Clovis Oncology

Raising Target on Heels of Recent LEAP Update

Overweight

CLVS, CLVS US

Price: $19.71

▲ **Price Target: $23.00**
Previous: $20.00

We reiterate our OW on CLVS and are raising our Dec 2012 PT to $23 from $20 based on the early analysis of patient demographics from the ongoing pivotal LEAP trial that strongly suggests that the addressable market for CO-101 is above our conservative estimate (see our initial Alert). Specifically, CO-101 is being developed for a specific subgroup of pancreatic cancer patients (those with low expression of the hENT1 transporter), which we now assume to be 65% rather than 50% of the population based on LEAP distribution. This was indeed one of three upside levers we previously highlighted, and we have confidence the other two (penetration and pricing) could materialize pending survival data from the study (4Q12e). We believe that CO-101 has the potential to become a standard of care in pancreatic cancer for the substantial hENT1 low group and that CLVS is well positioned with this wholly owned asset.

- **Three upside levers; one down, two to go.** In our initiation report, we highlighted three upside levers to our CO-101 sales estimates including 1) higher hENT1 low distribution, 2) greater penetration, and 3) upside to our pricing estimate. The first of those levers has already been realized, and we are incrementally more comfortable heading into the 4Qe data readout. As for the two additional upside levers, if the LEAP trial shows improved survival in hENT1 low pts, we think there is a good chance that both our penetration and especially pricing estimates will prove to be conservative. Below we provide our updated sensitivity analysis for the remaining upside levers.
- **Re-setting our base case with a higher number of hENT1 low patients.** Our prior assumption was based on historical views that the hENT1 low group represented ~50% of all front-line pancreatic cancer patients. Data from LEAP suggests this subgroup is more like 65%. Combined with three other recent studies with similar results, we think there is enough evidence that our 50% estimate was too conservative. We now comfortably assume that 65% of patients are addressable with CO-101, and the change boosts our 2019 US peak sales estimate from $506M to $658M (keeping all other assumptions unchanged). For the rest of our sensitivity analyses, we now use $658M in 2019 US sales as our base case projection.
- **Upside to pricing is the most obvious next lever.** We currently assume $40K/pt ($10K per month for 4 mos) but the company has more recently been suggesting a potential price of $50-60K/pt. The upside could come from either a higher monthly cost, longer duration based on improved survival, or both. If we assume $60K/pt at launch, then our 2019 US sales forecast goes to $822M from $658M.

Biotechnology

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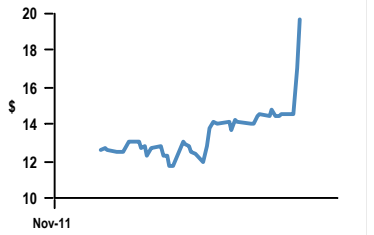
Price Performance



	YTD	1m	3m	12m
Abs	41.0%	65.2%	56.9%	56.9%

SMid Cap Research
THINK BIG, BUY SMALL

Clovis Oncology, Inc. (CLVS;CLVS US)

FYE Dec	2011E	2012E	2013E	2014E
EPS - Recurring ($)				
Q1 (Mar)	(2.15)A	(0.80)	-	-
Q2 (Jun)	(4.38)A	(0.65)	-	-
Q3 (Sep)	(1.38)A	(0.67)	-	-
Q4 (Dec)	(0.63)	(0.53)	-	-
FY	(5.33)	(2.62)	(2.57)	(1.31)

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

Company Data	
Price ($)	19.71
Date Of Price	19 Jan 12
52-week Range ($)	20.00 - 11.45
Mkt Cap ($ mn)	463.27
Fiscal Year End	Dec
Shares O/S (mn)	24
Price Target ($)	23.00
Price Target End Date	31 Dec 12

See page 9 for analyst certification and important disclosures.

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- **Our penetration assumptions could also prove conservative.** If CO-101 does indeed improve survival in the hENT1 low patients, there is little reason why most if not all hENT1 low patients will not see the drug. Our current peak penetration rate in 2019 is 65%. *If* penetration were to reach 80% (which we think is reasonable given there would be a survival benefit and lack of other options) then US sales would jump to $810M from $658M.

- **Incorporating the first lever (hENT1 distribution) into our model bumps our PT to $23.** At this point, we are boosting the hENT1 low distribution estimate to 65% (from 50%) while keeping all other assumptions unchanged. The net effect is an increase in our Dec 2012 target to $23 from $20. This still assumes a 55% probability of approval in 1Q14 with peak sales in the 2019/2020 timeframe, total patient cost of $40K and 65% peak penetration.

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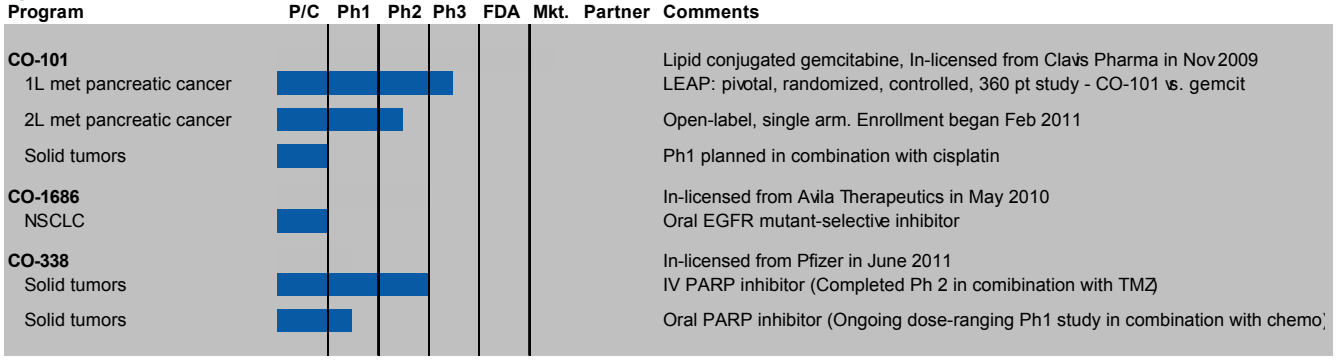
Product Pipeline

Figure 1: CLVS Pipeline



Program	P/C	Ph1	Ph2	Ph3	FDA	Mkt.	Partner	Comments
CO-101								Lipid conjugated gemcitabine, In-licensed from Clavis Pharma in Nov 2009
1L met pancreatic cancer								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								In-licensed from Avila Therapeutics in May 2010
NSCLC								Oral EGFR mutant-selective inhibitor
CO-338								In-licensed from Pfizer in June 2011
Solid tumors								IV PARP inhibitor (Completed Ph 2 in comibination with TMZ)
Solid tumors								Oral PARP inhibitor (Ongoing dose-ranging Ph1 study in combination 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	File an Investigational Drug Application (IND) with FDA	1Q12	Low
	Commence Ph1/2 clinical trial in 1L and 2L lung cancer	1H12	Low
	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	2013	Low

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

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Investment Thesis

We have an Overweight rating on CLVS shares. Our thesis is based primarily 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 $23 from $20. 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%	$ 500	2019
CO-101, EU	55%	$ 300	2020
Valuation methodology	Value	Weighting	Adj. value/ share
P/E 2015	$ -	0%	$ -
Real options scenario analysis	$ 20.86	50%	10.43
Risk adjusted NPV analysis	$ 24.91	50%	12.45
Total			$ 22.89
Catalyst/liquidity discount			0%
YE 2012 Price Target			**$ 23**

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

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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).

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Figure 3: CLVS Income Statement

Fiscal Year Ends Dec 31	2009A	2010A	2011E	1Q12E	2Q12E	3Q12E	4Q12E	2012E	2013E	2014E	2015E	2016E
CO-101:												
CO-101 - US sales										$ 85.2	$ 220.4	$ 410.7
CO-101 - EU sales	-	-	-	-	-	-	-	-	-	17.0	85.6	215.0
Total CO-101 sales	-	-	-	-	-	-	-	-	-	102.2	306.0	625.7
Total Revenue	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 102.2**	**$ 306.0**	**$ 625.7**
COGS & royalties	-	-	-	-	-	-	-	-	-	27.6	76.5	156.4
R&D	1.762	22.3	40.8	12.9	13.2	13.5	13.8	53.4	63.2	71.3	80.4	85.5
Acquired in-process R&D	13.1	12.0	7.0	4.0	-	-	-	4.0	-	-	-	-
SG&A	2.2	4.3	7.0	2.2	2.4	2.6	3.0	10.2	21.9	48.9	71.0	89.8
Total Operating Expenses	**$ 17.1**	**$ 38.6**	**$ 54.7**	**$ 19.1**	**$ 15.6**	**$ 16.1**	**$ 16.8**	**$ 67.7**	**$ 85.1**	**$ 147.8**	**$ 227.9**	**$ 331.7**
Operating income	(17.1)	(38.6)	(54.7)	(19.1)	(15.6)	(16.1)	(16.8)	(67.7)	(85.1)	(45.6)	78.1	294.0
Other income, net	(0.04)	0.795	(0.80)	0.1	0.1	0.1	0.1	0.3	1.8	1.7	2.6	7.1
Pretax Income	(17.1)	(37.830)	(55.5)	(19.0)	(15.5)	(16.1)	(16.7)	(67.3)	(83.3)	(43.9)	80.7	301.1
Income Tax (benefit)	-	-	-	-	-	-	-	-	-	-	8.1	75.3
Net Income	**$ (17.1)**	**$ (38)**	**$ (55.5)**	**$ (19.0)**	**$ (15.5)**	**$ (16.1)**	**$ (16.7)**	**$ (67.3)**	**$ (83.3)**	**$ (43.9)**	**$ 72.6**	**$ 225.8**
Average shares Outstanding	3.2	3.842	10.4	23.7	23.8	24.0	31.5	25.7	32.5	33.5	34.5	35.5
GAAP EPS	**$ (5.30)**	**$ (9.85)**	**$ (5.33)**	**$ (0.80)**	**$ (0.65)**	**$ (0.67)**	**$ (0.53)**	**$ (2.62)**	**$ (2.57)**	**$ (1.31)**	**$ 2.11**	**$ 6.37**
Margin Analysis:												
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	73%	75%	75%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	26%	47%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	24%	36%
Cost Analysis:												
COGS as % of tot. prod. sales				NM	NM	NM	NM	NM	NM	27%	25%	25%
R&D as % of tot. revenue				NM	NM	NM	NM	NM	NM	48%	23%	14%
SG&A as % of tot. revenue				NM	NM	NM	NM	NM	NM	70%	26%	14%
Year-over-year growth:												
Total revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
R&D Expense		1167%	83%	84%	36%	17%	11%	31%	18%	13%	NM	NM
SG&A Expense		95%	62%	56%	41%	45%	45%	46%	114%	124%	NM	NM
Total operating expenses		126%	42%	126%	-15%	21%	16%	24%	26%	74%	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	202%
Tax Rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	10%	25%

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

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Clovis Oncology: Summary of Financials

Income Statement - Annual	FY10A	FY11E	FY12E	FY13E	Income Statement - Quarterly	1Q11A	2Q11A	3Q11A	4Q11E
Revenues	0	0	0	0	Revenues	0A	0A	0A	0
Cost of products sold	0	0	0	0	Cost of products sold	0A	0A	0A	0
Gross profit	0	0	0	0	Gross profit	0A	0A	0A	0
SG&A	4	7	10	22	SG&A	1A	2A	2A	2
R&D	22	41	53	63	R&D	7A	10A	12A	12
Operating Income	(39)	(55)	(68)	(85)	Operating income	(8)A	(18)A	(13)A	(15)
Note: EBITDA	-	-	-	-	Note: EBITDA	-	-	-	-
Net interest income / (expense)	1	(1)	0	2	Net interest income / (expense)	0A	(0)A	(1)A	(0)
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Pretax income	-	-	-	-	Pretax income	-	-	-	-
Income taxes	0	0	0	0	Income taxes	0A	0A	0A	0
Net income - GAAP	(38)	(56)	(67)	(83)	Net income - GAAP	(8)A	(18)A	(14)A	(15)
Net income - recurring	-	-	-	-	Net income - recurring	-	-	-	-
Diluted shares outstanding	4	10	26	32	Diluted shares outstanding	4A	4A	10A	24
EPS - excluding non-recurring	-	-	-	-	EPS - excluding non-recurring	-	-	-	-
EPS - recurring	(9.85)	(5.33)	(2.62)	(2.57)	EPS - recurring	(2.15)A	(4.38)A	(1.38)A	(0.63)

Balance Sheet and Cash Flow Data	FY10A	FY11E	FY12E	FY13E	Ratio Analysis	FY10A	FY11E	FY12E	FY13E
Cash and cash equivalents	11	106	189	106	Sales growth	-	-	-	-
Accounts receivable	0	0	0	0	EBIT growth	-	-	-	-
Inventories	-	-	-	-	EPS growth	-	-	-	-
Other current assets	-	-	-	-					
Current assets	-	-	-	-	Gross margin	-	-	-	-
PP&E	1	1	1	0	EBIT margin	-	-	-	-
Total assets	26	122	204	121	EBITDA margin	-	-	-	-
					Tax rate	-	-	-	-
Total debt	-	-	-	-	Net margin	-	-	-	-
Total liabilities	5	2	2	2					
Shareholders' equity	21	120	203	120	Debt / EBITDA	-	-	-	-
					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									
Cash flow from operations	-	-	-	-	Enterprise value / sales	-	-	-	-
					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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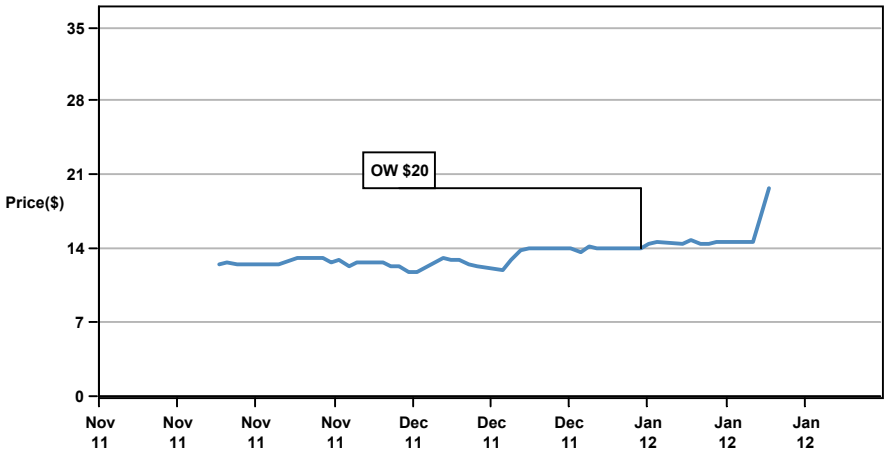
Clovis Oncology (CLVS) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
03-Jan-12	OW	13.98	20.00

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.
J.P. Morgan ratings: OW = Overweight, N= Neutral, UW = Underweight

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	Overweight (buy)	Neutral (hold)	Underweight (sell)
J.P. Morgan Global Equity Research Coverage	47%	42%	12%
IB clients*	52%	45%	36%
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IB clients*	72%	62%	58%

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