

AVEO Pharmaceuticals

AVEO : NASDAQ : US\$9.39

BUY

Target: US\$14.00

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COMPANY STATISTICS:

Shares Out (M): 27.6
 Market Cap (M): US\$259.2
 52-week Range: 8.16 - 9.61
 Avg. Daily Vol. (000s): 182.2

EARNINGS SUMMARY:

FYE Dec	2009A	2010E	2011E
Revenue (M):	20.7	33.6	22.5
EPS:	(27.43)	(1.44)	(1.42)

Revenue (M):	Q1	-	5.0	-
	Q2	-	18.5	-
	Q3	-	5.0	-
	Q4	-	5.0	-
Total		20.7	33.6	22.5
EPS:	Q1	-	(0.47)	-
	Q2	-	(0.00)	-
	Q3	-	(0.47)	-
	Q4	-	(0.49)	-
Total		(27.43)	(1.44)	(1.42)

SHARE PRICE PERFORMANCE:



COMPANY SUMMARY:

AVEO Pharmaceuticals is a biotechnology company devoted to the discovery and clinical development of oncologic therapeutics.

All amounts in US\$ unless otherwise noted.

Life Sciences -- Biotechnology

BEST-IN-CLASS CANCER DRUG MOVES FORWARD; INITIATING WITH A BUY

Tivozanib could be top in RCC. Driving most of AVEO's value, in our view, is its lead product, tivozanib, a small molecule inhibitor of a critical signaling pathway implicated in tumor growth. Results from a randomized discontinuation Phase II trial released last year indicate that the clinical activity of tivozanib in renal cell carcinoma (RCC) appears to be at least equivalent to that of the market-leading therapeutic in this space, Sutent (sunitinib; Pfizer).

Phase III results in 2012E. Going head-to-head against another approved RCC therapeutic, Nexavar, in a pivotal Phase III registration trial could be sufficient to convince practitioners to use tivozanib as drug of choice in the front-line RCC treatment setting. Pharmacokinetic and pharmacodynamic advantages of tivozanib (highlighted in our report) support this claim. We expect results in 2012.

Pipeline and platform. Mitigating investment risk, other targeted therapies in AVEO's pipeline have potential given their genesis based on established platforms, but we believe no meaningful data supports clinical success at this time. AVEO has also teamed up with other players in the oncology development space that we believe are attracted to the sophisticated murine cancer model to which AVEO owns rights for drug discovery efforts. This model could prove to be an extremely valuable asset.

\$14 price target. In our view, the \$1.0B in 2009 global Sutent sales represents a reasonable standard for tivozanib to potentially attain. Moreover, ownership of all worldwide rights (ex-Japan) makes eventual partnering prospects very attractive. Modeling for what we expect would be an aggressive capture of Sutent market share in RCC beginning in 2013 if data from TIVO-1 recapitulates what was observed in Phase II, we arrive at a \$14 price target based on a risk-adjusted DCF model. We initiate coverage of AVEO with a BUY rating.

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INVESTMENT SUMMARY

AVEO Pharmaceuticals is a biotechnology company focused on the discovery and development of agents for treatment of oncologic indications. Driving most of the company's value, in our view, is its lead product, tivozanib, a small molecule inhibitor of a critical signaling pathway implicated in tumor growth. Results from a randomized discontinuation Phase II trial released last year indicate that tivozanib has potent clinical activity in a renal cell carcinoma (RCC) treatment setting that appears to be at least equivalent to that of the market-leading small molecule therapeutic in this space, Sutent (sunitinib; Pfizer).

Once regarded as a tumor type unresponsive to conventional therapeutics, advanced RCC can now be treated with relative success although no therapy can be regarded as curative. Supplanting traditional cytokine therapeutics, small molecule targeted therapeutics falling into two distinct classes – VEGF receptor (VEGR) and mTOR inhibitors – dominate as treatments of choice. Tivozanib belongs in the former class. Differences among class members rely primarily on relative potency (based upon improvements over placebo or prior standard of care) and tolerability.

Although it is a crowded market, we believe the combined efficacy and safety profile of tivozanib highly supports its potential as the eventual market leader in the RCC treatment setting. However, in our view, tivozanib faces a higher regulatory hurdle than its established competitors by virtue of being evaluated against an active comparator in a pivotal trial (the three other drugs, Sutent, Nexavar, and Votrient, were all evaluated compared to placebo or cytokine therapy). This presents a unique challenge for AVEO, in our view, since powering assumptions for a Phase III trial already under way (TIVO-1) are based upon historical data collected at a time when much less was understood about VEGFR inhibitor therapy. Nevertheless, we believe the chance of failure is significantly mitigated by 1) the highly convincing results from the randomized discontinuation Phase II trial confirming tivozanib activity, 2) the pharmacokinetic and pharmacodynamic advantages of tivozanib, and 3) a clear appreciation of what to expect from the Phase III comparator (Nexavar).

Mitigating investment risk, other targeted therapies in AVEO's pipeline have potential given their genesis based on established platforms, but for now no meaningful data supports clinical success at this time, in our view. AVEO has also teamed up with other players in the oncology development space, including Merck, Biogen IDEC, and OSI Pharma, which have made equity investments in the company and/or provide research funding. We believe these partners are attracted to the sophisticated murine cancer model to which AVEO owns rights for drug discovery efforts and which could prove to be an extremely valuable asset.

In our view, the \$1.0B in 2009 global Sutent sales represents a reasonable standard for tivozanib to potentially attain. Moreover, AVEO owns 100% of the worldwide rights (ex-Japan) to this drug, which makes eventual partnering prospects very attractive. Modeling for what we expect would be an aggressive capture of Sutent market share in RCC beginning 2013 if data from TIVO-1 recapitulates what was observed in Phase II, we arrive at a \$14 price target based on a risk-adjusted DCF model. We initiate coverage of AVEO with a BUY rating on shares.

UPCOMING EVENTS

Figure 1: AVEO expected upcoming events

Event	Expected timing
Follow-up data from clinical pipeline programs	Q2/10
Overall survival results from the Phase II RDT tivozanib trial	Q1/11
Completion of TIVO-1 enrollment	2011
TIVO-1 results	2012

Source: Company reports and Canaccord Adams

PIPELINE

Figure 2: AVEO pipeline

Drug	Target	Partner	indication	Stage
Tivozanib	VEGFRs	None	RCC	Phase III
			Solid tumors	Phase I
AV-299	HGF-1	Merck	NSCLC	Phase II
			Solid tumors	Phase I
AV-203	ErbB3	Biogen IDEC	Solid tumors	Phase I

Source: Company reports

VALUATION

Consistent with how we view most small-cap biotech companies as potential take-out candidates, we value AVEO based on a modified DCF model assuming tivozanib product launch in 2013 for treatment of RCC. Other potential indications for tivozanib, sales estimates for earlier-stage therapeutic candidates AV-299 and AV-203, and value of net operating losses carry forwards are not considered in our valuation at this time. AVEO's estimated cash balance of \$108M after completion of the IPO is not considered, but its debt balance is. A summary of model assumptions are as follows:

- Tivozanib launch in 2013 for treatment of RCC;
- A potential acquirer would dissolve all company R&D efforts after integration;
- Out-year operating margins (including COGs and SG&A) of 46% in 2013 and eroding to 35% on tiered royalty payments to Kirin on tivozanib sales;
- Tax rate of 35%;
- 70% chance of TIVO-1 success; and
- A platform technology value of \$100M.

Figure 3: AVEO DCF valuation

	2010E	2011E	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Tivozanib U.S.	0.0	0.0	0.0	27.4	110.7	264.2	385.4	440.1	444.5	471.4	476.2	480.9	485.7
Tivozanib ex-U.S. (ex-Japan)	0.0	0.0	0.0	0.0	11.1	52.8	115.6	176.1	222.3	235.7	238.1	240.5	242.9
Total tivozanib sales	0.0	0.0	0.0	27.4	121.8	317.0	501.0	616.2	666.8	707.2	714.2	721.4	728.6
gross margin				80%	80%	80%	77%	77%	77%	77%	77%	77%	77%
SG&A				43%	38%	35%	33%	32%	32%	31%	31%	31%	31%
U.S. operating profits			0.0	12.5	54.9	137.4	198.8	230.5	232.8	250.5	253.0	255.5	258.1
operating margin				45.6%	45.1%	43.3%	39.7%	37.4%	34.9%	35.4%	35.4%	35.4%	35.4%
tax rate				35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
post-tax net income				8.1	35.7	89.3	129.2	149.8	151.3	162.8	164.4	166.1	167.7
revenue weighted handicap factor				70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
probability adjusted				5.7	25.0	62.5	90.5	104.9	105.9	114.0	115.1	116.3	117.4
NPV	0.0	0.0	0.0	4.0	15.9	35.5	45.8	47.4	42.8	41.1	37.1	33.4	30.1

discount rate	12%
sum NPVs	333.1
technology value	100.0
debt	(20.4)
shares outstanding	29.6
value per share	\$13.94

Source: Canaccord Adams estimates

Investment risks

- TIVO-1 could fail to hit its primary endpoint.
- Competitive products in development could appear similar or better than tivozanib.
- Deteriorating market conditions could complicate future financing needs.

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Figure 4: AVEO annual income statement (\$M except EPS)

	2009A	2010E	2011E	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Product revenues												
tivozanib (U.S.)	0.0	0.0	0.0	0.0	27.4	110.7	264.2	385.4	440.1	444.5	471.4	476.2
tivozanib (ex-U.S.)	0.0	0.0	0.0	0.0	0.0	11.1	52.8	115.6	176.1	222.3	235.7	238.1
other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total product revenues	0.0	0.0	0.0	0.0	27.4	121.8	317.0	501.0	616.2	666.8	707.2	714.2
Collaboration revenues	20.7	33.6	22.5	24.7	27.2	29.9	32.9	36.1	39.8	43.7	48.1	52.9
Total Revenues	20.7	33.6	22.5	24.7	54.6	151.7	349.9	537.2	656.0	710.5	755.2	767.1
COGs	0.0	0.0	0.0	0.0	(5.5)	(24.4)	(63.4)	(115.2)	(141.7)	(153.4)	(162.6)	(164.3)
as % product sales					20%	20%	20%	23%	23%	23%	23%	23%
Research & Development	(51.8)	(62.2)	(55.9)	(61.5)	(67.7)	(74.4)	(81.9)	(87.6)	(93.8)	(100.3)	(107.3)	(114.9)
General & Administrative	(10.1)	(11.1)	(12.2)	(13.5)	(14.8)	(16.3)	(17.9)	(19.7)	(21.7)	(23.9)	(26.2)	(28.9)
Total Operating Expenses	(61.9)	(73.3)	(68.2)	(75.0)	(88.0)	(115.1)	(163.2)	(222.6)	(257.2)	(277.6)	(296.2)	(308.0)
Operating Income	(41.2)	(39.7)	(45.7)	(50.3)	(33.4)	36.6	186.6	314.6	398.8	433.0	459.0	459.1
operating margin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest income	0.1	0.3	0.3	0.1	0.0	0.0	0.0	0.4	1.2	2.2	3.4	4.6
Interest expense	(2.8)	(2.8)	(2.0)	(1.6)	(0.8)	(0.8)	(0.8)	(0.8)	(0.8)	(0.8)	(0.8)	(0.8)
Other, net	(0.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pre-Tax Income	(44.2)	(42.2)	(47.4)	(51.8)	(34.2)	35.8	185.8	314.2	399.2	434.4	461.6	462.9
Taxes (benefit)	(0.1)	0.0	0.0	0.0	0.0	0.0	65.0	110.0	139.7	152.0	161.5	162.0
tax rate	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.4	0.4	0.4	0.4	0.4
Net Income	(44.1)	(42.2)	(47.4)	(51.8)	(34.2)	35.8	120.8	204.2	259.5	282.4	300.0	300.9
EPS (basic)	(\$27.43)	(\$1.44)	(\$1.42)	(\$1.39)	(\$0.83)	\$0.79	\$2.45	\$3.83	\$4.53	\$4.61	\$4.59	\$4.34
EPS (diluted)	(\$27.43)	(\$1.44)	(\$1.42)	(\$1.39)	(\$0.83)	\$0.75	\$2.34	\$3.67	\$4.35	\$4.44	\$4.44	\$4.20
Basic Shares (MM)	1.6	29.4	33.4	37.4	41.4	45.4	49.3	53.3	57.3	61.3	65.3	69.3
Diluted Shares (MM)	1.6	29.4	33.4	37.4	41.4	47.7	51.7	55.6	59.6	63.6	67.6	71.6

Source: Company data and Canaccord Adams estimates

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Figure 5: AVEO quarterly income statement (\$M except EPS)

	2009A	Mar-10	Jun-10	Sep-10	Dec-10	2010E
	FY2009	1Q10E	2Q10E	3Q10E	4Q10E	FY2010
Collaboration revenues	20.7	5.0	18.5	5.0	5.0	33.6
Total Revenues	20.7	5.0	18.5	5.0	5.0	33.6
Research & Development	(51.8)	(14.9)	(15.2)	(15.7)	(16.3)	(62.2)
General & Administrative	(10.1)	(2.7)	(2.7)	(2.8)	(2.9)	(11.1)
Total Operating Expenses	(61.9)	(17.6)	(18.0)	(18.5)	(19.2)	(73.3)
Operating Income	(41.2)	(12.6)	0.5	(13.5)	(14.2)	(39.7)
Interest income	0.1	0.1	0.1	0.0	0.0	0.3
interest expense	(2.8)	(0.7)	(0.7)	(0.7)	(0.7)	(2.8)
Other Income, net	(0.3)	0.0	0.0	0.0	0.0	0.0
Pre-tax income	(44.2)	(13.1)	(0.1)	(14.2)	(14.9)	(42.2)
Tax benefit	0.1	0.0	0.0	0.0	0.0	0.0
Net Income	(44.1)	(13.1)	(0.1)	(14.2)	(14.9)	(42.2)
Basic shares	1.6	27.6	29.6	30.0	30.3	29.4
EPS	(27.4)	(\$0.47)	(\$0.00)	(\$0.47)	(\$0.49)	(\$1.44)

Source: Company data and Canaccord Adams estimates

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(as of 1 April 2010)

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	#	%		%
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Speculative Buy	83	12.4%		59.0%
Hold	159	23.8%		16.4%
Sell	20	3.0%		0.0%
	668	100.0%		

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