed at a meeting of the ODAC. In February 2013, the FDA staff informed AVEO that Tivo would be evaluated at the ODAC meeting scheduled for May 2, 2013.

49. From September 2012 to March 2013, AVEO spent time redesigning TIVO-2 to reflect the FDA staff's comments from August 2012.

50. On or about March 8, 2013, AVEO submitted to the FDA a revised TIVO-2 study protocol. AVEO asked for a meeting to discuss the protocol with FDA staff. In the meeting request, AVEO explicitly asked, for the first time, whether the study could be done as a "postmarketing commitment or requirement."

51. On or about March 13, 2013, the FDA staff responded. Again, the staff rejected the proposed study design, citing a number of concerns. In so doing, the FDA staff wrote, "we encourage you to design the trial properly as soon as possible" and noted that "the design, conduct, and results of this trial will determine whether this one additional trial will be sufficient for approval purposes." To AVEO's question about whether the FDA agreed that the study could be "a postmarketing commitment or requirement," FDA staff answered, "No."

52. In anticipation of the ODAC meeting and before the market opened on April 30, 2013, the FDA staff and AVEO each publicly released briefing documents containing, among other background information, a description of prior communications between the FDA staff and

AVEO. The FDA staff's briefing document disclosed that, at the pre-NDA meeting in May 2012, the FDA staff had recommended that AVEO conduct a second, adequately powered, randomized trial in a population comparable to that in the United States. AVEO's briefing document did not mention this recommendation. The question posed to the ODAC by the FDA staff in its briefing document was "whether this single trial is sufficient to support approval of tivozanib for the indication of treatment of patients with advanced renal cell cancer or whether an additional trial is necessary before considering marketing approval."

53. On May 2, 2013, the ODAC voted 13 to 1 that TIVO-1 was not sufficient to support approval. Shortly thereafter, Astellas informed AVEO that it would not fund additional trials for Tivo as a treatment for RCC and would not seek approval in Europe. As a result of Astellas's withdrawal, AVEO lost the opportunity to earn up to approximately $1 billion in additional payments.

54. On June 10, 2013, the FDA followed the ODAC's lead and denied approval for Tivo.

Defendants' Communications Plan and Misleading Statements

55. Between May 11, 2012 and August 2, 2012, the defendants did not make any public statements about the content of the pre-NDA meeting.

56. On August 2, 2012, before the market opened, AVEO issued a press release announcing its results for the second quarter of fiscal year 2012 ("August 2 Press Release"). AVEO included the text of this release in a Form 8-K filed with the Commission. Ha-Ngoc and Johnston had ultimate authority and control over this press release. The August 2 Press Release contained a section entitled "Regulatory Update" that stated, in relevant part,

> [t]he FDA has expressed concern regarding the OS trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing as well as during the review of the NDA. AVEO is conducting additional analyses to be included in the NDA submission that demonstrate that the OS data from TIVO-1 are consistent with improved clinical outcomes in RCC patients receiving more than one line of therapy; analyses that the company believes will directly address this issue. AVEO is continuing to work toward submitting the NDA by end of the third quarter; however, there is a chance that the additional OS analyses may cause the submission to move into the fourth quarter.

57. The August 2 Press Release was misleading because it did not disclose the FDA staff's recommendation to conduct a second trial. By omitting this information, AVEO understated the FDA staff's level of concern about the OS results and misstated the FDA staff's recommended approach for addressing those concerns. The August 2 Press Release also was misleading because it suggested that AVEO's additional analyses were responsive to the FDA staff's concerns and that AVEO would be able to avoid the millions of dollars in costs and potential several years of delay that a second clinical trial would entail.

58. The August 2 Press Release and the related earnings call that same day were part of a communications strategy devised and implemented by AVEO. The process of preparing these communications started approximately three to four weeks before August 2. Working with AVEO's investor relations and corporate communications staff, Ha-Ngoc, Johnston, and other AVEO senior management devised a script to be used in connection with the August 2 communications. This script emphasized the additional data analyses that AVEO was conducting and downplayed the possibility of future pre-approval studies. It included anticipated questions from investors and analysts, as well as approved responses to those questions. For example, if asked about additional studies requested by the FDA, AVEO employees were to

respond that they were not going to get into the details of discussions with the agency, and that they were confident in the data package. The script went on to advise that, "IF PUSHED . . ." for details on discussions with the FDA, the response should be that AVEO "wouldn't want to speculate on what the Agency would do in the future." This communications strategy was misleading because it ignored the fact that (1) AVEO's explanations about two therapies versus one had not been persuasive to the FDA staff at the pre-NDA meeting, and (2) despite having heard those explanations, the FDA staff had recommended a new trial. The script contained no mention that AVEO was actively planning a second, large-scale, clinical trial.

59. In the days leading up to the earnings call, as was AVEO's practice, AVEO held meetings to discuss the communications strategy and to do mock question-and-answer sessions. These meetings involved the AVEO senior management who were expected to participate in the call, including the defendants.

60. On August 2, after AVEO issued the press release, the defendants participated in a conference call with analysts and investors about the earnings release for the second quarter ("August 2 Investor Call"). During the August 2 Investor Call, Ha-Ngoc and Johnston made prepared statements as scripted in the communications plan. Then Slichenmyer engaged in the following colloquies with stock analysts:

> Analyst 1: I guess the first question I have is can you share with us what exactly the FDA asked for and whether you have that data and how should you need to conduct further studies to get to that data?
>
> Slichenmyer: Right, so, in discussing this with the FDA, we -- I guess maybe I should first say that it's not our intention to get into details about our ongoing dialogue with the agency, but can share with you our thoughts about some of the additional analyses that we intend to include in the NDA to address this observation that we've got with the overall survival data from the study. [. . .]

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Analyst 2: And then, would you be able to help us understand, based on your discussions with the agency, let's say that these additional analyses that you're submitting actually are ultimately not sufficient to address their concerns on overall survival. What are the different pathways that you would have going forward to get Tivo approved? Is it waiting for the overall survival data to mature, or there are other possibilities that maybe the FDA outlined to you as a way to fix this issue?

Slichenmyer: Yes. So first I want to reaffirm that we believe that the current data package should be sufficient to gain approval. But in the unlikely scenario that we might get into something like you described there, I can't speculate on what the agency might be thinking or what additional actions might be necessary. But obviously, it would be tailored to what, if any, concerns they had.

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Analyst 3: [. . .] So, when you met with the FDA and they brought up their concerns, did they kind of point you towards a direction of what studies they wanted to acquire? And when you commented on these analyses that you're doing, were they comfortable with that or did they kind of push you into a different direction of maybe doing some additional new analyses or additional studies?

Slichenmyer: Yes. So, we're not going to get into the details of our ongoing discussions with the agency at this point. And really, the key thing about our updating today is because of the potential impact on our NDA submission timeline. And so regarding any future study, I think -- again, I just can't speculate on what the agency might want us to do in the future.

61. Slichenmyer's comments from the August 2 Investor Call followed AVEO's communications strategy. These statements were misleading because Slichenmyer did not disclose the FDA staff's recommendation to conduct a second trial. His statements that he could not speculate on what the FDA "might be thinking" and "might want [AVEO] to do in the future" were false because there was no need for speculation: he knew that the FDA staff had recommended at the pre-NDA meeting that AVEO conduct an additional study. Slichenmyer also misled investors when he characterized it as "unlikely" that the FDA would not be

persuaded by the additional OS analyses because he knew that (1) AVEO's explanations about two therapies versus one had not been persuasive to the FDA staff at the pre-NDA meeting, and (2) despite having heard these explanations, the FDA staff had recommended a new trial. Slichenmyer further misled investors when he described only one of the two things AVEO was doing to address the FDA staff's concerns, namely the additional analyses the company would perform, while omitting any reference to the plans for TIVO-2, which AVEO was actively planning. This was also consistent with AVEO's communications strategy, which included no reference to these plans.

62. On or about August 7, 2012, AVEO filed with the Commission its quarterly report on Form 10-Q ["August 7 Form 10-Q"]. The August 7 Form 10-Q stated in relevant part:

> An interim analysis of overall survival in TIVO-1 found that, while the data are not yet mature, there is a trend toward better overall survival in patients randomized to Nexavar, most of whom received tivozanib as second line therapy due to the one-way crossover design of TIVO-1. The FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has said that it will review these findings at the time of the NDA filing as well as during the review of the NDA. We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may successfully gain approval to market tivozanib... If the FDA or EMA determines that our phase 3 clinical trial results are not statistically significant or do not demonstrate a clinically meaningful benefit and an acceptable safety profile, or if the FDA or EMA requires us to conduct additional clinical trials of tivozanib in order to gain approval, we will incur significant additional development costs, commercialization of tivozanib would be prevented or delayed and our business would be adversely affected.

Johnston signed the August 7 Form 10-Q and Ha-Ngoc certified that it did not contain any untrue statements of material fact or omit to state a material fact necessary to make the statements therein not materially misleading.

63. The August 7 Form 10-Q was misleading because it did not disclose either the FDA staff's recommendation to conduct a second trial or the fact that AVEO was actively planning such a trial, including getting Board approval for it.

64. The same day, a member of Astellas' corporate communications group emailed Johnston and others to suggest that investors be told that "an additional study will also be conducted and is under discussion with FDA," but AVEO adhered to its communications strategy and did not make any such public statement.

65. Analyst coverage in the days following the August 2 Press Release, and throughout the following months, demonstrated that investors were focused on the details of the FDA's responses to the negative OS trend. In their reports following the August 2 Press Release and August 2 Investor Call, analysts expressed their uncertainty about how the FDA staff was judging the situation, and about the level of concern among the staff. One report noted that AVEO would only be analyzing the TIVO-1 data, and a new trial would not be required. Another wrote, "the issue is that approval now becomes a question of regulatory judgment and trying to guess whether the FDA will accept AVEO's logic [about the effect of the trial design on overall survival] or take a purist approach and merely see AVEO's arguments as hypothesis generating but requiring a confirmatory study." At least some of these reports were circulated to Ha-Ngoc and Johnston.

66. On or about August 16, 2012, Johnston presented at the Canaccord Genuity Global Growth Conference ("Canaccord Conference") and stated, in relevant part,

> In our trial, the tivozanib arm was 77% overall survival. And interestingly, the sorafenib arm showed 81% overall survival. When we met with the FDA in our pre-NDA meeting, this caught their eye, and it's—properly, it's the FDA's job to present safe and effective drugs to the U.S. population. And even though overall

> survival in this therapy is not an approvable endpoint, this is—the overall survival trend is moving in a different direction than PFS, and they expressed some concern and they would like an explanation. So along those lines, we are doing a lot of analyses to help address their concern and we expect to do so as we file our NDA later this quarter.

67. Johnston's statements at the Canaccord Conference were consistent with AVEO's communications strategy, and were misleading because he did not disclose the FDA staff's recommendation that AVEO conduct a second trial, nor that AVEO was planning such a trial. He further misled investors when he suggested the FDA had asked for an explanation of the OS results from TIVO-1. In reality, the FDA staff had listened to AVEO's proffered explanation of the OS results, and had nonetheless recommended doing a second trial, which was a much more expensive and time-consuming proposition. Johnston's statements also were misleading because they discussed only one of the two approaches AVEO was taking to address the FDA staff's concerns (the additional analyses), while omitting the other (the ongoing design of a second trial).

68. On or about September 10, 2012, Johnston presented at the Morgan Stanley Global Healthcare Conference ("Morgan Stanley Conference"), where he engaged in the following colloquy with an analyst:

> Analyst: ...why don't we start, of course, with Tivo and maybe we can chat about some of the –some of your recent discussions with the FDA about the overall survival analyses. So maybe just give a quick overview of the issue for people. And then where are your discussions currently and updated thoughts on this process.
>
> Johnston: ...when we first went to the FDA in the spring, we just presented top line data for our pre-NDA meeting. What they saw was in the one-year survival percentages of the two arms, those who were randomized to the sorafenib arm, once again those who are eligible to receive Tivo for second line, had an 81% survival rate after one year. And those patients who had been originally randomized to the tivozanib arm had a 77%

> survival rate. Now that led the FDA to then say, this is something that we need you to explain, and we expect to see it in your NDA submission and we expect to see from overall survival et cetera. So that's what we're up with the FDA on now.

69. Johnston's statements at the Morgan Stanley Conference were consistent with AVEO's communications strategy and were misleading because he did not disclose the FDA staff's recommendation that AVEO conduct a second trial, nor that AVEO was planning such a trial. He also misled investors when he stated that the FDA had asked for an explanation of the OS results from TIVO-1. In reality, the FDA staff had listened to AVEO's proffered explanation of the OS results, and had nonetheless recommended doing a second, adequately powered, randomized trial.

70. On or about September 20, 2012, Johnston presented at the UBS Global Healthcare Conference ("UBS Conference") and stated, in relevant part,

> For the TIVO-1 study, 77% of the patients initially randomized to tivozanib had survived after the 12-month—at the 12-month snapshot. The sorafenib arm showed 81% overall survival. And that was a statistic that was noticed at our pre-NDA meeting with the FDA. They were rightly concerned with the fact that the overall survival trends were going in a different direction of PFS. Now at that time, they didn't see any backup analysis. There was no explanation. They simply said, we need to understand this. And we think that's the right thing.

71. Johnston's statements at the UBS Conference were consistent with AVEO's communications strategy and were misleading because he did not disclose the FDA staff's recommendation that AVEO conduct a second trial, nor that AVEO was planning such a trial. He also misled investors when he stated that the FDA had asked for an explanation of TIVO-1's OS results. In reality, the FDA staff had listened to AVEO's proffered explanation of the OS results, and had nonetheless recommended that AVEO conduct a second, adequately powered,

randomized trial. Johnston also misrepresented that AVEO had not provided the FDA staff with any backup analysis or explanation for the difference in OS rates at the pre-NDA meeting. In truth, AVEO had presented the FDA staff its data analyses which aimed to demonstrate that the overall survival trends were a result of the study design, and not the result of any flaw in Tivo, and the FDA staff had nonetheless recommended that AVEO conduct a second trial.

72. Throughout the time period from August 2012 through May 2013, AVEO offered its stock to its employees through its Employee Stock Purchase Plan.

73. On or about November 8, 2012, AVEO filed with the Commission a quarterly report on Form 10-Q ("November 8 Form 10-Q") that contained the identical incomplete disclosure contained in the August 7 Form 10-Q. Johnston signed the November 8 Form 10-Q and Ha-Ngoc certified that it did not contain any untrue statements of material fact or omit to state a material fact necessary to make the statements therein not materially misleading. Like the August 7 Form 10-Q, the November 8 Form 10-Q was misleading because it did not disclose either the FDA staff's recommendation to conduct a second trial or the fact that AVEO was actively planning such a trial, including getting Board approval for it.

74. On or about January 16, 2013, AVEO filed with the Commission a current report on Form 8-K ("January 16 Form 8-K") for the purpose of updating and superseding the risk factor disclosure contained in its prior public filings. The revised disclosure stated, in relevant part,

> An analysis of overall survival in TIVO-1 found that there is a trend (which is not statistically significant) toward better overall survival in patients randomized to Nexavar, most of whom received tivozanib as second line therapy due to the one-way crossover design of TIVO-1. The FDA has expressed concern regarding the overall survival trend in the TIVO-1 trial and has

> said that these findings will be a subject of review during the review of the NDA.
>
> We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may successfully gain approval to market tivozanib.... If the FDA or EMA determines that our phase 3 clinical trial results are not statistically significant, do not demonstrate a clinically meaningful benefit and an acceptable safety profile, do not reflect an acceptable risk-benefit profile for any reason, including due to the trend in overall survival we observed in TIVO-1 or for other reasons or if the FDA or EMA requires us to conduct additional clinical trials of tivozanib in order to gain approval, we will incur significant additional development costs, commercialization of tivozanib would be prevented or delayed and our business would be adversely affected.

75. The January 16 Form 8-K was misleading because it did not disclose either the FDA staff's recommendation to conduct a second trial or the fact that AVEO was actively planning such a trial, including getting Board approval for it.

76. On or about January 17, 2013, AVEO filed with the Commission a Rule 424(b)(3) Prospectus Supplement in anticipation of the offering of 6,667,000 shares of common stock with the option of offering 1,000,050 additional shares of common stock at a price of $7.50 per share ("January Prospectus Supplement"). The January Prospectus Supplement incorporated by reference certain of AVEO's prior public filings, including the August 7 Form 10-Q, November 8 Form 10-Q, and January 16 Form 8-K, each of which contained materially misleading statements about the FDA's recommendation to conduct a second trial.

77. AVEO ultimately raised approximately $53.8 million in connection with this stock offering.

78. On or about February 27, 2013, Johnston presented at the RBC Capital Markets Global Healthcare Conference ("RBC Conference") and engaged in the following colloquy with

an analyst:

Analyst: So the company has been pretty upfront about disclosures, disclosing the OS risk et cetera, OS trend as a concern for the FDA.

Johnston: Absolutely.

79. Johnston's statement that AVEO had "absolutely" been upfront about disclosures was misleading because he knew AVEO had not disclosed the FDA staff's recommendation to conduct a second trial, nor AVEO's ongoing plans for such a trial, nor its discussions with the FDA staff about trial design. Furthermore, Johnston knew that AVEO's communications strategy dictated that the company not be "upfront" about disclosing its discussions with the FDA staff.

80. On or about March 11, 2013, AVEO filed with the Commission its annual report on Form 10-K for the period ending December 31, 2012 ("March 11 Form 10-K"). The March 11 Form 10-K contained a disclosure identical to that in the January 16 Form 8-K. Johnston signed the March 11 Form 10-K and Ha-Ngoc certified that it did not contain any untrue statements of material fact or omit to state a material fact necessary to make the statements therein not materially misleading. Like the January 16 Form 8-K, the March 11 Form 10-K was misleading because it did not disclose either the FDA staff's recommendation to conduct a second trial or the fact that AVEO was actively planning such a trial, including getting Board approval for it.

Public Disclosure of the FDA's Recommendation

81. On or about April 30, 2013, in anticipation of the May 2 ODAC meeting, the FDA publicly disclosed the staff's prior recommendation that AVEO conduct a second randomized trial in a population comparable to that of the United States. The market reacted

strongly: AVEO's stock price closed down 31% for the day, the largest one-day drop in the stock's history to that point.

82. Following the FDA's disclosure, analysts covering AVEO focused largely on the previously undisclosed FDA recommendation to do a second trial. According to one analyst,

> given the unexpected FDA disclosure of 'recommending' another study at the pre-NDA meeting, risk-reward which was 50-50 for the Street going into ODAC has clearly become more negative with investors believing that an approval with the current study is unlikely. Our view of risk-reward would also have been more cautious were we aware of the FDA's request.

FIRST CLAIM
Fraud in the Purchase or Sale of Securities in Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Thereunder (Against All Defendants)

83. The Commission repeats and incorporates by reference the allegations in paragraphs 1-82 above as if set forth fully herein.

84. Defendants engaged in a fraudulent course of conduct that included making material misrepresentations and omissions regarding an FDA recommendation to conduct a second trial for Tivo.

85. By engaging in the conduct described above, defendants, directly or indirectly, acting knowingly or recklessly, by the use of means or instrumentalities of interstate commerce or of the mails, in connection with the purchase or sale of securities, have employed devices, schemes or artifices to defraud; made untrue statements of material fact or omitted to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading; and engaged in acts, practices or courses of business which operate as a fraud or deceit upon certain persons.

86. By reason of the forgoing, each of the defendants violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5].

SECOND CLAIM
Fraud in the Offer or Sale of Securities in Violation of Section 17(a) of the Securities Act (Against All Defendants)

87. The Commission repeats and incorporates by reference the allegations in paragraphs 1-82 above as if set forth fully herein.

88. Defendants engaged in a fraudulent course of conduct that included making material misrepresentations and omissions regarding an FDA recommendation to conduct a second trial for Tivo.

89. By engaging in the conduct described above, defendants, directly and indirectly, acting knowingly, recklessly, or negligently, in the offer or sale of securities by the use of means or instrumentalities of interstate commerce or the mails, have employed devices, schemes or artifices to defraud; obtained money or property by means of untrue statements of material fact or the omission of a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading; and engaged in transactions, practices or courses of business which operate as a fraud or deceit upon purchasers of the securities.

90. By reason of the forgoing, each of the defendants violated Section 17(a) of the Securities Act [15 U.S.C. §77q(a)].

THIRD CLAIM
Violations of Exchange Act Rule 13a-14
(Against Ha-Ngoc and Johnston)

91. The Commission repeats and incorporates by reference the allegations in paragraphs 1-82 above as if set forth fully herein.

92. As the principal executive officers of AVEO, Ha-Ngoc and Johnston were required to and did sign and certify AVEO's annual report on Form 10-K for 2012, filed in 2013, and its quarterly reports on Form 10-Q for the fiscal quarters ending June 30, 2012, September 30, 2012 and March 31, 2013. Among other things, Ha-Ngoc and Johnston certified that the reports did not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made not misleading. These certifications were materially false.

93. By reason of the forgoing, defendants Ha-Ngoc and Johnston each violated Exchange Act Rule 13a-14 [17 C.F.R. § 240.131-14].

FOURTH CLAIM
Violations of Section 13(a) of the Exchange Act and
Exchange Act Rules 12b-20, 13a-1, 13a-11 and 13a-13
(Against AVEO)

94. The Commission repeats and incorporates by reference the allegations in paragraphs 1-82 above as if set forth fully herein.

95. Section 13(a) of the Exchange Act and Rules 13a-1, 13a-11, and 13a-13 thereunder require issuers of registered securities to file with the Commission factually accurate annual and quarterly reports (Form 10-K and Form 10-Q) and certain current information with the Commission (Form 8-K). Rule 12b-20 further provides that, in addition to the information expressly required to be included in a statement or report, there shall be added such further

material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they were made, not misleading.

96. By reason of the forgoing, AVEO violated Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11, and 13a-13 thereunder.

PRAYER FOR RELIEF

WHEREFORE, the Commission requests that this Court:

A. Enter a permanent injunction restraining defendants and each of their agents, servants, employees and attorneys and those persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in the conduct described above, or in conduct of similar purport and effect;

B. Require defendants to disgorge their ill-gotten gains, plus pre-judgment interest;

C. Require defendants to pay an appropriate civil monetary penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. §77t(d)], and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)];

D. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

E. Award such other and further relief as the Court deems just and proper.

Respectfully submitted,

SECURITIES AND EXCHANGE COMMISSION
By its attorneys,

/s/ Rachel Hershfang

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DATED: March 29, 2016