UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. AVEO PHARMACEUTICALS, INC., TUAN HA-NGOC, DAVID B. JOHNSTON, and WILLIAM SLICHENMYER, Defendants.	**Case No.** **CLASS ACTION** **COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

CLASS ACTION COMPLAINT

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

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than defendants who purchased Aveo securities between January 3, 2012 and May 1, 2013,

inclusive (the "Class Period"), seeking to recover damages caused by defendants' violations of the federal securities laws and to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Aveo is a biopharmaceutical company focused on discovering, developing, and commercializing cancer therapeutics. The Company's lead product is an oral inhibitor of the vascular endothelial growth factor ("VEGF") receptors.

3. Throughout the Class Period, Defendants conditioned investors to believe that the Company's drug Tivopath or tivozanib, for the treatment of advanced kidney cancer, would receive approval from the U.S. Food and Drug Administration ("FDA") through a host of materially false and misleading statements regarding the phase 3 trial design and results. Specifically: (a) the Company failed to disclose to investors that the FDA had recommended to the Company to conduct an additional phase 3 trial due to adverse trends in the Company's first Phase III trial; (b) the Company misled investors regarding the overall safety and efficacy of the product, including by misleading investors regarding the 25% higher rate of death associated with tivozanib therapy compared to the control drug, sorafenib; (c) the Company failed to disclose that almost 90% of the patients studied in TIVO-1 were enrolled from sites in Central and Eastern Europe with inconsistent treatment patterns from those in the US. As a result of the foregoing, the Company's statements were materially false and misleading at all relevant times.

4. On April 30, 2013, the FDA released its Oncologic Drugs Advisory Committee ("ODAC") briefing document (the, "Briefing Document") that, among other matters, took particular issue with the rigor of the tivozanib trial:

> In considering the results from a single randomized trial submitted in support of marketing approval of a new molecular entity, FDA expects that the trial will be adequately designed and well conducted and that the results will be internally consistent. We are asking the ODAC's advice on 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.

5. The Briefing Document also highlighted the regulatory history of Tivopath, and the fact that the Company disregarded explicit FDA recommendations for the Company to conduct an additional Phase III trial, "[a] pre-NDA meeting was held in May 2012. Here, the FDA expressed concern about the adverse trend in overall survival in the single Phase 3 trial ("TIVO-1") and recommended that the sponsor [Aveo] conduct a second adequately powered randomized trial in a population comparable to that in the US."

6. In response to this news the Company's shares fell $2.33 or 31.31% per share to close at $5.11 on April 30, 2013, on volume of over 15 million shares.

7. On May 2, 2013, the Company and the FDA made presentations to the ODAC regarding the new drug application of tivozanib. The FDA noted in its presentation to the ODAC that: a) tivozanib was studied in a Phase 3 trial with inconsistent results; b) tivozanib increased potential risk of death by 25% compared to the control drug, sorafenib; c) tivozanib therapy induced higher rates of hypertension, hemorrhage and dysphonia than sorafenib; d) TIVO-1 had a flawed trial design; e) TIVO-1 provided internally inconsistent trial results; f) TIVO-1 provided uninterpretable overall survival results; and g) TIVO-1 provided inconclusive risk-benefit assessment data.

8. On May 2, 2013, the ODAC voted by an overwhelming majority (13 to 1) not to recommend approval of tivozanib, because, "the application for investigational agent tivozanib did not demonstrate a favorable benefit-to-risk evaluation for the treatment of advanced renal cell carcinoma (RCC) in an adequate and well-controlled trial."

9. As a result of this announcement, Aveo shares declined $2.61 per share or nearly 50%, to close at $2.65 per share on May 2, 2013, on volume of over 15 million shares.

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

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections l0(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule l0b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

13. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Aveo maintains its principal place of business in this District and many of the acts and practices complained of occurred in substantial part herein.

14. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

15. Plaintiff , as set forth in the accompanying certification, incorporated by reference herein, purchased Aveo securities at artificially inflated prices during the Class Period and was damaged thereby.

16. Defendant Aveo is a corporation organized under the laws of the state of Delaware, maintaining its principal place of business at 75 Sidney Street, Cambridge, Massachusetts 02139.

Aveo's common stock trades on the NASDAQ Global Stock Market ("NASDAQ") under the ticker symbol "AVEO."

17. Defendant Tuan Ha-Ngoc ("Ha-Ngoc") has served as president and Chief Executive Officer of Aveo, and as a member of the Company's Board of Directors since June 2002, and sold 4,613 Company shares during the Class Period.

18. Defendant David N. Johnston ("Johnston") has served as Aveo's Chief Financial Officer since October 2007, and sold 19,704 Company shares during the Class Period.

19. Defendant William Slichenmyer ("Slichenmyer") has served as Aveo's Chief Medical Officer since September 2009, and sold 14,257 Company shares during the Class Period.

20. The defendants referenced above in ¶¶ 17 - 19 are referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

BACKGROUND

21. Aveo is a biopharmaceutical company focused on discovering, developing, and commercializing cancer therapeutics. The Company's lead product candidate is an oral inhibitor of the vascular endothelial growth factor ("VEGF") receptors. One of the Company's principal products is Tivopath or tivozanib, marketed by the Company for the treatment of advanced kidney cancer.

MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

22. On January 3, 2012, the Company issued a press release announcing that tivozanib successfully demonstrated progression-free survival superiority over sorafenib in patients with

advanced renal cell cancer in the phase 3 TIVO-1 trial. Specifically, the Company stated the following, in relevant part:

> [T]hat tivozanib demonstrated superiority over sorafenib in the primary endpoint of progression-free survival (PFS) in TIVO-1, a global, randomized Phase 3 clinical trial evaluating the efficacy and safety of investigational drug tivozanib compared to sorafenib in 517 patients with advanced renal cell carcinoma (RCC). TIVO-1 is the first registration study in first-line RCC that is comparing an investigational agent against an approved VEGF therapy.
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> All patients in TIVO-1 had clear cell RCC, had undergone a prior nephrectomy, and had not previously been treated with either a VEGF or mTOR therapy. Based on the top-line analysis of events in TIVO-1, determined by a blinded, independent review committee, key top-line findings include:
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> - tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib in the overall study population
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> - tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median PFS of 9.1 months for sorafenib in the pre-specified subpopulation of patients who were treatment naïve (no prior systemic anti-cancer therapy); this subpopulation was approximately 70% of the total study population
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> - tivozanib demonstrated a well-tolerated safety profile consistent with the Phase 2 experience; the most commonly reported side effect was hypertension, a well- established on-target and manageable effect of VEGFR inhibitors

23. On February 14, 2012, the Company issued a press release announcing its 2011 financial results, and reviewed key progress achieved with its tivozanib development programs in the fourth quarter of 2011. The Company stated the following, in relevant part:

> "The recent success of our Phase 3 registration trial of tivozanib in RCC, TIVO-1, marks an important milestone for AVEO as we prepare for our first NDA submission later this year," said Tuan Ha-Ngoc, president and chief executive officer of AVEO. "Tivozanib's favorable efficacy and tolerability have now been demonstrated in two large, well-controlled studies. We believe the longest median progression-free survival reported to-date in a first-line pivotal trial in treatment naïve RCC patients combined with its well-tolerated safety profile positions tivozanib to provide patients with a significantly differentiated treatment option."

Fourth Quarter 2011 Key Accomplishments:

Completed top-line analysis of pivotal tivozanib Phase 3 trial, TIVO-1: Notably, in the fourth quarter, AVEO completed top-line analysis of TIVO-1, a global, randomized, Phase 3, superiority clinical trial evaluating the efficacy and safety of tivozanib compared to sorafenib in 517 patients with advanced renal cell carcinoma (RCC). Top-line data were announced in January 2012 and showed that tivozanib successfully demonstrated superiority over sorafenib in the primary endpoint of progression-free survival (PFS) in TIVO-1. Key top-line findings from TIVO-1 include:

Tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib in the overall study population.

24. On March 30, 2012, the Company filed with the SEC its annual report for the period ending December 31, 2011. In the annual report, the Company stated in relevant part:

Tivozanib, our lead product candidate, which we partnered with Astellas Pharma Inc., or Astellas, in 2011, is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor, or VEGF, receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Our clinical trials of tivozanib to date have demonstrated a favorable safety and efficacy profile for tivozanib. In January 2012, we announced top-line data from our global, phase 3 clinical trial comparing the efficacy and safety of tivozanib with Nexavar® (sorafenib), an approved therapy, for first-line treatment in renal cell carcinoma, or RCC, which we refer to as the TIVO-1 study. The TIVO-1 study is being conducted in patients with advanced clear cell RCC who have undergone a prior nephrectomy (kidney removal) and who have not received any prior VEGF- and mTOR-targeted therapy. In this trial, we measured, among other things, each patient's progression-free survival, or PFS, which refers to the period of time that began when a patient entered the clinical trial and ended when either the patient died or the patient's cancer had grown by a specified percentage or spread to a new location in the body. PFS is the primary endpoint in the TIVO-1 study. In the TIVO-1 study, tivozanib demonstrated a statistically significant improvement in PFS over Nexavar with a median PFS of 11.9 months for tivozanib compared to a median PFS of 9.1 months for Nexavar in the overall study population. Tivozanib also demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median PFS of 9.1 months for Nexavar in the pre-specified subpopulation of patients who received no prior systemic anti-cancer therapy for metastatic disease—a subpopulation that comprised approximately 70% of the total study population. In the TIVO-1 study, tivozanib demonstrated a well-tolerated safety profile consistent with the results from our tivozanib phase 2 clinical trial in patients with advanced RCC; the most commonly reported side effect was hypertension, a well-established on-target and

> manageable effect of VEGF receptor inhibitors. The most common treatment-related side effects seen in the phase 2 clinical trial were hypertension (44.9%) and dysphonia, or hoarseness of voice (21.7%). Additionally, the incidence of other side effects in the phase 2 clinical trial that are commonly associated with other VEGF receptor inhibitors, such as diarrhea, rash, mucositis, stomatitis, fatigue, and hand-foot syndrome, was relatively low.

25. On April 12, 2012, the Company issued a press release announcing publication of positive tivozanib Phase 2 clinical trial results in the Journal of Clinical Oncology. In the press release, Defendant Slichenmyer commented the following in relevant part:

> We believe that the efficacy and safety profile consistently demonstrated by tivozanib and recently validated in our Phase 3 TIVO-1 trial represent an important step forward in the treatment of patients who have advanced RCC. We are pleased with the opportunity to collaborate with tivozanib study investigators on publishing these positive Phase 2 data in the Journal of Clinical Oncology, and look forward to advancing our work with our global partners at Astellas to bring tivozanib to patients who can benefit from this therapy.

26. On May 9, 2012, the Company filed its quarterly report for the period ending March 31, 2012. The Company reported in relevant part:

> Tivozanib, our lead product candidate, the development of which is part of our 2011 partnership with Astellas Pharma Inc., or Astellas, is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor, or VEGF, receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Our clinical trials of tivozanib to date have demonstrated a favorable safety and efficacy profile for tivozanib. In January 2012, we announced top-line data from our global, phase 3 clinical trial comparing the efficacy and safety of tivozanib with Nexavar (sorafenib), an approved therapy, for first-line treatment in advanced renal cell carcinoma, or RCC, which we refer to as the TIVO-1 study. The TIVO-1 study is being conducted in patients with advanced clear cell RCC who have undergone a prior nephrectomy (kidney removal) and who have not received any prior VEGF and mTOR-targeted therapy. In this trial, we measured, among other things, each patient's progression-free survival, or PFS, which refers to the period of time that began when a patient entered the clinical trial and ended when either the patient died or the patient's cancer had grown by a specified percentage or spread to a new location in the body. PFS is the primary endpoint in the TIVO-1 study. In the TIVO-1 study, tivozanib demonstrated a statistically significant improvement in PFS over Nexavar with a median PFS of 11.9 months for tivozanib compared to a median PFS of 9.1 months for Nexavar in the overall study population. Tivozanib also demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median

> PFS of 9.1 months for Nexavar in the pre-specified subpopulation of patients who received no prior systemic anti-cancer therapy for metastatic disease—a subpopulation that comprised approximately 70% of the total study population. In the TIVO-1 study, tivozanib demonstrated a well-tolerated safety profile consistent with the results from our tivozanib phase 2 clinical trial in patients with advanced RCC; the most commonly reported side effect was hypertension, a well established on-target and manageable effect of VEGF receptor inhibitors. The most common treatment-related side effects seen in the phase 2 clinical trial were hypertension (44.9%) and dysphonia, or hoarseness of voice (21.7%). Additionally, the incidence of other side effects in the phase 2 clinical trial that are commonly associated with other VEGF receptor inhibitors, such as diarrhea, rash, mucositis, stomatitis, fatigue, and hand-foot syndrome, was relatively low.

27. On May 16, 2012, the Company issued a press release announcing positive findings from TIVO-1, "Superiority Study of Tivozanib in First-Line Advanced RCC." The press release stated in relevant part:

> TIVO-1 is the first superiority pivotal study in first-line advanced renal cell carcinoma (RCC) in which an investigational agent (tivozanib) has demonstrated statistically significant and clinically meaningful progression-free survival (PFS) superiority versus an approved targeted agent (sorafenib) in advanced RCC.
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> "TIVO-1 is novel in that this Phase 3 clinical study used an approved targeted comparator drug to evaluate first-line RCC treatment," said Dr. Motzer. "Patients in the study who had no prior treatment for advanced kidney cancer and who were given tivozanib met the primary PFS endpoint and tolerated the drug well."
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> A total of 517 patients were randomized to tivozanib (N=260) or sorafenib (N=257). The performance status and other prognostic indicators of patients enrolled in this study were consistent with other pivotal trials in first-line advanced RCC.
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> "Despite recent advances in the treatment of kidney cancer, patients are in need of new options which are effective and well-tolerated," said Daniel George, M.D., director, GU Medical Oncology and director, prostate clinic, Duke University. "The superior PFS and favorable tolerability demonstrated by tivozanib in TIVO-1 represents an important potential step forward for patients in the treatment of kidney cancer."

28. On August 7, 2012, the Company filed with the SEC a quarterly report for the period ending, June 30, 2012. In the quarterly report the Company stated in relevant part:

> Tivozanib, our lead product candidate, the development of which is part of our 2011 partnership with Astellas Pharma Inc., or Astellas, is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor, or VEGF, receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Our clinical trials of tivozanib to date have demonstrated a favorable safety and efficacy profile for tivozanib. In May 2012, we announced detailed data from our global, phase 3 clinical trial comparing the efficacy and safety of tivozanib with Nexavar ® (sorafenib), an approved therapy, for first-line treatment in advanced renal cell carcinoma, or RCC, which we refer to as the TIVO-1 study. The TIVO-1 study is being conducted in patients with advanced clear cell RCC who have undergone a prior nephrectomy (kidney removal) and who have not received any prior VEGF- and mTOR-targeted therapy. In this trial, we measured, among other things, each patient's progression-free survival, or PFS, which refers to the period of time that began when a patient entered the clinical trial and ended when either the patient died or the patient's cancer had grown by a specified percentage or spread to a new location in the body. PFS is the primary endpoint in the TIVO-1 study.

29. On September 28, 2012, the Company issued a press release announcing that Aveo had submitted a New Drug Application ("NDA") to the FDA seeking approval for tivozanib in patients with advanced rencal cell carcinoma. The press release stated in relevant part:

> The NDA submission is based on results of the global Phase 3 TIVO-1 (Tivozanib Versus Sorafenib in 1st line Advanced RCC) trial, a randomized superiority-designed pivotal trial evaluating the efficacy and safety of tivozanib compared to sorafenib in 517 patients with advanced RCC who had no prior treatment with a systemic therapy, as well as data from 17 clinical studies involving over 1,000 subjects who received tivozanib. In TIVO-1, tivozanib demonstrated a statistically significant improvement in progression-free survival (PFS) versus sorafenib, an approved targeted agent, and a favorable tolerability profile.

30. On October 1, 2012, the Company issued a press release announcing new data demonstrating the safety and tolerability profile of tivozanib in patients with advanced kidney cancer. The press release reported that the Company had recently submitted a NDA to the FDA seeking approval for tivozanib. The press release reported in relevant part:

> Investigators evaluated drug-related AEs versus sorafenib with the goal of better understanding the tivozanib safety profile. The results of the safety analysis showed:

- Investigator-reported adverse events for tivozanib showed lower rates of dose reductions, interruptions, and discontinuations compared to sorafenib: dose reductions (11.6% vs. 42.8%, p<0.001), interruptions (17.8% vs. 35.4%, p<0.001), and discontinuations (4.2% vs. 5.4%).

- Drug-related AEs occurred in fewer patients on tivozanib than patients on sorafenib (67.6% vs. 83.3%).

- Fewer patients in the tivozanib group had ≥Grade 3 drug-related AEs than patients in the sorafenib group (36.3% vs. 51.0%, respectively). ≥Grade 3 hypertension, an established on-target effect of angiogenesis inhibitors, was more common in the tivozanib group (23.6% vs. 15.2%), and ≥Grade 3 hand-foot syndrome (1.9% vs. 16.7%), diarrhea (1.9% vs. 5.8%) and lipase elevation (0.8% vs. 5.8%) were more common in the sorafenib group.

"Our tivozanib development program in RCC is comprehensive and ongoing. With positive safety and efficacy data from TIVO-1 in-hand, we continue to explore the role of biomarkers and patient preference with the ultimate goal of helping clinicians optimize RCC treatment," said William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO. "Additional analyses from our ongoing biomarker program will be presented at future congresses and our TAURUS patient preference study vs. Sutent (sunitinib) is now underway.

31. On November 8, 2012, the Company filed with the SEC its quarterly report for the period ending September 30, 2012. The report stated in relevant part:

> We recently submitted a New Drug Application to the U.S. Food and Drug Administration seeking approval for tivozanib, our lead product candidate, in patients with advanced renal cell carcinoma, or RCC. Tivozanib, the development of which is part of our 2011 partnership with Astellas Pharma Inc., or Astellas, is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor, or VEGF, receptors which is designed to optimize VEGF blockade while minimizing off-target toxicities. Our clinical trials of tivozanib to date have demonstrated a favorable safety and efficacy profile for tivozanib. We announced detailed data from our global, phase 3 clinical trial comparing the efficacy and safety of tivozanib with Nexavar ® (sorafenib), an approved therapy, for first-line treatment in advanced RCC, which we refer to as the TIVO-1 study. The TIVO-1 study was conducted in patients with advanced clear cell RCC who had undergone a prior nephrectomy (kidney removal) and who had not received any prior VEGF- and mTOR-targeted therapy. In this trial, we measured, among other things, each patient's progression-free survival, or PFS, which refers to the period of time that began when a patient entered the clinical trial and ended when either the patient died or the patient's cancer had grown by a specified percentage or spread to a new location in the body.

32. On February 27, 2013, the Company issued a press release announcing that the FDA Oncologic Drugs advisory Committee ("ODAC") will review the Company's NDA for tivozanib for the treatment of patients with advanced renal cell carcinoma during the morning session of its meeting on May 2, 2013. The press release also stated in relevant part:

> The NDA includes results of the global Phase 3 TIVO-1 (TIvozanib Versus sOrafenib in 1st line advanced RCC) trial, a randomized superiority-designed pivotal trial evaluating the efficacy and safety of tivozanib compared to sorafenib, an approved targeted agent, in 517 patients with advanced RCC, as well as data from 16 additional AVEO-sponsored studies involving over 1,000 subjects who received tivozanib.

33. On March 11, 2013, the Company filed with the SEC its annual report for the period ending December 31, 2012. The Company stated in relevant part:

> In the TIVO-1 study, tivozanib demonstrated a statistically significant improvement in PFS over Nexavar with a median PFS of 11.9 months for tivozanib compared to a median PFS of 9.1 months for Nexavar in the overall study population. Tivozanib also demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median PFS of 9.1 months for Nexavar in the pre-specified subpopulation of patients who received no prior systemic anti-cancer therapy for metastatic disease—a subpopulation that comprised approximately 70% of the total study population.
>
> Overall survival was a secondary endpoint of the TIVO-1 study. The final overall survival, or OS, analysis, as specified by the TIVO-1 protocol, showed a median OS of 28.8 months (95% confidence interval, or CI: 22.5–NA) for the tivozanib arm versus a median OS of 29.3 months (95% CI: 29.3–NA) for the Nexavar arm. No statistical difference between the two arms (HR=1.245, p=0.105) was observed. Due to the fact that patients in the Nexavar arm who developed disease progression were given the option to receive tivozanib, a substantial difference in the use of subsequent therapies resulted. Of 189 patients who discontinued their initial therapy on the tivozanib arm, 36% received some form of subsequent therapy, including 10% who received subsequent anti-VEGF therapy. Of 226 patients who discontinued their initial therapy on the Nexavar arm, 74% received some form of subsequent therapy, including 70% who received subsequent anti-VEGF therapy (98% of whom received tivozanib). We believe that the different utilization of second line therapies in the two arms of the TIVO-1 study impacted the relative performance of the two arms in the OS endpoint.
>
> Dose interruptions due to an adverse event occurred in 46 (18%) tivozanib-treated patients compared to 91 (35%) Nexavar-treated patients ($p<0.001$). Dose

> reductions due to an adverse event occurred in 30 (12%) tivozanib-treated patients compared to 110 (43%) Nexavar-treated patients (p<0.001). There were 11 (4%) tivozanib-treated patients who discontinued the study due to drug-related adverse events compared to 14 (5%) Nexavar-treated patients (p=0.683).

34. The statements referenced in ¶¶ 22-33 above were materially false and/or misleading because they misrepresented and failed to disclose that: a) the FDA had recommended to the Company as early as May 2012 that it should conduct an additional phase 3 trial due to adverse trends in the TIVO-1 study; b) the Company misled investors regarding the overall safety and efficacy of the product, including by misleading investors regarding the 25% higher rate of death associated with tivozanib therapy compared to the control drug, sorafenib; c) almost 90% of the patients studied in TIVO-1 were enrolled from sites in Central and Eastern Europe with inconsistent treatment patterns from those studied in the US.

THE TRUTH IS REVEALED

35. On April 30, 2013, the FDA released its Oncologic Drugs Advisory Committee Briefing Document, which found a number of flaws with the TIVO-1 trial.

> In considering the results from a single randomized trial submitted in support of marketing approval of a new molecular entity, FDA expects that the trial will be adequately designed and well conducted and that the results will be internally consistent. We are asking the ODAC's advice on 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.

36. The Briefing Document also highlighted the regulatory history of Tivopath, and the fact that the Company disregarded FDA recommendations for improving its clinical studies, "[a] pre-NDA meeting was held in May 2012. Here, the FDA expressed concern about the adverse trend in overall survival in the single Phase 3 trial and recommended that the sponsor [Aveo] conduct a second adequately powered randomized trial in a population comparable to that in the US."

37. The Briefing Document continued to criticize the Company's clinical trial design:

> The Phase 3 study was carried out at 76 sites. It was initiated in February 2010 and was ongoing at the time of submission. As shown in Table 5, *most of the study sites were in Eastern Europe with potentially different standard of care and practice patterns compared to the US.* Patients on the sorafenib arm of the Phase 3 study with PD could receive tivozanib on an extension/crossover study. Patients on the tivozanib arm of the Phase 3 study with PD could receive additional medications. *However, the 2nd line use of targeted therapies was not considered the standard of care in many of the countries participating in the trial.*

Table 5: Geographic Distribution of Patient Accrual		
Geographic Region	Tivozanib N = 260	Sorafenib N = 257
Central/Eastern Europe	229 (88%)	228 (89%)
North America/Western Europe	22 (9%)	18 (7%)
Rest of World	9 (4%)	11 (4%)

> The majority of the patients on the sorafenib arm received tivozanib after the development of INV-determined PD while most of the patients on the tivozanib arm did not receive subsequent targeted therapy. *The majority of patients were enrolled from sites in Central and Eastern Europe where 2nd line targeted therapy was not available. This is not consistent with the practice patterns in the US and it is, therefore, unclear whether the patients in this study were representative of those in the US.*

(emphasis added).

38. The Briefing Document also noted certain adverse events of special interest, including that one patient died due to pancreatitis:

> Adverse events of special interest in the tivozanib arm of the Phase 3 trial include: hypertension (45%), hemorrhage (12%), proteinuria (9%), arterial embolic and thrombotic events (3%), hypothyroidism (5%), GI perforation/fistula (1%), and pancreatitis (0.8%). In the Safety Database, 1 patient developed hepatic failure and a 2nd patient developed posterior reversible encephalopathy syndrome. Note that the incidence of elevated TSH (62%) and proteinuria by dipstick (32%) along with grade 3-4 amylase (5%) and lipase (10%), was much higher than the number of reports of the corresponding adverse events. Importantly, 1 patient died due to pancreatitis.

39. In response to this announcement, the Company's shares fell $2.33 or 31.31% per share to close at $5.11 on April 30, 2013, on volume of over 15 million shares.

40. On May 2, 2013, the Company disclosed that the Oncologic Drugs Advisory Committee ("ODAC") of the FDA voted by an overwhelming majority (13 to 1, with no abstentions) not to recommend approval of tivozanib. The ODAC found, "that the application for investigational agent tivozanib did not demonstrate a favorable benefit-to-risk evaluation for the treatment of advanced renal cell carcinoma (RCC) in an adequate and well-controlled trial."

41. The FDA noted in its presentation to the ODAC that: a) tivozanib was studied in a Phase 3 trial with inconsistent results; b) tivozanib increased potential risk of death by 25% compared to the control drug, sorafenib; c) tivozanib therapy induced higher rates of hypertension, hemorrhage and dysphonia than sorafenib; d) TIVO-1 had a flawed trial design; e) internal inconsistency in the TIVO-1 trial results; f) TIVO-1 provided uninterpretable overall survival results; and, g) TIVO-1 provided an inconclusive risk-benefit assessment.

42. As a result of this disclosure, Aveo shares declined $2.61 per share or nearly 50%, to close at $2.65 per share on May 2, 2013, on volume of over 15 million shares.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

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

44. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aveo securities were actively traded on the

NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Aveo or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

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

46. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

47. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by defendants' acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Aveo;
- whether the Individual Defendants caused Aveo to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Aveo securities during the Class Period were artificially inflated because of the defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

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

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

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

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

NO SAFE HARBOR

51. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Aveo who knew that those statements were false when made.

COUNT I

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

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

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

54. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state

material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Aveo securities; and (iii) cause Plaintiff and other members of the Class to purchase Aveo securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

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

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

knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

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

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

59. During the Class Period, Aveo securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased shares of Aveo securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members

of the Class known the truth, they would not have purchased said securities or would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of Aveo securities were substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Aveo securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

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

61. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period, upon the disclosure that the Company had disseminated false financial statements to the investing public related to its prospects for FDA approval.

COUNT II

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

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

63. During the Class Period, the Individual Defendants participated in the operation and management of Aveo, and conducted and participated, directly and indirectly, in the conduct of Aveo's business affairs. Because of their senior positions, they knew the adverse non-public information regarding Aveo's NDA submission to the FDA.

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

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

66. Each of the Individual Defendants, therefore, acted as a controlling person of Aveo. By reason of their senior management positions and/or being directors of Aveo, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Aveo to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Aveo and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants as follows:

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

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

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

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

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: