Clovis Oncology

3Q12 Snapshot...On the Edge, Ready to LEAP

Overweight

CLVS, CLVS US

Price: $22.37

Price Target: $28.00

We reiterate our OW rating on CLVS following an expectedly quiet 3Q12 report. Management reiterated 2012 cash burn guidance and provided a progress update on the pipeline. Most importantly, the company is still on track to report top-line data from the pivotal LEAP study for CO-101 in pancreatic cancer this quarter.

- **Impact to our thesis: negligible**. We continue to see CLVS as a well positioned small cap biotech with a strong management team overseeing an emerging pipeline of intriguing oncology assets and a solid balance sheet. The key catalyst is upcoming data from the LEAP trial and if positive, this product could quickly become standard of care for roughly two-thirds of pancreatic cancer patients. Our 2013 PT of $28 currently assumes a 55% probability of approval with conservatively skewed commercial scenarios.
- **Key incremental takeaways: LEAP trial data to be released this quarter, pivotal trials for the other programs are not too far off.** While high risk, we remain intrigued by the hENT1 hypothesis as a predictive biomarker for gemcitabine response and optimistic that the LEAP results could show that CO-101 is superior in the roughly two-thirds of pancreatic cancer patients that are hENT1 low. For C0-1686, dose optimization is ongoing (initial data at ASCO) and planned expansion cohorts will enroll 2L pts with the T790M mutation (Tarceva and Iressa failures) and front-line patients with activating EGFR mutations. Based on the data from the expanded cohorts, a pivotal trial may start in 1H14. Rucaparib, a PARP-1/2 inhibitor, is also expected to start a global registrational trial in platinum sensitive ovarian cancer (with germline mutations in BRACA1 and other DNA repair genes) in 2013.
- **3Q results: in-line with expectations.** CLVS reported EPS of ($0.71) which was slightly wider than both JPMe/consensus of ($0.65)/($0.67), but this is not an earnings story. A slightly higher R&D spend drove the variance from our estimates.
- **Estimate revisions.** We have adjusted our model to reflect the Q but remain within unchanged 2012 cash burn guidance of $67-$72M and YE2012 cash of ~$140M.
- **Balance sheet status: good shape.** The company has $163M in cash and no debt which should be sufficient to fund operations through important POC data.
- **Key upcoming event: waiting to LEAP.** The critical event to watch for remains top-line survival data from the pivotal LEAP trial expected in 4Q.

Biotechnology

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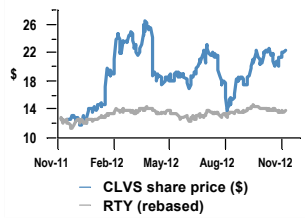
Price Performance



	YTD	1m	3m	12m
Abs	60.0%	0.3%	58.9%	78.1%
Rel	49.4%	3.1%	55.0%	68.1%

Clovis Oncology, Inc. (CLVS;CLVS US)

FYE Dec	2011A	2012E (Prev)	2012E (Curr)	2013E (Prev)	2013E (Curr)
EPS - Recurring ($)					
Q1 (Mar)	(2.14)	(0.86)A	(0.86)A	-	-
Q2 (Jun)	(4.37)	(0.61)A	(0.61)A	-	-
Q3 (Sep)	(1.38)	(0.65)	(0.71)A	-	-
Q4 (Dec)	(1.30)	(0.68)	(0.75)	-	-
FY	(14.42)	(2.77)	(2.91)	(2.41)	(2.37)
Bloomberg EPS FY ($)	(5.14)	-	(2.87)	-	(3.82)

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

Company Data	
Price ($)	22.37
Date Of Price	05 Nov 12
52-week Range ($)	27.55 - 11.45
Mkt Cap ($ mn)	579.52
Fiscal Year End	Dec
Shares O/S (mn)	26
Price Target ($)	28.00
Price Target End Date	31 Dec 13

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								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
NSCLC								Ph1 ongoing in combination with cisplatin; started 3Q12
CO-1686								In-licensed from Avila Therapeutics in May 2010
NSCLC								Oral EGFR mutant-selective inhibitor; started Ph1 in 1Q12
Rucaparib (CO-338)								In-licensed from Pfizer in June 2011
Breast/Ovarian Cancers								Oral PARP inhibitor (monotherapy and 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	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	Dosing data from Ph1 dose escalation of Ph1 trial at ASCO	2H13	Medium
	Data from 1L and 2L (T790m) expansion cohorts in NSCLC	1H14	Medium-High
	Start pivotal trial in 1L and/or 2L NSCLC	1H14	Medium
CO-338	Data from two Ph1 monotherapy (oral) trials in solid tumors	2Q13	Low
	Initiate pivotal trial in platinum sensitive ovarian cancer with BRACA1 and other mutations	2013	Medium

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 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 64% 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 have a 2013 PT of $28 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%		
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	$ 24.81	50%	12.40
Risk adjusted NPV analysis	$ 30.25	50%	15.12
Total			$ 27.53
Catalyst/liquidity discount			0%
YE 2013 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 $17 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.

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 (~$121M at 1Q12) 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	2011A	1Q12A	2Q12A	3Q12A	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	12.6	12.6	15.5	16.2	56.8	57.3	78.4	95.4	125.5
Acquired in-process R&D	13.1	12.0	7.0	4.0	0.3	-	-	4.3	-	-	-	-
SG&A	2.2	4.3	6.9	2.4	2.7	2.8	3.4	11.3	23.3	54.4	82.4	108.8
Total Operating Expenses	**$ 17.1**	**$ 38.6**	**$ 54.6**	**$ 19.0**	**15.5**	**$ 18.220**	**$ 19.6**	**$ 72.3**	**$ 80.6**	**$ 169.8**	**$ 285.0**	**$ 445.4**
Operating income	(17.1)	(38.6)	(54.6)	(19.0)	(15.5)	(18.2)	(19.6)	(72.3)	(80.6)	(42.0)	97.5	336.7
Other income, net	(0.04)	0.8	(0.96)	(0.004)	(0.172)	(0.05)	0.0	(0.2)	(0.2)	3.1	4.7	9.1
Pretax Income	(17.1)	(37.8)	(55.5)	(19.0)	(15.7)	(18.3)	(19.6)	(72.5)	(80.8)	(39.0)	102.2	345.7
Income Tax (benefit)	-	-	(0.027)	(0.0)	0.04	-	-	0.0	-	-	10.2	86.4
Net Income	**$ (17.1)**	**$ (38)**	**$ (55.6)**	**$ (19.0)**	**$ (15.7)**	**$ (18.3)**	**$ (19.6)**	**$ (72.5)**	**$ (80.8)**	**$ (39.0)**	**$ 92.0**	**$ 259.3**
		3.8										
Average shares Outstanding	3.2	3.8	3.9	22.041	25.7	25.9	26.1	24.9	34.1	36.1	38.1	40.1
GAAP EPS	**$ (5.30)**	**$ (9.85)**	**$ (14.42)**	**$ (0.86)**	**$ (0.61)**	**$ (0.71)**	**$ (0.75)**	**$ (2.91)**	**$ (2.37)**	**$ (1.08)**	**$ 2.42**	**$ 6.47**
Margin Analysis:												
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	24%	33%
Cost Analysis:												
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	43%	22%	14%
SG&A as % of tot. revenue				NM	NM	NM	NM	NM	NM	61%	25%	16%
Year-over-year growth:												
Total revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
R&D Expense		1167%	82%	78%	30%	34%	30%	40%	1%	37%	NM	NM
SG&A Expense		95%	59%	75%	59%	58%	67%	64%	107%	133%	NM	NM
Total operating expenses		126%	41%	125%	-15%	37%	35%	33%	11%	111%	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	168%
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	FY11A	FY12E	FY13E	FY14E
Revenues	0	0	0	128
Cost of products sold	0	0	0	37
Gross profit	0	0	0	91
SG&A	7	11	23	54
R&D	41	57	57	78
Operating Income	(55)	(72)	(81)	(42)
Note: EBITDA	-	-	-	-
Net interest income / (expense)	(1)	(0)	(0)	3
Other income / (expense)	-	-	-	-
Pretax income	-	-	-	-
Income taxes	(0)	0	0	0
Net income - GAAP	(56)	(73)	(81)	(39)
Net income - recurring	-	-	-	-
Diluted shares outstanding	4	25	34	36
EPS - excluding non-recurring	-	-	-	-
EPS - recurring	(14.42)	(2.91)	(2.37)	(1.08)

Income Statement - Quarterly	1Q12A	2Q12A	3Q12A	4Q12E
Revenues	0A	0A	0A	0
Cost of products sold	0A	0A	0A	0
Gross profit	0A	0A	0A	0
SG&A	2A	3A	3A	3
R&D	13A	13A	15A	16
Operating income	(19)A	(16)A	(18)A	(20)
Note: EBITDA	-	-	-	-
Net interest income / (expense)	(0)A	(0)A	(0)A	0
Other income / (expense)	-	-	-	-
Pretax income	-	-	-	-
Income taxes	(0)A	0A	0A	0
Net income - GAAP	(19)A	(16)A	(18)A	(20)
Net income - recurring	-	-	-	-
Diluted shares outstanding	22A	26A	26A	26
EPS - excluding non-recurring	-	-	-	-
EPS - recurring	(0.86)A	(0.61)A	(0.71)A	(0.75)

Balance Sheet and Cash Flow Data	FY11A	FY12E	FY13E	FY14E
Cash and cash equivalents	138	134	233	192
Accounts receivable	0	0	0	0
Inventories	-	-	-	-
Other current assets	-	-	-	-
Current assets	-	-	-	-
PP&E	2	1	1	3
Total assets	143	139	238	199
Total debt	-	-	-	-
Total liabilities	12	9	9	9
Shareholders' equity	132	130	229	190
Net income (including charges)	-	-	-	-
D&A	-	-	-	-
Change in working capital	-	-	-	-
Other				
Cash flow from operations	-	-	-	-
Capex	-	-	-	-
Free cash flow	-	-	-	-
Cash flow from investing activities	-	-	-	-
Cash flow from financing activities	-	-	-	-
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Ratio Analysis	FY11A	FY12E	FY13E	FY14E
Sales growth	-	-	-	-
EBIT growth	-	-	-	-
EPS growth	-	-	-	-
Gross margin	-	-	-	-
EBIT margin	-	-	-	-
EBITDA margin	-	-	-	-
Tax rate	-	-	-	-
Net margin	-	-	-	-
Debt / EBITDA	-	-	-	-
Debt / Capital (book)	-	-	-	-
Return on assets (ROA)	-	-	-	-
Return on equity (ROE)	-	-	-	-
Return on invested capital (ROIC)	-	-	-	-
Enterprise value / sales	-	-	-	-
Enterprise value / EBITDA	-	-	-	-
Free cash flow yield	-	-	-	-

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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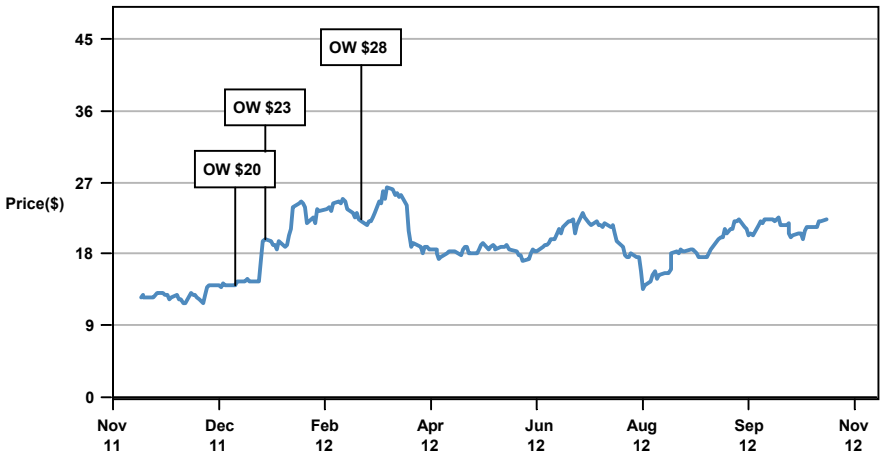
Clovis Oncology (CLVS, CLVS US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
03-Jan-12	OW	13.98	20.00
19-Jan-12	OW	19.90	23.00
08-Mar-12	OW	22.40	28.00

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.
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	Overweight (buy)	Neutral (hold)	Underweight (sell)
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JPMS Equity Research Coverage	42%	48%	10%
IB clients*	69%	61%	53%

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