AVEO Pharmaceuticals, Inc.

Tivozanib: A Potential Game Changer in RCC and Other Indications; Conf Call at 12:30 pm ET Today

Overweight

AVEO, AVEO US
Price: $14.57

▲ **Price Target: $22.00**
Previous: $20.00

AVEO shares have a potentially transformative catalyst in mid 2011 with phase 3 results of tivozanib in renal cell carcinoma (RCC; TIVO-1 trial). To assess the probability of success and what the results may mean to the RCC paradigm, we spoke with several oncologists and reviewed data across the RCC landscape. Pfizer dominates RCC with Sutent (approved) and axitinib (in phase 3), the latter of which will be important to watch in 2011/2012. For tivozanib, we think that a 12+ mos progression free survival (PFS) is likely, which combined with a favorable tolerability profile (similar to phase 2) confers significant differentiation. From a valuation perspective, the reward/risk profile looks quite good for AVEO with a best case outcome (12+ mos PFS; differentiated safety) potentially driving upside to the $32/sh range, while a worst case outcome (<10 mos PFS; slightly differentiated safety profile) would lead to valuation in the $16/share range on our estimates. In this report, we fully evaluate the TIVO-1 study in RCC as well new indications for tivozanib (breast and GI cancers) and the value for AV-299, in phase 2 studies for NSCLC. Overall, we're bullish on AVEO shares ahead of the data and we are raising our price target to $22 from $20. **We are hosting a conference call TODAY with slides, to discuss our views ahead of the TIVO-1 results. Please join us at 12:30 pm ET (dial in: 888-889-1309 (US); 773-756-0161 (OUS); passcode: BIOTECH).**

- **On efficacy, a 12+ mos PFS would be impressive, in our view.** Recall, in the phase 2 trial, the PFS for tivozanib was 14.8 mos in clear-cell RCC patients with prior history of nephrectomy (TIVO-1 enrollment criteria). The overall PFS was 11.8 mos for tivozanib in a large phase 2 study (n=272), which to us indicates good potential for differentiated efficacy (and safety) in phase 3. For reference, the PFS for Sutent is ~11 mos, and physicians we've talked to stressed the need for further PFS improvements. Based on our KOL discussions, it was clear to us that a 12+ mos PFS benefit in TIVO-1 would be enough to alter physician treatment patterns and make tivozanib an attractive first-line treatment choice in RCC.

Biotechnology

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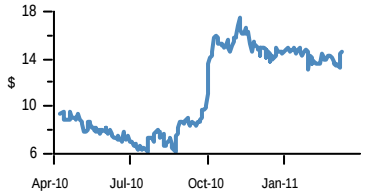
Price Performance



	YTD	1m	3m	12m
Abs	-2.0%	6.7%	3.6%	55.8%

AVEO Pharmaceuticals, Inc. (AVEO;AVEO US)

	2010A	2011E (Old)	2011E (New)	2012E (Old)	2012E (New)
EPS Reported ($)					
Q1 (Mar)	(2.27)				
Q2 (Jun)	(0.50)				
Q3 (Sep)	(0.60)				
Q4 (Dec)	(0.30)				
FY	(2.31)	(0.45)	(0.70)	0.32	(0.84)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	14.57
Date Of Price	09 Mar 11
52-week Range ($)	17.93 - 6.01
Mkt Cap ($ mn)	494.13
Fiscal Year End	Dec
Shares O/S (mn)	34
Price Target ($)	22.00
Price Target End Date	31 Dec 11

See page 17 for analyst certification and important disclosures.

- **Safety differentiated; physicians not concerned about hypertension.** Experts we spoke to were very impressed with the low dose interruption rate in the phase 2 tivovanib study (3.7%), given the "real world" dose interruption rate with Sutent / Bayer/Onyx's Nexavar, which is estimated at 10-20%, respectively. We think that this could ultimately be a major advantage for tivozanib. Additionally, physicians don't appear concerned about the hypertension rate in phase 2 (overall - 54.4%; Grade 3/4 - 8.5%), given this AE is easily controlled with anti-hypertensives and is often seen with VEGF-targeted therapies such as Avastin. At minimum, we believe that tivozanib safety (and to a lesser degree efficacy) may be the major differentiation among the marketed RCC agents.

- **Regulatory hurdle is reasonable if safety is good and 12+ mos PFS is seen.** The primary endpoint of the TIVO-1 trial is PFS (tivozanib versus Nexavar) with 90% power to detect at least a 3 mos improvement. KOLs we've spoken to have noted that PFS experience with Nexavar (~5.5 mos benefit) is very reliable with a likely TIVO-1 result that is highly statistically significant.

- **Will be important to watch Pfizer's axitinib, but we think tivozanib should be fine.** Axitinib's two phase 3 trials enroll patients mostly in the refractory setting (tivozanib being assessing exclusively in the first-line). Top-line data from one of the studies (AXIS study in second-line RCC) showed that axitinib significantly extended PFS versus Nexavar (full data at ASCO 2011). Data from the second study (which allows for first-line patients and refractory patients) could come 2H11, but it could be difficult to get a first-line label based on this trial (not solely a first-line trial), in our view. On the safety side, given prior data of axitinib in phase 2, we believe tivozanib could have a differentiated/favorable safety profile.

- **Scenario analysis points to upside.** Our base case assumption is that in the TIVO-1 trial, tivozanib produces an 11 mos PFS benefit with a highly differentiated safety profile. This results in a $22/share valuation. In a best case scenario (12+ month PFS; highly differentiated safety), we arrive at a value per share in the $32 range, while a worst case (<10 month PFS; slightly differentiated safety profile) yields a value per share in the $16 range, still above current levels.

- **Multiple attractive call options beyond RCC, and brain metastases could be a future indication.** We were encouraged by the early phase 1b data with tivozanib in both breast and GI cancers. While early, it does appear the full 1.5 mg/kg dose is safe/well-tolerated in both indications and AVEO plans to move forward in the breast and colorectal indications in 2011. Additionally, there are a number of studies which link VEGF to brain metastases. Furthermore, some studies noted VEGFR-1, but not VEGFR-2/3, were more commonly present in brain micro-vessels. Indeed, of all the VEGF inhibitors, it appears tivozanib is the most potent VEGFR-1 inhibitor. Though AVEO has not talked about this indication to our knowledge, we believe proof of concept is supported by a retrospective analysis of phase 3 TARGET study of Nexavar, which showed statistically significant decrease in the incidence of brain metastases versus placebo. We acknowledge the brain metastases has historically been a difficult indication; however, we think it would be interesting for AVEO to include an assessment of brain metastases in the upcoming studies of breast and GI cancers**.**

- **Reiterate Overweight rating.** Raising PT to $22 from $20, on higher probability of success for TIVO-1 trial and market potential of tivozanib.

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Overview

With the recent e.x.-Asia partnership for tivozanib (with Astellas) and pivotal phase 3 data in renal cell carcinoma (RCC) approaching mid-2011 (TIVO-1), we sought to better understand the probability of success of the TIVO-1 trial and what ultimate approval of tivozanib could mean for AVEO shares under various scenarios. We spoke to 2 community oncologists and 1 KOL specialized in RCC to gain a better perspective of where tivozanib may fall in the treatment paradigm. ***Overall, we believe a 12+ month PFS combined with a similar AE profile to the phase 2 experience would very likely place tivozanib as the first-line treatment option of choice.*** Additionally, in this report, we also assess the tivozanib's potential in other indications. We found phase 1b breast and GI cancer data to be encouraging (albeit early), and would not rule out brain metastases (i.e., reduction in incidence of brain metastases) as a potential future indication. ***Based on KOL feedback, we believe there is high probability of success for the TIVO-1 trial, and would be buyers of AVEO shares ahead of this potentially transformational catalyst for the company.***

Quick Refresher on Renal Cell Carcinoma

Renal cell carcinoma (RCC) is the third most common genitourinary cancer in the US (see Table 1 for RCC statistics in the US). There are very few warning signs / symptoms for RCC, and as a result ~33% of patients present with metastatic disease at the time of diagnosis. Categorized by histology / cell type, there are five major RCC subtypes (clear-cell, chromophilic, chromophobic, oncocytic, and collecting-duct), with clear-cell histology being the most common (75-85% of RCC).[1]

Table 1: RCC Statistics In The US

	Statistics
Prevalence	~280-300K
Incidence / year	~58-60K
Mortality / year	~12-14K
5-year Survival	~68%

Source: National Cancer Institute - SEER

While surgery and immunotherapy can be options for patients, the vast majority of patients receive targeted therapy. All six approved RCC therapies target one of two major pathways - vascular endothelial growth factor (VEGF – Roche's Avastin, Pfizer's Sutent, Bayer/Onyx's Nexavar, and GSK's Votrient) and mammalian target of rapamycin (mTOR – Pfizer's Torisel and Novartis's Afinitor). Tivozanib's mechanism follows suit, as the agent inhibits the tyrosine kinase activity of VEGF receptors (1, 2, and 3). While the market is crowded, based on physician feedback, it was clear to us currently Sutent is the first-line treatment option in RCC.

"Sutent is generally my first-line choice, followed by Nexavar."

[1] Tang et al, Community Oncology, 6:24-28 (2009)

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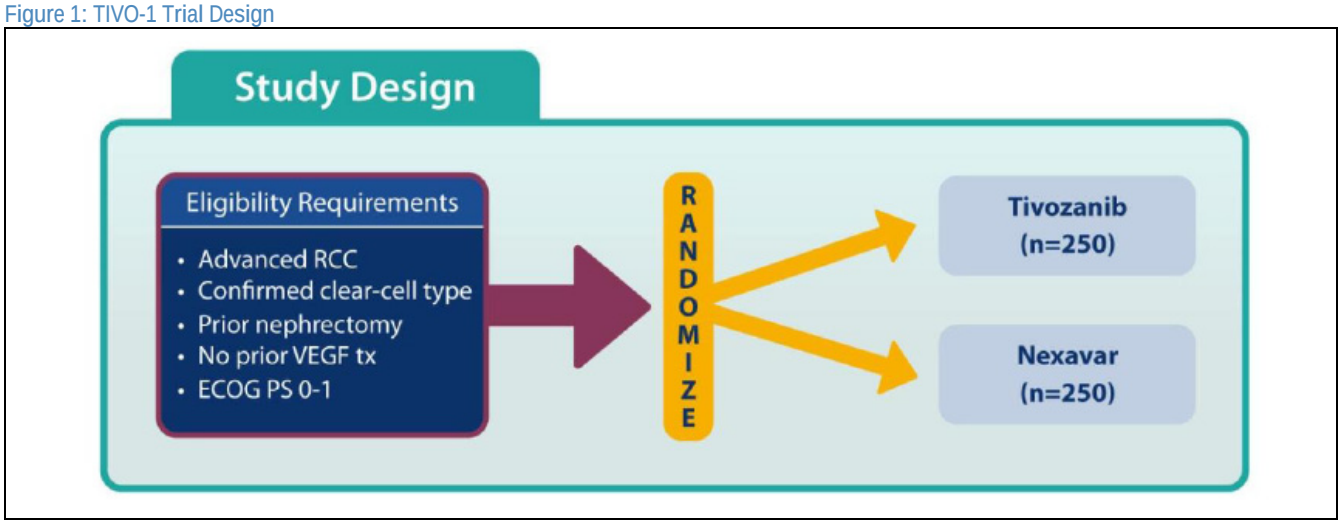
Previewing TIVO-1: Physician Insights

Clinical Trial Design

Recall, AVEO began the pivotal trial of tivozanib (TIVO-1) in advanced RCC in December 2009 and enrollment in the trial completed in August 2010, approximately 6 months ahead of schedule (n=517).[2] In the randomized, open-label, controlled trial, patients were randomized 1:1 to receive 1.5 mg QD tivozanib or 400 mg BID Nexavar. The TIVO-1 trial enrolled only clear-cell RCC patients who have had prior nephrectomy (see Figure 1). ***The primary endpoint of the trial is to compare progression free survival (PFS) of tivozanib versus Nexavar, and is 90% powered to detect at least a 3 month improvement.*** TIVO-1 includes secondary endpoints of overall survival (OS), overall response rate (ORR), durability of response (DOR) and safety / tolerability.

Figure 1: TIVO-1 Trial Design



Source: Company documents

Efficacy – PFS Of 12+ Months Would Be a Home Run

In the phase 2 trial (n=272), tivozanib produced robust efficacy and PFS better than currently marketed agents. ORR was 27%, with overall median PFS of 11.8 months. Though comparing across trials is difficult, a ~12 month PFS is approximately one month better than first-line standard of care Sutent (see Table 2). ***Perhaps even more impressive, in an analysis of patients (n=176) with clear-cell histology and history of prior nephrecotomy (which is the patient being enrolled in the TIVO-1 study), these patients had a PFS benefit of 14.8 months.*** Overall, physician feedback on efficacy observed in the phase 2 trial has been encouraging.

> *"The phase 2 results are promising, particularly the 14.8 month PFS benefit in clear-cell patients. Now the question is…can it be reproduced in phase 3?"*

[2] AVEO Investor Presentation – January 2011

Table 2: Tivozanib Phase 2 PFS vs. PFS of Marketed RCC Therapies (Phase 3)

Agent	Setting	Phase 3 PFS Benefit In RCC
Tivozanib (Phase 2)	*1st-line, metastatic RCC*	*11.8 months (14.8 months in phase 3 population)*
Nexavar	Clear-cell, Advanced RCC	5.5 months
Sutent	1st-line, clear-cell	11 months
Avastin	1st-line, clear-cell	10.2 months
Votrient	1st-line, clear-cell	9.2 months
Torisel	1st-line, poor risk group	5.5 months
Afinitor	2nd-line	4.9 months

Source: JP Morgan Research

As it relates to efficacy, the focus of our conversation with physicians was related to what would be an impressive PFS benefit in TIVO-1. ***It was clear to us that physicians would like to see a 12+ month PFS benefit in the phase 3.***

> *"There is still a need to improve PFS in RCC."*
>
> *"A 12+ month benefit in phase 3 would make tivozanib my first-line treatment choice."*

Importantly, all physicians felt that Nexavar is not the appropriate choice as an active comparator, as Sutent is generally used first-line. ***Given this sentiment, combined with existing comfort with marketed therapeutics, we believe a 12+ month benefit will be important to convince physicians to alter their treatment patterns.***

> *"Nexavar is not the right comparator choice for the end-user. It is the obvious first question for community oncologists to ask…"why not use Sutent?""*
>
> *"A similar PFS profile will be difficult to sell to physicians, we need a reason to change."*
>
> *"Prior experience with an agent is important, but an improvement in PFS beyond that observed with standard of care is a compelling reason to switch."*

Safety – Looks To Be Highly Differentiated

Physicians were very comfortable with the safety profile observed in the phase 2 trial. ***Importantly, physicians were unconcerned with the rates of hypertension observed in the trial (by far the most common toxicity – overall - 54.4%, Grade 3/4 - 8.5%), as this AE is easily managed by anti-hypertensives.*** See Table 3 for comparison of hypertension rates.

> *"Hypertension is seen with other VEGFs, it is common with the class."*
>
> *"As with the other agents, the hypertension is easily manageable."*

Table 3: Comparison Of Hypertension Rates

Agent	Hypertension Rate	Grade 3/4
Tivozanib	*54.4%*	*8.5%*
Sutent	30%	12%
Nexavar	17%	4%
Votrient	40%	4%
Torisel	7%	-
Afinitor	2%	-

Source: JP Morgan Research

Additionally, physicians were very impressed with the low dose interruption rate observed in the phase 2 trial of tivozanib (3.7%). Our sense from talking to physicians is that in the "real-world" setting the dose interruption rate for Nexavar is 15-20% and 10% for Sutent. ***We expect this to be a leverage point for AVEO / Astellas when marketing, should similar results be produced in the TIVO-1 trial.***

> *"A 4% dose interruption rate is extremely low, and not an issue at all."*

> *"The rate of dose interruption with tivozanib is a clear advantage versus current treatment options."*

Interestingly, the RCC KOL noted AE reporting in the phase 2 trial could be less stringent than in the TIVO-1 trial (given the only international enrollment), leaving the door open for an overall increase in the rate of reported AEs. Recall, phase 2 trial was run under US IND in Russia, Ukraine and India (30 total sites), while TIVO-1 enrolled patients in the US, Canada, South America, Europe, and India. Interestingly, however, this physician did not share this same concern on the efficacy side. ***We do not view this as a major risk, as rates of AEs associated with tivozanib were generally meaningfully lower than marketed RCC agents (particularly the active comparator in TIVO-1, Nexavar), leaving room for slight increases in the rate of various AEs.*** In Table 4, we compare the phase 2 AE profile of tivozanib and Nexavar, which we believe highlights the aforementioned point.

> *"Less stringent AE reporting criteria internationally is something I have always been concerned with in any trial."*

Table 4: AEs - Tivozanib vs. Nexavar

Single Agent Toxicity All grades (Grade 3 /4)	Nexavar	Tivozanib
Hypertension	17% (4%)	54.4% (8.5%)
Dysphonia	-	21% (0)
Mucositis / Stomatitis	-	4.4% (0)
Hand-foot syndrome	30% (6%)	3.0% (0)
Rash	40% (1%)	5.8% (0.7%)
Diarrhea	43% (2%)	10.7% (0.4%)
Fatigue	37% (5%)	9.9% (1.5%)
Anemia	8% (3%)	15.1% (1.8%)
Neutropenia	-	10.0% (2.2%)
LFT elevation (AST)	-	20% (<1%)

Source: JP Morgan Research

Regulatory – High Likelihood Of Approval

In the TIVO-1 trial, should tivozanib achieve a statistically significant PFS benefit versus Nexvar and produce a similar AE profile to the phase 2 experience, we and physicians believe there is a very high probability of regulatory approval. The RCC KOL noted, given the PFS benefit observed with Nexavar, he expects the TIVO-1 trial to be highly statically significant on the PFS endpoint. Recall, on its 4Q10 earnings call, AVEO noted that it would have a better idea of the event-rate in the trial in 2Q11, but as of now, data are expected mid-2011. We would expect NDA filing in year-end 2011 / early-2012, with potential approval 2H12. In Europe, the EMEA has granted AVEO orphan drug designation for tivozanib in RCC (not the case in the US).

> *"If a 12 month benefit is observed with tivozanib, there is no way Nexavar produces an 9+ month benefit. I expect the trial to be highly statistically significant and approval should not be a problem."*

Tivozanib Combination Therapy In the Future?

Physicians we spoke to appeared enthusiastic on the potential of combining tivozanib with an mTOR, particularly given tivozanib's tolerability profile. In a phase 1b study (n=36) in advanced RCC patients, the combination of tivozanib (1.5 mg / day) plus Torisel (weekly IV) appeared to be well tolerated with encouraging signs of efficacy. The combination showed a high rate of tumor shrinkage in 12 of 16 patients, with 2 patients achieving a partial response. ***We believe if an impressive PFS is observed (12+ months) in the TIVO-1 study, a few more progressive KOLs may inclined to try the tivozanib + mTOR combination, but do not expect this to be the norm by any means.*** We expect a larger clinical study and label inclusion will likely be needed for this combination to garner uptake in the community setting.

> *"Oncology has long history of combination therapy. With tivozanib's safety and tolerability profile, the drug could be ideally suited for combination therapies in the future."*

Scenario Analysis

We conducted a scenario analysis, to better understand the impact to AVEO shares based on various TIVO-1 results.

Market considerations:

- **Market estimate:** The current global RCC market is >1.5 billion, with Sutent and Nexavar combined sales totaling >1.0 billion. As the population increases, the incidence of RCC is also expected to increase.[3]

- **Partnership with Astellas:** Recall, AVEO recently signed an ex-Asia partnership for the development and commercialization of tivozanib (both companies will equally split costs and profits). AVEO will lead North

[3] AVEO Investor Presentation – January 2011

American commercialization, while Astellas will lead commercialization in Europe. In rest of world, AVEO will receive a double digit royalty on sales.

- **Pricing:** We assume a tivozanib launch price of $6,500 / month (similar to the 2011 price of Nexavar / Sutent; 80% discount to WAC).[4]

- **Future competition:** Based on physician feedback, we believe Pfizer's axitinib (JP Morgan analyst: Chris Schott) is the key competitive agent to monitor. However, importantly, based on our review of ongoing trials of axitinib, it appears the agent is currently in two phase 3 trials ***mostly*** in the refractory setting (tivozanib being assessing exclusively in the first-line).[5] In November 2010, Pfizer reported positive top-line data from one of these trials (phase 3 AXIS study; exclusively in second-line patients), and noted axitinib significantly extended PFS versus Nexavar (full data expected at ASCO 2011). Data from the other trial, which includes first-line patients and patients failing Sutent and/or cytokines (breakdown between first-line and refractory populations unknown), could come 2H11 (clinicaltrials.gov indicates primary completion date August 2011). ***Given there is no exclusive first-line trial, we believe it could be difficult for axitinib to get a first-line label.***

  For reference, in a single-arm phase 2 trial in Nexavar-refractory clear-cell metastatic RCC, axitinib demonstrated ORR of 23% and PFS was 7.4 months.[6] The most common Grade ≥3 AEs this trial included hypertension (16%), fatigue (16%), hand-foot syndrome (16%), dyspenea (15%) and diarrhea (15%). These AE rates are higher than the rates observed with Sutent. In another phase 2 study, in patients who had failed cytokine based therapies, ORR was 44% and TTP was 15.7 months.[7] The AE profile in this population looked better, with the most common Grade ≥3 AEs being hypertension (8%), diarrhea (5%), and fatigue (4%).[8] ***In our view, the phase 3 axitinib profile could look more similar to the aforementioned Nexavar-refractory trial, given the phase 3 population is predominantly second-line (tivovanib AE profile would be superior in this case, though the argument could be made these are different populations).*** See Table 4 for tivozanib AE profile.

  "Axitnib is the only other developmental RCC agent to watch at this point."

- **Intellectual Property:** In both the US and EU, tivozanib composition of matter runs to 2022 (in the US potential extension available till 2025).

With these market considerations, we outline below the earnings estimate impact and NPV impact under various TIVO-1 results (Table 5; and Table 6– tivozanib revenue build). ***We assume a similar AE profile to the phase 2 experience in the best and base scenarios (assume only slightly differentiation in worst case).*** Our valuation is off 2014, ~ 2+ years post launch in the US (1+ year in the EU) and the first year of profitability for AVEO.

[4] Price Rx
[5] Clinicaltrials.gov
[6] Bhargava et al, Current Oncology Reports, 13(2):103-11 (2011)
[7] Rixe etc, Lancet Oncology, 8(11):956-7 (2007)
[8] Bhargava et al, Current Oncology Reports, 13(2):103-11 (2011)

Scenario analyses:

- **Base Case Scenario (PFS benefit of 11 months; highly differentiated safety):** Our base case assumption is $404 million in tivozanib revenues and $0.13 EPS in 2014. This leads to a valuation of $22.

- **Best Case Scenario (PFS benefit of 12+ months; highly differentiated safety):** In this scenario, our tivozanib revenues, EPS, and valuation, ***increase*** by +197 million, +$1.59, and +$10 (+45%), respectively.

- **Worst Case Scenario (PFS benefit of <10 months; slight safety differentiation):** In this scenario, our tivozanib revenues, EPS, and valuation, ***decrease*** by -$110 million, -$0.90, and -$6 (-27%), respectively.

Table 5: Scenario Analysis Summary

	2014 Tivovanib Revenues	2014 EPS	Valuation
Base Case	$404M	$0.13	$22
Best Case	$601M (+$197M)	$1.72 (+$1.59)	$32 (+$10, +45%)
Worst Case	$294M (-$110M)	-0.77 (-$0.90)	$16 (-$6, -27%)

Source: JP Morgan Research

Table 6: Global Tivozanib RCC Revenue Build, 2011-2014

RCC Market Model	2011E	2012E	2013E	2014E
US Tivozanib Sales	$0	$59	$149	$226
EU Tivozanib Sales	$0	$0	$81	$179
WW Tivozanib Sales	$0.0	$59.1	$230.3	$404.4
Newly RCC Diagnosed Patients (US)	52,470	53,781	55,126	56,504
% Metastatic Disease + 5% of Stage 3	30%	30%	30%	30%
Available Patients	15,741	16,134	16,538	16,951
Penetration	*0.0%*	*5.0%*	*12.0%*	*17%*
Treated Patients	0	807	1985	2933
Duration of treatment (months)	11	11	11	11
Monthly cost	6,500	6,663	6,829	7,000
US Tivozanib Sales ($M)	$0.0	$59.1	$149.1	$225.8
			152.2%	*51.5%*
Newly RCC Diagnosed Patients (EU)	61,311	62,844	64,415	66,025
% Metastatic Disease + 5% of Stage III	30%	30%	30%	30%
Available Patients	18,393	18,853	19,324	19,808
Penetration	*0.0%*	*0.0%*	*6.0%*	*13.0%*
Treated Patients	0	0	1159	2575
Duration of treatment (months)	11	11	11	11
Monthly cost	6,500	6,435	6,371	6,307
EU Tivozanib Sales ($M)	$0.0	$0.0	$81.3	$178.6

Source: JP Morgan estimates

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Tivozanib: Beyond RCC

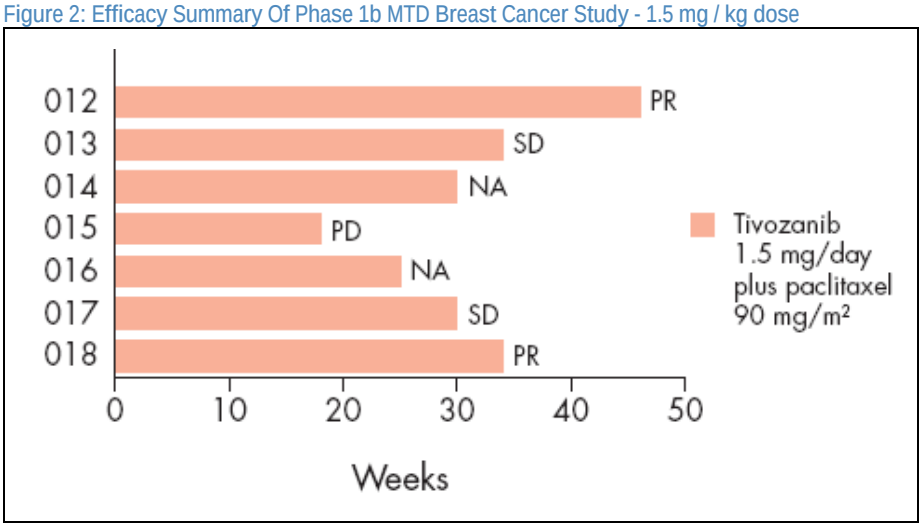
Here we briefly review the early data of tivozanib in various GI cancers and breast cancer. Recall, AVEO / Astellas plan to move tivozanib forward in breast and colorectal cancer in 2011. We have been encouraged by the early phase 1b data observed in both indications. Importantly, in both indications, the full 1.5 mg / day dose appears to be well tolerated (the same dose being used in the phase 3 TIVO-1 study). ***However, given the early stage of both the breast and colon cancer indications, we currently view the programs as attractive call options (not yet included in our or Street models), as they could be longer-term drivers.*** Additionally, we outline our thoughts on a potential future indication for tivozanib – reduction in incidence of brain metastases.

Breast Cancer

In early December 2010, data from the phase 1b maximally tolerated dose (MTD) study of tivozanib + paclitexel in breast cancer were presented (n=18). Overall, there were ten patients that required dose reduction and two patients had grade 3 hypertension (1 patient had dose reduction). There were 2 deaths, but none were related to tivozanib. The most common AEs were fatigue, diarrhea, alopecia and nausea. It was concluded that the tivozanib 1.5 mg / day dose can be further evaluated in breast cancer.

On the efficacy side, the ORR was 28% and all of the patients had a PR (n=5; 3 patients had stable disease). At the 1.5 mg / day dose there were 2 PRs and 2 patients with stable disease. Figure 2 summarizes the efficacy results from the 1.5 mg / kg dose.

Figure 2: Efficacy Summary Of Phase 1b MTD Breast Cancer Study - 1.5 mg / kg dose



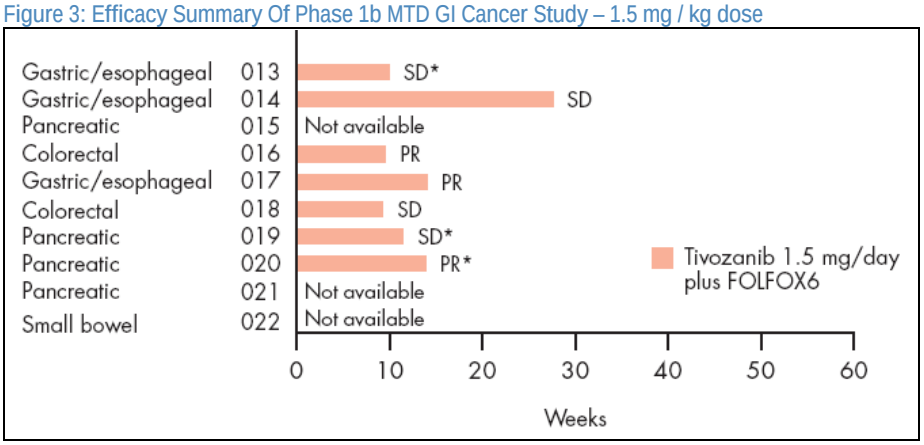
Source: Mayer et al. – San Antonio Beast Cancer Symposium 2010; NA= not available, PR= partial response, PD= progressive disease, SD= stable disease.

Colorectal Cancer

In a phase 1b MTD study of tivozanib in combination with FOLFOX6 in patients with GI cancers (n=22; gastric/esophageal=10, colorectal=6, pancreatic=5, small bowel=1), it appeared that the 1.5 mg / day dose was well tolerated (other tested doses: 0.5 and 1.0 mg / day). There was no progressive disease observed at the 1.5mg/day dose, and 3 patients achieved a PR, while 4 had stable disease. The safety profile looks generally in line with previous clinical trials of tivozanib and there were 4 tivozanib discontinuations (diarrhea, increased transaminase levels, malignant ascites, and dizziness) and 5 dose reductions.

Of note, there were 2 colorectal cancer patients on the 1.5 mg / day dose in the phase 1b study, one patient who achieved a PR, while the other achieved stable disease. Figure 3 summarizes the efficacy results of the 1.5 mg / kg dose in all the aforementioned cancer types in the phase 1b study.

Figure 3: Efficacy Summary Of Phase 1b MTD GI Cancer Study – 1.5 mg / kg dose



Source: Eskens et al. – ETORC 2010; PR= partial response, PD= progressive disease, SD= stable disease.

Future Indication – Reduction In Incidence of Brain Metastases?

Below we assess the potential of tivozanib in the reduction in incidence of brain metastases. While AVEO has not spoken about this indication, we believe it could be an interesting option for the company to purse, given unmet need. Below, we will discuss epidemiology, pathophysiology, current treatments, and why tivozanib mechanism of action / potency is ideal for the indication.

- **Epidemiology:** Brain metastases begin at another primary cancer site. The incidence of brain metastases is estimated to be ~170,000 / year.[9] The most common cancers from which brain metastases arise from are lung, breast, melanoma, and GI.[10] The incidence of brain metastases in RCC is estimated to range from 2-17%; however, based on our literature review, our sense is that the incidence is at the lower end of this range. For reference, the

[9] Nathoo et al, Journal of Clinical Pathology, 58:237-242 (2005)
[10] Massard et al, Annals of Oncology, 21(5):1027-31 (2010)

overall 1 year survival for RCC patients with brain metastases is ~48% (decreases to 12% at 5 years).[11] See Table 7.

Table 7: Incidence Of Brain Metastasis From Common Primary Tumors

Primary Tumor	Incidence Of Brain Metastasis
Lung	50-60%
Breast	15-20%
Melanoma	5-10%
GI	4-6%
RCC	2-17%

Source: JP Morgan Research

- **Brief pathophysiology overview:** In our literature review, there were a number of studies which link VEGF to brain metastases. Recall, angiogenesis (growth of blood vessels) is required for tumor growth, and VEGF tyrosine kinase is known to stimulate this growth.[12] A preclinical study by Yano and colleagues shows that VEGR tyrosine kinase expression correlates with brain metastasis via angiogenesis.[13] As such, it can be inferred that VEGF tyrosine kinase inhibitors could be a potential target for brain metastases.[14]

- **Current treatments:** Treatments are limited for brain metastases, and the standard treatment for a small number of lesions is surgery and radiosurgery. For multiple lesions, whole brain radiation therapy (WBRT) is conducted. Limited targeted therapeutic treatment used for the treatment of brain metastases, though chemotherapy is used.[15] A couple of the physicians we spoke too highlighted the significant unmet the indication.

  "There is an enormous therapeutic unmet need metastatic brain tumors."

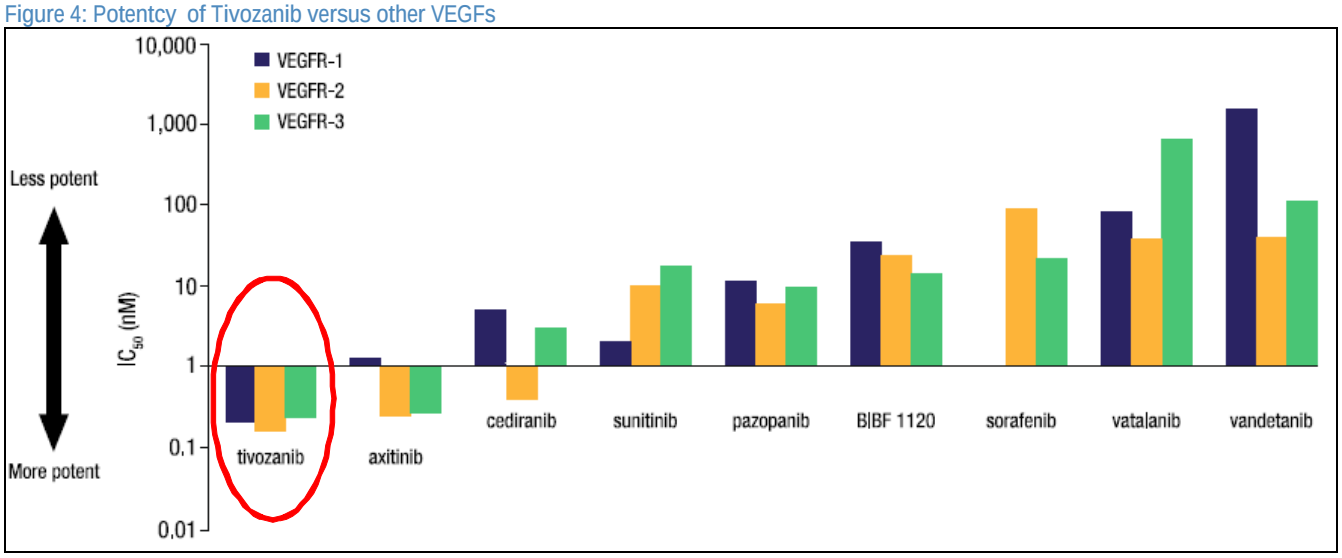
- **Proof of concept:** Recall, Nexavar has the same mechanism of action as tivozanib. In a retrospective study of phase 3 TARGET study of Nexavar, it was shown that overall incidence of brain metastases was 3% in patients receiving Nexavar versus 12% on placebo ($p<0.05$). Additionally, the incidence of brain metastases was statistically significantly lower in Nexavar after 1 ($p=0.0447$) and 2 ($p=.005$) years.[16] We note reduction of brain metastases is not in the label for Nexavar.

- **Tivozanib potency may be ideally suited for brain metastases:** Tivozanib potently inhibits tyrosine kinase activity of all 3 VEGF inhibitors (1, 2, and 3).[17] Interestingly, a study by Witmer and colleagues showed that VEGFR-1, but not VEGFR-2 and 3, were commonly present in the micro-vessels of the brain.[18] Indeed, of all the VEGF tyrosine kinase inhibitors, it appears

[11] Shuch et al, Cancer, 113(7):1641-8 (2008)
[12] Nathoo et al, Journal of Clinical Pathology, 58:237-242 (2005)
[13] Yano et al, Cancer Research, 60:4959-4967 (2000)
[14] Medioni et al, Annals of Oncology, 18(7):1282-3 (2007)
[15] National Brian Tumor Society
[16] Massard et al, Annals of Oncology, 21(5):1027-31 (2010)
[17] Bhargava et al, Current Oncology Reports, 13(2):103-11 (2011)
[18] Witmer et al, Journal of Histochemistry & Cytochemistry, 50(6):767-777 (2002)

that tivozanib is the most potent inhibitor of VEGFR-1.[19] Given a reduction on the incidence of brain metastases is observed with Nexavar, more potent inhibition with tivozanib (particularly at VEFGR-1) may result in a more robust efficacy outcome. See Figure 4.

Figure 4: Potentcy of Tivozanib versus other VEGFs



Source: Bhargava et al, Current Oncology Reports, 13(2):103-11 (2011)

- **Take home:** We acknowledge the brain metastases indication has historically been a difficult indication. However, we think it would be interesting for AVEO to explore the incidence of brain metastases in the upcoming phase 2 studies in breast and GI cancer. If a reduction in incidence of brain metastases is observed, we would recommend greater emphasis put on the indication, given the unmet need. We note that "CNS metastases" is listed as part of the exclusion criteria in the TIVO-1 study. At worst, we believe language referring to the reduction in incidence of brain metastases from other tumor studies could be included in the tivozanib label (which would be differentiated).

A Quick Look At AV-299

AV-299 is highly potent monoclonal anti-body which targets the hepatocyte growth factor (HGF), a pathway thought to play an important role in tumor growth, metastasis, and survival. Recall, September 2010, AVEO regained the full commercial rights to AV-299 from then partner Merck (due to Merck's portfolio prioritization).

AV-299 is currently in a phase 2 trial in first-line NSCLC. The trial is being run head-to-head against AstraZeneca's Iressa in Asia (AV-299 + Iressa versus Iressa alone).[20] We do not currently ascribe any value to the AV-299 program, and view it as an attractive future call option. Data from the ongoing phase 2 trial is expected

[19] Bhargava et al, Current Oncology Reports, 13(2):103-11 (2011)
[20] AVEO Investor Presentation – January 2011

early-2012. Details of the ongoing phase 2 trials are outlined in Table 8. While the NSCLC cancer program is furthest along, AV-299 is also being studied in patients with solid tumors, lymphomas, multiple myeloma, and liver metastases.

Table 8: Phase 2 AV-299 Trial Design in NSCLC

Title	A Phase 1b/2 Study of AV-299 (Formerly SCH 900105) in Combination With Gefitinib in Asian Subjects With Non-Small Cell Lung Cancer
Sample	188 (Asia Only)
Eligibility Requirements	Advanced or metastatic stage 3b/4 NSCLC No Prior Chemotherapy ECOG PS 0-2
Patient Population	~50/50 wild-type to mutant EGFR
Dose & Schedule	20 mg/kg IV; Days 1 & 15 out of 28-day cycles
Primary Endpoints	PFS and Response
Data Timeline	2012

Source: Company Documents, clinicaltrials.gov

Changes to our model

We are updating our model to better reflect the recent partnership with Astellas and feedback from our physician calls. In particular, we adjusted our go-forward expenses and royal payments. We also adjusted our revenue model for tivozanib slightly. Our 2011, 2012, and 2013 change to ($0.70), ($0.84), and ($0.40), respectively, from ($0.45), $0.32, and $0.50. See Table 9.

Table 9: AVEO - Changes To Model

	2011E	2011E	2012E	2012E	2013E	2013E
	OLD	NEW	OLD	NEW	OLD	NEW
Total Revenue	71.1	69.1	126.3	93.6	171.5	156.7
R&D	52.0	64.0	62.4	76.8	71.8	88.3
SG&A	34.0	29.0	40.8	37.7	46.9	45.2
Total Op Ex	86.0	93.0	111.1	124.3	148.5	171.6
Net income	(17.0)	(26.0)	1.6	(32.3)	21.9	(16.0)
EPS (excl. FAS123R)	(0.45)	(0.70)	0.32	(0.84)	0.50	(0.40)

Source: JP Morgan Research

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Valuation, Rating and Price Target Analysis

We are raising our December 2011 price target to $22 from $20. Our price target is based on applying a 6x revenue multiple to our 2014 revenue estimate of $202 million (total tivozanib revenues $404 million; AVEO gets 50% via profit split), and discounting back to the present at 15% per year. Our 6x multiple is at the higher end of the range of 3-7x revenue multiple for SMid biotechs over the last three years. Our discount rate is consistent with the rate afforded by many SMids with phase 3 trials (having de-risked phase 2 data).

Risks to Rating and Price Target

We see four primary risks to our Overweight rating on AVEO: 1) the failure of key later-stage clinical program of tivozanib in RCC; 2) AVEO has not developed a commercial team, and the RCC market is quite competitive with more than 6 players in the space, including major pharmas with deep pockets – hence, even with differentiated data for tivozanib, AVEO may not be able to compete effectively in the US market; 3) regulatory risk for FDA approval of tivozanib in RCC; and 4) there is risk the AVEO could seek to raise capital through an equity offering, which could dilute shareholders.

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AVEO Pharmaceuticals, Inc.: Summary of Financials

Income Statement - Annual	FY10A	FY11E	FY12E	FY13E
Revenues	45	69	94	157
Cost of products sold	0	0	10	38
Gross profit	45	69	84	119
SG&A	15	29	38	45
R&D	86	64	77	88
Operating Income	(56)	(24)	(31)	(15)
Note: EBITDA	(56)	(24)	(31)	(15)
Net interest income / (expense)	(3)	(2)	(2)	(1)
Other income / (expense)	1	0	0	0
Pretax income	(59)	(26)	(32)	(16)
Income taxes	0	0	0	0
Net income - GAAP	-	-	-	-
Net income - recurring	(59)	(26)	(32)	(16)
Diluted shares outstanding	25	37	38	40
EPS - excluding non-recurring	(2.31)	(0.70)	(0.84)	(0.40)
EPS - recurring	(2.31)	(0.70)	(0.84)	(0.40)

Income Statement - Quarterly	1Q11E	2Q11E	3Q11E	4Q11E
Revenues	-	-	-	-
Cost of products sold	-	-	-	-
Gross profit	-	-	-	-
SG&A	-	-	-	-
R&D	-	-	-	-
Operating income	-	-	-	-
Note: EBITDA	-	-	-	-
Net interest income / (expense)	-	-	-	-
Other income / (expense)	-	-	-	-
Pretax income	-	-	-	-
Income taxes	-	-	-	-
Net income - GAAP	-	-	-	-
Net income - recurring	-	-	-	-
Diluted shares outstanding	-	-	-	-
EPS - excluding non-recurring	-	-	-	-
EPS - recurring	-	-	-	-

Balance Sheet and Cash Flow Data	FY10A	FY11E	FY12E	FY13E
Cash and cash equivalents	-	-	-	-
Accounts receivable	0	0	0	0
Inventories	-	-	-	-
Other current assets	2	2	2	3
Current assets	81	135	209	207
PP&E	3	1	(0)	(2)
Total assets	87	138	211	207
Total debt	12	12	12	12
Total liabilities	64	64	64	64
Shareholders' equity	23	75	148	144
Net income (including charges)	(59)	(26)	(32)	(16)
D&A	1	2	2	2
Change in working capital	(0)	(0)	(0)	(0)
Other	-	-	-	-
Cash flow from operations	(53)	(17)	(19)	(3)
Capex	0	0	0	0
Free cash flow	(53)	(17)	(19)	(3)
Cash flow from investing activities	0	0	0	0
Cash flow from financing activities	81	70	93	0
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Ratio Analysis	FY10A	FY11E	FY12E	FY13E
Sales growth	-	-	-	152.2%
EBIT growth	37.2%	(57.6%)	28.4%	(51.5%)
EPS growth	13.4%	(69.5%)	19.4%	(52.3%)
Gross margin	100.0%	100.0%	89.6%	75.7%
EBIT margin	(126.3%)	(34.6%)	(32.8%)	(9.5%)
EBITDA margin	(126.3%)	(34.6%)	(32.8%)	(9.5%)
Tax rate	0.0%	0.0%	0.0%	0.0%
Net margin	(131.6%)	(37.6%)	(34.5%)	(10.2%)
Debt / EBITDA	-	-	-	-
Debt / Capital (book)	34.7%	14.1%	7.7%	7.9%
Return on assets (ROA)	(67.9%)	(18.8%)	(15.3%)	(7.7%)
Return on equity (ROE)	-	-	-	-
Return on invested capital (ROIC)	-	-	-	-
Enterprise value / sales	7.4	4.8	3.5	2.1
Enterprise value / EBITDA	-	-	-	-
Free cash flow yield	(16.7%)	(5.3%)	(6.0%)	(0.8%)

Source: Company reports and J.P. Morgan estimates.

Note: $ in millions (except per-share data). Fiscal year ends Dec

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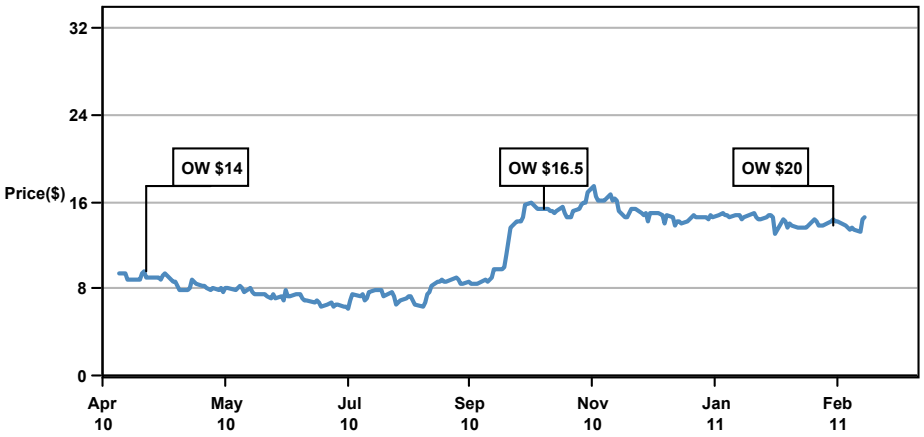
AVEO Pharmaceuticals, Inc. (AVEO) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
21-Apr-10	OW	9.63	14.00
15-Oct-10	OW	15.35	16.50
22-Feb-11	OW	13.89	20.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Apr 21, 2010. This chart shows J.P. Morgan's continuing coverage of this stock; the current analyst may or may not have covered it over the entire period.
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IB clients*	71%	63%	59%

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