AVEO Pharmaceuticals

AVEO : NASDAQ : US$14.26

BUY

Target: US$23.00 ↑

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COMPANY STATISTICS:

Market Cap (M):	439.5
52-week Range:	6.01 - 14.43
Avg. Daily Vol. (000s):	51.5

EARNINGS SUMMARY:

FYE Dec		2009A	2010E	2011E
Revenue (M):		20.7	43.6	18.3
EPS:		(27.43)	(2.69)	(2.88)
Revenue (M):	Q1	3.7	10.9A	--
	Q2	5.1	15.6A	--
	Q3	--	8.3	--
	Q4	--	8.8	--
Total		20.7	43.6	18.3
EPS:	Q1	(5.93)	(2.27)A	--
	Q2	(6.41)	(0.50)A	--
	Q3	--	(0.59)	--
	Q4	--	(0.60)	--
Total		(27.43)	(2.69)	(2.88)

SHARE PRICE PERFORMANCE:

COMPANY DESCRIPTION:
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

AV-299 RETURN DIVERSIFIES RISK PROFILE; INCREASING TARGET

Investment recommendation: Including risk-adjusted revenue potential for AV-299 as a novel treatment for non-small cell lung cancer (NSCLC), we increase our price target to $23 from $14. We reiterate our BUY recommendation of AVEO shares ahead of two major clinical events expected in 2011 and on our positive view of the company's diversified business model.

Investment highlights

- Based on a recent run-up of AVEO shares, we believe the Street is beginning to price in the previously ignored potential of AV-299 in NSCLC. Now a wholly owned asset after its return from Merck, AV-299 revenue potential is now much more substantial to AVEO, in our view.
- Designed to target a high-profile signaling pathway already validated as viable cancer target (discussed herein), AV-299 could demonstrate meaningful activity in a randomized Phase II trial from which interim data read-out is expected in H2/11.
- Based on our view of the high potential of tivozanib (under evaluation in a renal cell carcinoma Phase III FDA registration trial from which top-line data is expected mid-2011), we expect share demand to continue. Furthermore, we now see a much more attractive business model comprised of two unencumbered late/mid-stage clinical assets, and a unique drug discovery platform with value already validated by a number of corporate partnerships.

Valuation and risks: Our new $23 target is based on a DCF considering success rates of 80% and 10% for tivozanib and AV-299, respectively, and exit via acquisition. Results from both trials, expected in 2011, would modify our conviction. Nearest-term stock risks include trial failures.

Figure 1: Selected AVEO expected upcoming events

Event	Expected timing
Top-line results from TIVO-1 evaluating tivozanib vs. sorafenib (Nexavar) in front-line Stage IV renal cell carcinoma (RCC)	Mid-2011E
Interim results from a randomized Phase II trial evaluating AV-299 in combination with gefitinib (Iressa) in treatment-naïve NSCLC	H2/11E

Source: Company data and Canaccord Genuity

Figure 2: AVEO clinical pipeline

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

Source: Company data

MET INHIBITION AND AV-299 POTENTIAL

The potential role that MET signaling plays in NSCLC progression was most convincingly demonstrated in a Science paper published in 2007 (Engelman et al.). This group demonstrated that a NSCLC cell line selected for resistance to gefitinib (Iressa) had increased copies of the MET gene and corresponding activation of downstream EGFR signaling pathways. Blocking MET gene expression in these cells restored sensitivity to gefitinib supporting this correlation further. This data suggests that inhibiting both MET and EGFR pathways could lead to an enhanced therapeutic effect in NSCLC patients.

As reported at ASCO last June, results from a randomized Phase II trial comparing erlotinib (Tarceva) treatment alone vs. erlotinib plus ARQ 197 (Arqule, Inc.), a small molecule targeted therapeutic shown to have preferential activity against MET, showed encouraging progression-free and overall survival benefits with the combination. Although results were not statistically significant in this exploratory trial, this data also supports the potential of combining EGFR and other MET inhibitors for treatment of NSCLC.

AVEO's Phase II product candidate, AV-299, is a monoclonal antibody designed to perturb the activity of hepatocyte growth factor (HGF), which is the ligand responsible for activating MET signaling. Hence, treatment with AV-299 should theoretically accomplish the same goals as any other inhibitor directly targeting MET. To this end, AV-299 is being

evaluated in a 170-patient randomized Phase II trial comparing treatment with gefitinib alone vs. gefitinib/AV-299 in Asian NSCLC patients with treatment-experienced and -inexperienced disease naive to prior therapy. Consistent with results obtained with ARQ 197 and erlotinib, one could predict that AV-299 and gefitinib should cooperate in a similar fashion.

Results from the ARQ 197 study support the view that EGFR genotype may not predict response to an EGFR/MET inhibitor combination. Nevertheless, the prevailing view among treating physicians appears biased towards reserving EGFR inhibitors for treatment of patients with tumor EGFR genotypes predictive of gefitinib and erlotinib hypersensitivity. Best estimates suggest that these genotypes are represented in only about 12-15% of the total NSCLC treatment population, which limits the ultimate penetration of these agents for treatment of this disease. Hence, although available data suggests that MET inhibitors could be effective therapies for all NSCLC patients regardless of EGFR genotype, their most immediate application would be used in combination with EGFR inhibitors for treatment of patients with activating tumor EGFR mutations, in our view.

Given the limited market size, we believe it makes sense that a large pharmaceutical company such as Merck would return rights of AV-299 to AVEO. To a small biotech company such as AVEO, potential AV-299 revenues could be substantial. Based on our estimates shown in Figure 3, we believe AV-299 could achieve peak sales of $776M in 2021 as treatment of EGFR+ Stage IIIB/IV NSCLC patients if a possible Phase III registration study supported US approval. These assumptions are based on:

- a 13% prevalence of EGFR activating mutations in the NSCLC treatment population
- initial pricing at $65K per patient consistent with that of other oncology biologics
- a peak penetration rate of 55%

Figure 3: AV-299 sales estimates

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
# Stage IIIB/IV NSCLC patients	86,700	88,434	90,203	92,007	93,847	95,724	97,638	99,591	101,583	103,615	105,687	107,801	109,957
% with activating EGFR mutations	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%	13%
treatable patients	11,271	11,496	11,726	11,961	12,200	12,444	12,693	12,947	13,206	13,470	13,739	14,014	14,294
penetration							5%	15%	25%	40%	55%	55%	55%
# patients							635	1,942	3,301	5,388	7,557	7,708	7,862
cost per patient							65,000	65,000	65,000	68,250	71,663	75,246	79,008
revenue ($M)							41.3	126.2	214.6	367.7	541.5	580.0	621.2
ex-US sales as %US								5%	10%	15%	25%	25%	25%
ex-US sales ($M)								6.3	21.5	55.2	135.4	145.0	155.3
total AV-299 sales ($M)							**41.3**	**132.5**	**236.1**	**422.9**	**676.9**	**725.0**	**776.4**

Source: Canaccord Genuity estimates

Model impact

Given the rapid increase in stock price after return of AV-299 rights to AVEO, we believe that the market is now factoring in the potential of this antibody in AVEO's pipeline. This pipeline, in our view, has suddenly become much more attractively diversified with one Phase III (tivozanib) and one Phase II (AV-299) asset, both of which are entirely owned by the company (note: Kirin owns tivozanib rights in Japan). Meaningful data from both programs is expected in 2011. With lack of specific clinical data supporting HGF inhibition as a potential NSCLC treatment approach, we assign only a 10% probability of AV-299 US approval in 2015. Our prior valuation assumptions did not include AV-299 potential. Based on this modification, we arrive at a new price target of $23 (was $14).

Consistent with 2010 cash balance guidance, we estimate $61M on the balance sheet at year-end and see sufficient cash through top-line data read-out of TIVO-1, excluding the potential impact of funding from corporate partnerships.

Figure 4: AVEO DCF valuation

	2010E	2011E	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
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	0.0
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	0.0
AV-299 US	0.0	0.0	0.0	0.0	0.0	41.3	126.2	214.6	367.7	541.5	580.0	621.2	652.2	684.8
AV-299 ex-US	0.0	0.0	0.0	0.0	0.0	0.0	6.3	21.5	55.2	135.4	145.0	155.3	163.1	171.2
Total product sales	**0.0**	**0.0**	**0.0**	**27.4**	**121.8**	**358.3**	**633.5**	**852.3**	**1089.7**	**1384.1**	**1439.2**	**1497.8**	**1543.8**	**856.0**
gross margin				80%	80%	81%	80%	81%	82%	83%	84%	84%	84%	90%
SG&A				43%	43%	38%	38%	35%	35%	35%	35%	35%	35%	35%
U.S. operating profits			**0.0**	**12.5**	**55.5**	**180.3**	**313.1**	**446.5**	**581.1**	**749.9**	**781.6**	**813.4**	**838.4**	**500.8**
operating margin				*45.6%*	*45.6%*	*50.3%*	*49.4%*	*52.4%*	*53.3%*	*54.2%*	*54.3%*	*54.3%*	*54.3%*	*58.5%*
tax rate				38%	38%	38%	38%	38%	38%	38%	38%	38%	38%	38%
post-tax net income				**7.7**	**34.4**	**111.8**	**194.1**	**276.8**	**360.3**	**465.0**	**484.6**	**504.3**	**519.8**	**310.5**
revenue weighted handicap factor				70%	70%	70%	57%	53%	47%	41%	40%	39%	39%	10%
probability adjusted				5.4	24.1	78.2	111.5	147.8	168.3	189.0	192.7	196.2	202.2	31.0
NPV	**0.0**	**0.0**	**0.0**	**4.2**	**16.7**	**48.4**	**61.6**	**72.9**	**74.1**	**74.3**	**67.7**	**61.5**	**56.6**	**7.8**

discount rate	12%
sum NPVs	545.8
PV terminal value	79.1
technology value	100.0
debt	(20.4)
shares outstanding	30.8
value per share	**$22.86**

Source: Canaccord Genuity 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

Figure 5: 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
AV-299 (U.S.)	0.0	0.0	0.0	0.0	0.0	0.0	41.3	126.2	214.6	367.7	541.5	580.0
AV-299 (ex-U.S.)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	6.3	21.5	55.2	135.4	145.0
Total product revenues	**0.0**	**0.0**	**0.0**	**0.0**	**27.4**	**121.8**	**358.3**	**633.5**	**852.3**	**1,089.7**	**1,384.1**	**1,439.2**
Collaboration revenues	20.7	43.6	18.3	20.1	22.1	24.3	26.7	29.4	32.3	35.5	39.1	43.0
Total Revenues	**20.7**	**43.6**	**18.3**	**20.1**	**49.5**	**146.1**	**385.0**	**662.9**	**884.6**	**1,125.2**	**1,423.2**	**1,482.2**
COGs	0.0	0.0	0.0	0.0	(5.5)	(24.4)	(67.5)	(128.5)	(165.3)	(195.7)	(230.3)	(236.8)
as % product sales					20%	20%	19%	20%	19%	18%	17%	16%
Research & Development	(51.8)	(93.2)	(83.9)	(92.3)	(101.5)	(111.7)	(122.8)	(131.4)	(140.6)	(150.5)	(161.0)	(172.3)
General & Administrative	(10.1)	(15.2)	(15.9)	(16.7)	(20.1)	(52.4)	(136.1)	(240.7)	(298.3)	(381.4)	(484.4)	(503.7)
Total Operating Expenses	**(61.9)**	**(108.4)**	**(99.8)**	**(109.0)**	**(127.1)**	**(188.4)**	**(326.5)**	**(500.7)**	**(604.3)**	**(727.5)**	**(875.8)**	**(912.8)**
Operating Income	(41.2)	(64.8)	(81.6)	(88.9)	(77.6)	(42.3)	58.5	162.3	280.3	397.7	547.4	569.4
Interest income	0.1	0.3	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.3	1.3	2.6
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)	0.1	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)**	**(67.2)**	**(83.4)**	**(90.5)**	**(78.4)**	**(43.1)**	**57.7**	**161.5**	**279.5**	**397.2**	**547.8**	**571.2**
Taxes (benefit)	(0.1)	0.0	0.0	0.0	0.0	0.0	21.9	61.4	106.2	150.9	208.2	217.1
tax rate	0%	0%	0%	0%	0%	0%	38%	38%	38%	38%	38%	38%
Net Income	**(44.1)**	**(67.2)**	**(83.4)**	**(90.5)**	**(78.4)**	**(43.1)**	**35.8**	**100.1**	**173.3**	**246.3**	**339.7**	**354.2**
EPS (basic)	($27.43)	($2.69)	($2.88)	($2.75)	($2.12)	($1.05)	$0.80	$2.05	$3.28	$4.33	$5.58	$5.46
EPS (diluted)	($27.43)	($2.69)	($2.88)	($2.75)	($2.12)	($1.05)	$0.76	$1.95	$3.14	$4.16	$5.37	$5.27
Basic Shares (MM)	1.6	25.0	29.0	33.0	36.9	40.9	44.9	48.9	52.9	56.9	60.9	64.9
Diluted Shares (MM)	1.6	25.0	29.0	33.0	36.9	40.9	47.2	51.2	55.2	59.2	63.2	67.2

Source: Company data and Canaccord Genuity estimates

Figure 6: AVEO quarterly income statement ($M except EPS)

	Mar-09	Jun-09	2009A	Mar-10	Jun-10	Sep-10	Dec-10	2010E
	1Q09A	2Q09A	FY2009	1Q10A	2Q10A	3Q10E	4Q10E	FY2010
Collaboration revenues	3.7	5.1	20.7	10.9	15.6	8.3	8.8	43.6
Total Revenues	3.7	5.1	**20.7**	**10.9**	**15.6**	**8.3**	**8.8**	**43.6**
Research & Development	(9.7)	(12.1)	(51.8)	(22.6)	(26.0)	(21.9)	(22.7)	(93.2)
General & Administrative	(2.6)	(2.4)	(10.1)	(2.8)	(3.8)	(4.2)	(4.4)	(15.2)
Total Operating Expenses	0.0	0.0	**(61.9)**	**(25.4)**	**(29.8)**	**(26.1)**	**(27.1)**	**(108.4)**
Operating Income	**0.0**	**0.0**	(41.2)	(14.5)	(14.2)	(17.8)	(18.3)	(64.8)
Interest income	0.0	0.0	0.1	0.0	0.0	0.0	0.2	0.3
interest expense	(0.7)	(0.7)	(2.8)	(0.6)	(0.7)	(0.7)	(0.8)	(2.8)
Other Income, net	(0.1)	(0.2)	(0.3)	0.7	(0.6)	0.0	0.0	0.1
Pre-tax income	(9.4)	(10.2)	**(44.2)**	**(14.4)**	**(15.5)**	**(18.5)**	**(18.9)**	**(67.2)**
Tax benefit	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0
Net Income	(9.4)	(10.2)	**(44.1)**	**(14.4)**	**(15.5)**	**(18.5)**	**(18.9)**	**(67.2)**
Basic shares	1.6	1.6	1.6	6.3	30.8	31.2	31.5	25.0
EPS	($5.93)	($6.41)	($27.43)	($2.27)	($0.50)	($0.59)	($0.60)	($2.69)

Source: Company data and Canaccord Genuity estimates

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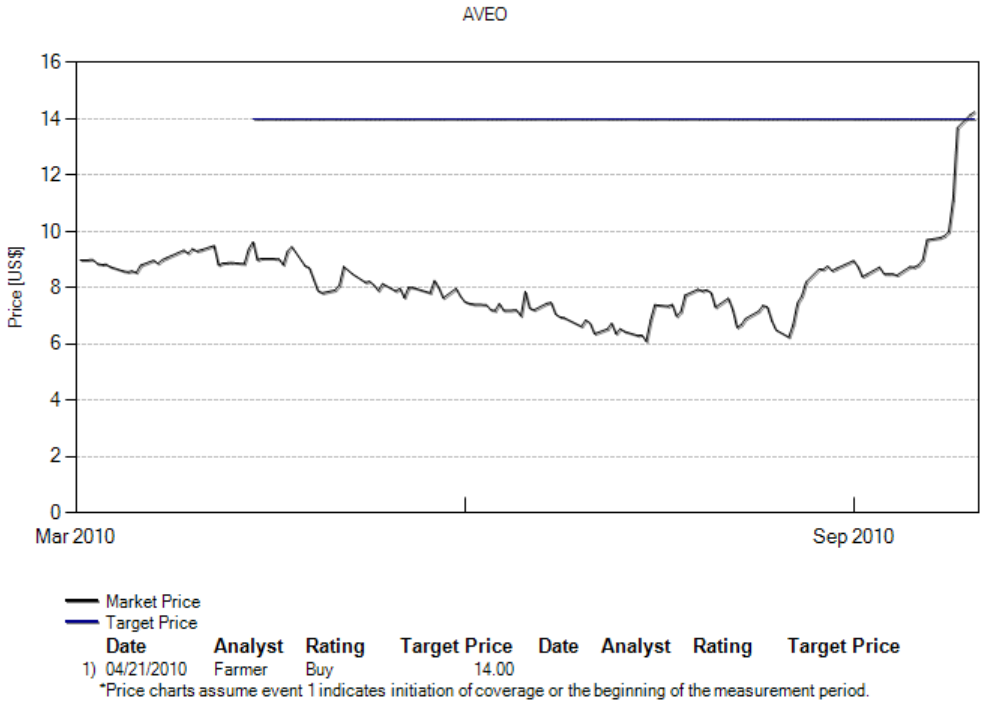
Price Chart:*



Date	Analyst	Rating	Target Price	Date	Analyst	Rating	Target Price
1) 04/21/2010	Farmer	Buy	14.00				

*Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

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(as of 5 October 2010)

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	711	100.0%	

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Company	Disclosure
AVEO Pharmaceuticals	1A, 2, 3, 5, 7

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