

Clovis Oncology

On Track for Pivotal Data in 4Q; Increasing PT Again

We reiterate our OW rating on CLVS following an expectedly quiet 4Q11 report. Management reiterated 2012 cash burn guidance and provided a progress update on the pipeline. Most importantly, the company is on track to report top-line data from the pivotal LEAP study evaluating CO-101 in pancreatic cancer in 4Q. We are raising our Dec 2012 PT to \$28 from \$23 after revaluing CO-101 pricing assumption, which we previously highlighted as being overly conservative. Reiterate OW.

- **Key incremental takeaway: LEAP trial still on track for data in 4Q12.** Enrollment of the pivotal CO-101 LEAP trial should complete (~360 pts) by the end of the month, and mgmt still expects overall survival data by YE12 (although the timing is event driven). The company also plans to initiate a Ph1 combo trial with cisplatin in NSCLC in 3Q12.
- **4Q results: expenses in-line with expectations.** CLVS reported EPS of (\$1.30), wider than both JPME of (\$0.63) and consensus of (\$0.79 from n=2). OpEx of \$14.5 were in-line with our estimate of \$14.6M and the variance was related to share count. That said, CLVS is not yet an earnings story, in our view.
- **Estimate revisions.** We have adjusted our model to reflect the quarter but remain within 2012 cash burn guidance of \$67-\$72M.
- **Balance sheet status: good shape.** The company has \$140M in cash after last Nov's IPO, which should be sufficient to fund operations through the LEAP study in 4Q and potential POC data for 1686 and rucaparib in 2013.
- **Key upcoming event: waiting to LEAP.** We expect to see progress with all 3 of the company's clinical programs in 2012, but obviously the critical event to watch for is top-line survival data from the pivotal LEAP trial expected in 4Q.
- **Impact to our OW investment thesis: negligible but raising 2012 PT to \$28.** We still believe that CO-101 has the potential to become standard of care in pancreatic cancer for the substantial hENT1 low group. We previously commented on several possible upside levers to our valuation, one of which was the hENT1 distribution (65% hENT1 low vs. the 50% we previously assumed) that we adjusted earlier this year. Another is our pricing assumption for CO-101. We previously assumed \$40k/pt, but management has indicated it will likely be closer to \$50-\$60k if 101 does indeed demonstrate a survival benefit in LEAP. After taking our starting price to \$50k, we are raising our PT to \$28 from \$23 but our probabilities (55% chance of approval) and commercial scenarios remain conservatively skewed.

Clovis Oncology, Inc. (CLVS;CLVS US)

FYE Dec	2011E	2012E	2012E	2013E	2013E	2014E	2014E
		(Prev)	(Curr)	(Prev)	(Curr)	(Prev)	(Curr)
EPS - Recurring (\$)							
Q1 (Mar)	(2.14)A	(0.80)	(0.83)	-	-	-	-
Q2 (Jun)	(4.37)A	(0.65)	(0.68)	-	-	-	-
Q3 (Sep)	(1.38)A	(0.67)	(0.72)	-	-	-	-
Q4 (Dec)	(1.30)	(0.53)	(0.77)	-	-	-	-
FY	(14.42)	(2.62)	(3.01)	(2.57)	(2.68)	(1.31)	(1.21)
Bloomberg EPS FY (\$)	(5.14)	(3.24)	(3.24)	(4.22)	(4.22)	(2.44)	(2.44)

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

Overweight

CLVS, CLVS US

Price: \$23.00

▲ **Price Target: \$28.00**
Previous: \$23.00

Biotechnology

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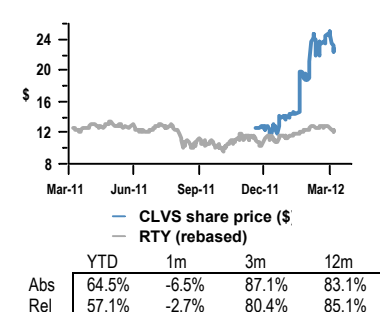
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Price Performance



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THINK BIG, BUY SMALL

Company Data	
Price (\$)	23.00
Date Of Price	07 Mar 12
52-week Range (\$)	27.29 - 11.45
Mkt Cap (\$ mn)	515.20
Fiscal Year End	Dec
Shares O/S (mn)	22
Price Target (\$)	28.00
Price Target End Date	31 Dec 12

See page 8 for analyst certification and important disclosures.

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Product Pipeline

Figure 1: CLVS Pipeline

Program	P/C	Ph1	Ph2	Ph3	FDA	Mkt.	Partner	Comments
CO-101								
1L met pancreatic cancer								Lipid conjugated gemcitabine, In-licensed from Clavis Pharma in Nov2009 LEAP: pivotal, randomized, controlled, 360 pt study - CO-101 vs. gemcit
2L met pancreatic cancer								Open-label, single arm. Enrollment began Feb 2011
Solid tumors								Ph1 planned in combination with cisplatin
CO-1686								
NSCLC								In-licensed from Avila Therapeutics in May 2010 Oral EGFR mutant-selective inhibitor
CO-338								
Solid tumors								In-licensed from Pfizer in June 2011 IV PARP inhibitor (Completed Ph 2 in combination with TMZ)
Solid tumors								Oral PARP inhibitor (Ongoing dose-ranging Ph1 study with chemo)

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

Upcoming Events

Figure 2: CLVS Upcoming Events

Program	Event	Expected Timing	Significance
CO-101	Complete enrollment for pivotal Ph2 LEAP study	1Q12	Low-Medium
	Report top-line results (OS in low hENT1 pts)	4Q12	High
	Complete enrollment for Ph2 study in 2L panc cancer	4Q12	Low
	File NDA with FDA and MAA with EMA	mid-2013	Medium
	Potential FDA approval	1Q14	High
CO-1686	Commence Ph1/2 clinical trial in 1L and 2L lung cancer (US/EU)	2Q12	Low
	Initiate Ph1/2 study in Japan	3Q12	
	Data from Ph1/2 POC trial	2H13	Medium-High
	Goal to file NDA within 4 years of IND filing	1Q16	Low-Medium
CO-338	Data from two Ph1 monotherapy (oral) trials in solid tumors	4Q12/1Q13	Low

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

Investment Thesis

We have an Overweight rating on CLVS shares. Our thesis is primarily based on the potential for CO-101, the company's lead asset for pancreatic cancer to become standard of care in a subgroup (hENT1 low) of patients. Furthermore, this subgroup represents a significant proportion of all front-line pancreatic cancer patients (~65%). Our positive view of CO-101 is also driven by multiple upside drivers to our sales assumptions, one of which has already materialized (hENT1 low % confirmed to be 65% rather than 50%). Underpinning CO-101 is the rest of Clovis' early but interesting pipeline and a strong management team with an excellent track record of success. Additionally, a unique feature of all of the company's candidates is the development of companion diagnostics for patient selection, which could provide a regulatory and commercial benefit. The key event for 2012 is top-line results from the pivotal LEAP study in 4Qe.

Valuation

We are increasing our December 2012 price target to \$28 from \$23 but our probability of approval and commercial scenarios remain conservatively skewed. Our target is based on a blended average of our proprietary probability-adjusted sum-of-the-parts scenario analysis (50% weighting) and risk-adjusted NPV model (50% weighting).

Table 1: CLVS Valuation Summary

CLVS : Valuation Summary			
Discount rate	20.0%		
Main value driver	Prob of approval	Peak sales est (avg. scenario)	Avg peak yr
CO-101, US	55%	\$ 600	2019
CO-101, EU	55%	\$ 300	2020
Valuation methodology	Value	Weighting	Adj. value/ share
P/E 2015	\$ -	0%	\$ -
Real options scenario analysis	\$ 24.88	50%	12.44
Risk adjusted NPV analysis	\$ 30.77	50%	15.38
Total			\$ 27.82
Catalyst/liquidity discount			0%
YE 2012 Price Target			\$ 28

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

Proprietary real options scenario analysis (50% weighting)

Using this model, we estimate the value of the company's development programs (predominantly CO-101) by assigning a range of probabilities to six different commercial scenarios (ranging from an ineffective product that generates zero value to a breakthrough treatment option) and analyze them over several possible peak sales years. Discount rates in our universe are typically based on the company's weighted average cost of capital and generally fall within a range of 10% to 15%. We apply a rate of 20%, higher than our typical range, which we believe is appropriate for a new issue, though we expect the rate will track down.

Value contribution of CO-101

Below, we demonstrate our analysis for CO-101 in the US and EU. As Clovis' key value driver, this product contributes \$12 to our SOTP analysis. We assume a 55% probability that CO-101 reaches the market in each territory (slightly above historical

success rates for clinical candidates in randomized Phase 2 trials in oncology given the support for the hENT1 thesis, the companion diagnostic, and early survival data). Our timeline to reach peak sales is 2019-2020 depending on the geographic location, which we acknowledge may be a bit too conservative. Typically, drugs for life threatening cancer conditions peak quickly (often within a few years for a given indication) as opposed to a more gradual ramp (as we are assuming). However, we await LEAP data prior to reconsidering our expectations. We also assume a 15% royalty paid to Clavis Pharma on CO-101 sales. As indicated, a discount rate of 20% is applied, which also may be conservative given the probability adjustments already in place. See Table 16 for a detailed view of our analysis.

Risk-adjusted NPV analysis (50% weighting)

In our risk-adjusted NPV analysis, we estimate the revenues and associated expenses (including taxes) over the expected patent life of a product. We complete this exercise for conservative, moderate, and aggressive sales scenarios and then assign a range of probabilities to each of these outcomes as well as to the possibility that the product is ineffective and generates zero value. For CO-101, we assume a formulation patent will be granted so that protection extends to 2030. As with our scenario analysis, we apply a discount rate of 20%, which we believe is appropriate given the applied probability adjustments. The key assumptions in our rNPV model are outlined below.

P/E analysis (no weighting)

We assign no weighting to our P/E analysis given that we project the first year of profitability to be 2015 and the variation in multiples in the first year of profitability is extremely broad.

Risks to Rating and Price Target

Clovis is susceptible to the standard risks that apply to the entire biotechnology industry, including development, regulatory, commercial, manufacturing, financing and IP pitfalls. Other risks specific to the company are listed below.

LEAP outcome in 2H12 is a highly binary event

CO-101 is the main component of the company's valuation and future performance is highly dependent on the outcome of the LEAP trial. This makes for a very binary story with significant downside risk if the trial fails.

Limited proof-of-concept data

Rationale for the pivotal LEAP trial is based on evidence from an abbreviated Phase 2 program. Moreover, dosing studies were not highly robust and the safety profile of CO-101 is relatively immature, in our view. Additionally, the hENT1 theory is based primarily on retrospective analyses and has not been definitively proven in a prospective clinical trial. Thus, until the more rigorous LEAP study proves otherwise, we believe CO-101's potential is more hypothesis based than data driven.

Companion diagnostic adds an element of complexity to the regulatory process

While we believe the hENT1 diagnostic will help drive rapid adoption and ultimately be an advantage, it also adds an element of risk. Approval of CO-101 is contingent on approval of the hENT1 test, which is currently in development and projected to be filed along with the CO-101 drug application. Our understanding is that it is a very

standard test and we believe that the approval process will also be relatively straightforward; however, we can't totally discount some unforeseen risk that could delay the approval of CO-101.

Enough cash for now but more capital needed for commercialization.

Management believes it has sufficient cash (~\$140M at YE11) to complete the clinical and regulatory development of CO-101 but will require additional funding to globally commercialize the drug. Seeing that management plans to market CO-101 in the US and EU, we assume an additional financing post LEAP data, albeit at a materially higher valuation (if the results are indeed positive).

Figure 3: CLVS Income Statement

CLVS Income Statement (\$ millions, except EPS)

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Fiscal Year Ends Dec 31	2009A	2010A	2011A	1Q12E	2Q12E	3Q12E	4Q12E	2012E	2013E	2014E	2015E	2016E
CO-101:												
CO-101 - US sales										\$ 106.5	\$ 275.5	\$ 513.3
CO-101 - EU sales										21.3	107.0	268.8
Total CO-101 sales										127.7	382.5	782.1
Total Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 127.7	\$ 382.5	\$ 782.1
COGS & royalties	-	-	-	-	-	-	-	-	-	37.0	107.1	211.2
R&D	1.762	22.3	40.7	12.9	13.4	14.1	14.9	55.3	63.2	80.3	100.4	127.5
Acquired in-process R&D	13.1	12.0	7.0	4.0	-	-	-	4.0	-	-	-	-
SG&A	2.2	4.3	6.9	2.2	2.4	2.6	3.0	10.2	21.9	52.9	81.0	108.8
Total Operating Expenses	\$ 17.1	\$ 38.6	\$ 54.6	\$ 19.1	\$ 15.8	\$ 16.7	\$ 17.9	\$ 69.6	\$ 85.1	\$ 170.3	\$ 288.5	\$ 447.4
Operating income	(17.1)	(38.6)	(54.6)	(19.1)	(15.8)	(16.7)	(17.9)	(69.6)	(85.1)	(42.5)	94.0	334.7
Other income, net	(0.04)	0.795	(0.96)	0.1	0.1	0.1	0.0	0.3	1.2	2.2	3.4	7.7
Pretax income	(17.1)	(37.830)	(55.5)	(19.0)	(15.7)	(16.6)	(17.9)	(69.3)	(83.9)	(40.4)	97.4	342.4
Income Tax (benefit)	-	-	(0.027)	-	-	-	-	-	-	-	9.7	85.6
Net Income	\$ (17.1)	\$ (38)	\$ (55.6)	\$ (19.0)	\$ (15.7)	\$ (16.6)	\$ (17.9)	\$ (69.3)	\$ (83.9)	\$ (40.4)	\$ 87.7	\$ 256.8
Average shares Outstanding	3.2	3.8	3.9	22.8	23.0	23.1	23.3	23.0	31.3	33.3	35.3	37.3
GAAP EPS	\$ (5.30)	\$ (9.85)	\$ (14.42)	\$ (0.83)	\$ (0.68)	\$ (0.72)	\$ (0.77)	\$ (3.01)	\$ (2.68)	\$ (1.21)	\$ 2.49	\$ 6.89
<i>Margin Analysis:</i>												
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	71%	72%	73%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	25%	43%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	23%	33%
<i>Cost Analysis:</i>												
COGS as % of tot. prod. sales				NM	NM	NM	NM	NM	NM	29%	28%	27%
R&D as % of tot. revenue				NM	NM	NM	NM	NM	NM	41%	21%	14%
SG&A as % of tot. revenue				NM	NM	NM	NM	NM	NM	63%	26%	16%
<i>Year-over-year growth:</i>												
Total revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
R&D Expense		1167%	82%	84%	38%	22%	20%	36%	14%	27%	NM	NM
SG&A Expense		95%	59%	58%	42%	49%	48%	49%	114%	142%	NM	NM
Total operating expenses		126%	41%	127%	-14%	25%	24%	27%	22%	100%	NM	NM
Operating income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
EPS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	177%
<i>Tax Rate</i>	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	10%	25%

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

Clovis Oncology: Summary of Financials

Income Statement - Annual	FY11A	FY12E	FY13E	FY14E	Income Statement - Quarterly	1Q12E	2Q12E	3Q12E	4Q12E
Revenues	0	0	0	128	Revenues	0	0	0	0
Cost of products sold	0	0	0	37	Cost of products sold	0	0	0	0
Gross profit	0	0	0	91	Gross profit	0	0	0	0
SG&A	7	10	22	53	SG&A	2	2	3	3
R&D	41	55	63	80	R&D	13	13	14	15
Operating Income	(55)	(70)	(85)	(43)	Operating income	(19)	(16)	(17)	(18)
Note: EBITDA	-	-	-	-	Note: EBITDA	-	-	-	-
Net interest income / (expense)	(1)	0	1	2	Net interest income / (expense)	0	0	0	0
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Pretax income	-	-	-	-	Pretax income	-	-	-	-
Income taxes	(0)	0	0	0	Income taxes	0	0	0	0
Net income - GAAP	(56)	(69)	(84)	(40)	Net income - GAAP	(19)	(16)	(17)	(18)
Net income - recurring	-	-	-	-	Net income - recurring	-	-	-	-
Diluted shares outstanding	4	23	31	33	Diluted shares outstanding	23	23	23	23
EPS - excluding non-recurring	-	-	-	-	EPS - excluding non-recurring	-	-	-	-
EPS - recurring	(14.42)	(3.01)	(2.68)	(1.21)	EPS - recurring	(0.83)	(0.68)	(0.72)	(0.77)
Balance Sheet and Cash Flow Data	FY11A	FY12E	FY13E	FY14E	Ratio Analysis	FY11A	FY12E	FY13E	FY14E
Cash and cash equivalents	106	37	133	91	Sales growth	-	-	-	-
Accounts receivable	0	0	0	0	EBIT growth	-	-	-	-
Inventories	-	-	-	-	EPS growth	-	-	-	-
Other current assets	-	-	-	-	Gross margin	-	-	-	-
Current assets	-	-	-	-	EBIT margin	-	-	-	-
PP&E	1	1	0	3	EBITDA margin	-	-	-	-
Total assets	122	52	149	108	Tax rate	-	-	-	-
Total debt	-	-	-	-	Net margin	-	-	-	-
Total liabilities	2	2	2	2	Debt / EBITDA	-	-	-	-
Shareholders' equity	120	51	147	107	Debt / Capital (book)	-	-	-	-
Net income (including charges)	-	-	-	-	Return on assets (ROA)	-	-	-	-
D&A	-	-	-	-	Return on equity (ROE)	-	-	-	-
Change in working capital	-	-	-	-	Return on invested capital (ROIC)	-	-	-	-
Other	-	-	-	-	Enterprise value / sales	-	-	-	-
Cash flow from operations	-	-	-	-	Enterprise value / EBITDA	-	-	-	-
Capex	-	-	-	-	Free cash flow yield	-	-	-	-
Free cash flow	-	-	-	-					
Cash flow from investing activities	-	-	-	-					
Cash flow from financing activities	-	-	-	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

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

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

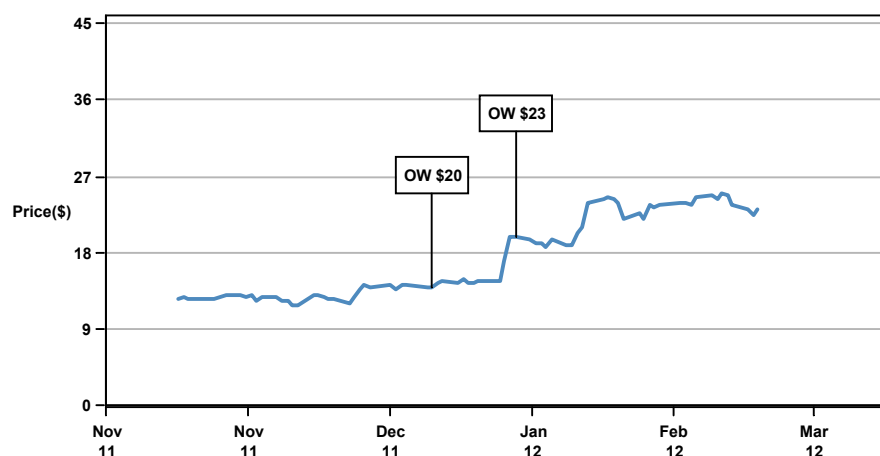
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Clovis Oncology (CLVS, CLVS US) Price Chart



Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jan 03, 2012.

The chart(s) show J.P. Morgan's continuing coverage of the stocks; the current analysts may or may not have covered it over the entire period.

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