

## Clovis Oncology

### Model Update on LEAP Miss; Target to \$18

We are updating our model following this morning's announcement that the pivotal LEAP trial (CO-101 in pancreatic cancer) did not meet its primary endpoint (see our initial reaction to the data in this Alert: [A LEAP of Faith Ends with a Thud](#)). The program is highly unlikely to move forward in any indication, and as such, we entirely removed it from our model. The net effect of this is that our 2013 target falls to \$18 from \$28. Nevertheless, as we've previously highlighted, we believe the company's remaining pipeline (EGFR inhibitor CO-1686 and PARP inhibitor rucaparib) warrant a closer look from investors, and we are maintaining our OW rating.

- **We anticipate CO-1686 will be pushed along an aggressive timeline.** We suspect greater focus will shift to 1686 and believe it's noteworthy that this is where mgmt's greatest excitement has been all along. Recall that Ph1 dose escalation data are expected at ASCO 2013 followed by interim data in 2H13 from an expanded cohort using a selected dose in 2L pts (T790M pts that failed Tarceva/Iressa). Pivotal trials in 2L NSCLC are expected to start in 1H14 with a goal to file for approval in 2016. Front-line trials are also planned but on a slightly longer timeline.
- **CO-1686 accounts for ~\$7.50/sh of our valuation.** We currently assign a 20% probability of approval given the lack of clinical data to date. Our average peak revenue scenario is roughly \$800M, which we also believe could be conservative. For context Eli Lilly (Neutral, covered by JPM Analyst Chris Schott) recorded ~\$2.5B in Alimta sales in 2011 for NSCLC (1L/2L) and Roche (OW, covered by JPM Analyst Alexandra Hauber) reported Tarceva sales of roughly \$1.3B, which includes predominant use in NSCLC (with a modest amount in pancreatic cancer). Mgmt still plans to develop and commercialize without a partner, and we assume revenues until at least 2030. Royalties (mid single digits to low teens starting at \$500M in sales) are also due to Avila/Celgene.
- **Rucaparib accounts for a little less than \$5/share.** We also assign a 20% probability of success for "ruca", which is expected to move into pivotal development for ovarian cancer in 2013. Mid double digit royalties are due to PFE (OW, covered by JPM Analyst Chris Schott), and we assume some patent extensions to ensure revenues to 2024 (expiration in 2020 with up to 5 years of extension). We believe that the shorter IP window and smaller ovarian cancer market leaves less upside to our valuation of ruca unless expansion into other indications (ie. breast cancer) are approved.

#### Clovis Oncology, Inc. (CLVS;CLVS US)

FYE Dec	2011A	2012E	2013E (Prev)	2013E (Curr)
EPS - Recurring (\$)				
Q1 (Mar)	(2.14)	(0.86)A	-	-
Q2 (Jun)	(4.37)	(0.61)A	-	-
Q3 (Sep)	(1.38)	(0.71)A	-	-
Q4 (Dec)	(1.30)	(0.75)	-	-
FY	(14.42)	(2.91)	(2.37)	(1.87)
Bloomberg EPS FY (\$)	(5.14)	(2.94)	-	(3.83)

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

#### See page 8 for analyst certification and important disclosures.

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## Overweight

CLVS, CLVS US

Price: \$12.50

▼ **Price Target: \$18.00**

Previous: \$28.00

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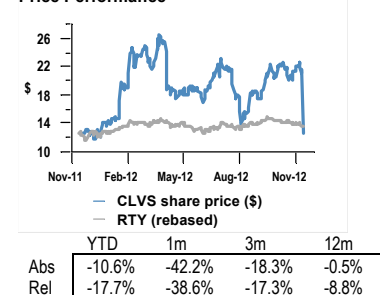
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J.P. Morgan Securities LLC

#### Price Performance



**SMid Cap Research**  
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#### Company Data

Price (\$)	12.50
Date Of Price	12 Nov 12
52-week Range (\$)	27.55 - 11.45
Mkt Cap (\$ mn)	323.83
Fiscal Year End	Dec
Shares O/S (mn)	26
Price Target (\$)	18.00
Price Target End Date	31 Dec 13

- **YE2013 cash contributes the final \$6/sh.** While current cash runway of \$163M (\$6.27/share) is enough to initiate the pivotal trails for CO-1686 and rucaparib, we expect additional financing in 2013 to complete the trials. Accordingly YE13 cash contributes roughly \$6 to our 2013 PT.
- **Changes to estimates.** We have removed all CO-101 revenues and related costs from our model that tweaked our estimates from 2013 on. We also assume some costs will be shifted to support CO-1686 and rucaparib.

## Product Pipeline

Figure 1: CLVS Pipeline

Program	P/C	Ph1	Ph2	Ph3	FDA	Mkt.	Partner	Comments
<b>CO-1686</b> NSCLC								In-licensed from Avila Therapeutics in May 2010 Oral EGFR mutant-selective inhibitor; started Ph1 in 1Q12
<b>Rucaparib (CO-338)</b> Breast/Ovarian Cancers								In-licensed from Pfizer in June 2011 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
<b>CO-1686</b>	Dosing data from Ph1 dose escalation of Ph1 trial at ASCO	2Q13	Medium
	Interim data from 1L and 2L (T790M) expansion cohorts in NSCLC	2H13	Medium-High
	Start pivotal trial in 1L and/or 2L NSCLC	1H14	Medium
	Goal to file (IND to filing in 4 yrs)	2016	High
<b>CO-338</b>	Data from two Ph1 monotherapy (oral) trials in solid tumors	2Q13	Low
	Initiate pivotal trial in platinum sensitive ovarian cancer with BRCA1 and other mutations	2013	Medium

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

## Investment Thesis

We have an Overweight rating on CLVS shares. Our thesis is primarily based on optimism of the early stage pipeline after CO-101 missed the primary survival endpoint in its trial for pancreatic cancer. Despite the disappointment, both rucaparib (ovarian cancer) and CO-1686 (NSCLC) are on fast timelines with pivotal testing planned to begin in 2013 and early 2014. Both assets also remain wholly owned with no plans to bring in a commercial partner at this time. Underpinning the promising pipeline is 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 events for 2013 are early Ph1 data at ASCO and potentially Ph2 proof-of-concept in the second half of the year.

## Valuation

We are lowering our 2013 PT to \$18 from \$28 now that the CO-101 program is no longer continuing. We assume 20% probability of success for both CO-1686 and rucaparib. 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	11%		
<b>Main value driver</b>	Prob of approval	Peak sales est (avg. scenario)	Avg peak yr
CO-1686, WW	20%	\$ 800	2020
Rucaparib, WW	20%	\$ 600	2020
<b>Valuation methodology</b>	Value	Weighting	Adj. value/ share
P/E 2015	\$ -	0%	\$ -
Real options scenario analysis	\$ 19.11	50%	9.55
Risk adjusted NPV analysis	\$ 17.22	50%	8.61
Total			\$ 18.16
Catalyst/liquidity discount			0%
<b>YE 2013 Price Target</b>			<b>\$ 18</b>

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 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 11%, in-line with the company's WACC. CO-1686 and rucaparib each contribute a little under \$8 and \$6 each using this valuation methodology.

### 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-1686, we assume a 20% probability of success with patent protection that extends to 2030. The value contribution of CO-1686 to our analysis is ~\$7.50. We also assume a 20% probability of approval for rucaparib with IP extensions to 2025. Rucaparib accounts for a little over \$4 to our final valuation analysis.

**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 beyond 2016 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.

**Little proof-of-concept data.**

Both early stage pipeline candidates have not yet reported proof-of-concept data in any indication. While we conservatively assume a 20% probability of success, much of the optimism is driven by the company's plans to progress into pivotal trials in the near future.

**CO-1686 and rucaparib are being developed in very competitive markets.**

Both the NSCLC and ovarian/breast cancer markets have many drugs in development as well as standard of care already established. Approval in either of these markets will not necessarily translate into strong adoption as competitive dynamics will have a strong impact.

**Enough cash for now but more capital needed for commercialization.**

Management believes it has sufficient cash (~\$163M at 3Q12) to begin pivotal testing of CO-1686 and rucaparib but will likely require additional capital to complete the registrational programs. We assume a return to the capital markets in 2013.

Figure 3: CLVS Income Statement

Fiscal Year Ends Dec 31	2009A	2010A	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	2013E	2014E	2015E	2016E
CO-1686	-	-	-	-	-	-	-	-	-	-	-	-
Rucaparib	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
COGS & royalties	-	-	-	-	-	-	-	-	-	-	-	-
R&D	1.762	22.3	40.7	12.6	12.6	15.5	16.2	56.8	55.3	78.4	80.4	57.5
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	14.3	17.4	22.4	24.0
<b>Total Operating Expenses</b>	<b>\$ 17.1</b>	<b>\$ 38.6</b>	<b>\$ 54.6</b>	<b>\$ 19.0</b>	<b>\$ 15.5</b>	<b>\$ 18.2</b>	<b>\$ 19.6</b>	<b>\$ 72.3</b>	<b>\$ 69.6</b>	<b>\$ 95.7</b>	<b>\$ 102.9</b>	<b>\$ 81.5</b>
Operating income	(17.1)	(38.6)	(54.6)	(19.0)	(15.5)	(18.2)	(19.6)	(72.3)	(69.6)	(95.7)	(102.9)	(81.5)
Other income, net	(0.04)	0.8	(0.96)	(0.00)	(0.17)	(0.05)	0.0	(0.2)	(0.2)	2.2	2.6	2.2
Pretax Income	(17.1)	(37.8)	(55.5)	(19.0)	(15.7)	(18.3)	(19.6)	(72.5)	(69.8)	(93.5)	(100.3)	(79.3)
Income Tax (benefit)	-	-	(0.03)	(0.0)	0.04	-	-	0.0	-	-	-	-
<b>Net Income</b>	<b>\$ (17.1)</b>	<b>\$ (38)</b>	<b>\$ (55.6)</b>	<b>\$ (19.0)</b>	<b>\$ (15.7)</b>	<b>\$ (18.3)</b>	<b>\$ (19.6)</b>	<b>\$ (72.5)</b>	<b>\$ (69.8)</b>	<b>\$ (93.5)</b>	<b>\$ (100.3)</b>	<b>\$ (79.3)</b>
Average shares Outstanding	3.2	3.8	3.9	22.041	25.7	25.9	26.1	24.9	37.4	39.4	48.9	50.9
<b>GAAP EPS</b>	<b>\$ (5.30)</b>	<b>\$ (9.85)</b>	<b>\$ (14.42)</b>	<b>\$ (0.86)</b>	<b>\$ (0.61)</b>	<b>\$ (0.71)</b>	<b>\$ (0.75)</b>	<b>\$ (2.91)</b>	<b>\$ (1.87)</b>	<b>\$ (2.37)</b>	<b>\$ (2.05)</b>	<b>\$ (1.56)</b>
<i>Margin Analysis:</i>												
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
<i>Cost Analysis:</i>												
COGS as % of tot. prod. sales				NM	NM	NM	NM	NM	NM	NM	NM	NM
R&D as % of tot. revenue				NM	NM	NM	NM	NM	NM	NM	NM	NM
SG&A as % of tot. revenue				NM	NM	NM	NM	NM	NM	NM	NM	NM
<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%	78%	30%	34%	30%	40%	-3%	42%	NM	NM
SG&A Expense		95%	59%	75%	59%	58%	67%	64%	27%	21%	NM	NM
Total operating expenses		126%	41%	125%	-15%	37%	35%	33%	-4%	38%	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	NM
<i>Tax Rate</i>	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM

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

## Clovis Oncology: Summary of Financials

Income Statement - Annual	FY11A	FY12E	FY13E	FY14E	Income Statement - Quarterly	1Q12A	2Q12A	3Q12A	4Q12E
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	7	11	14	17	SG&A	2A	3A	3A	3
R&D	41	57	55	78	R&D	13A	13A	15A	16
Operating Income	(55)	(72)	(70)	(96)	Operating income	(19)A	(16)A	(18)A	(20)
Note: EBITDA	-	-	-	-	Note: EBITDA	-	-	-	-
Net interest income / (expense)	(1)	(0)	(0)	2	Net interest income / (expense)	(0)A	(0)A	(0)A	0
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Pretax income	-	-	-	-	Pretax income	-	-	-	-
Income taxes	(0)	0	0	0	Income taxes	(0)A	0A	0A	0
Net income - GAAP	(56)	(73)	(70)	(94)	Net income - GAAP	(19)A	(16)A	(18)A	(20)
Net income - recurring	-	-	-	-	Net income - recurring	-	-	-	-
Diluted shares outstanding	4	25	37	39	Diluted shares outstanding	22A	26A	26A	26
EPS - excluding non-recurring	-	-	-	-	EPS - excluding non-recurring	-	-	-	-
EPS - recurring	(14.42)	(2.91)	(1.87)	(2.37)	EPS - recurring	(0.86)A	(0.61)A	(0.71)A	(0.75)
Balance Sheet and Cash Flow Data	FY11A	FY12E	FY13E	FY14E	Ratio Analysis	FY11A	FY12E	FY13E	FY14E
Cash and cash equivalents	138	134	204	111	Sales growth	-	-	-	-
Accounts receivable	0	0	0	0	EBIT growth	-	-	-	-
Inventories	-	-	-	-	EPS growth	-	-	-	-
Other current assets	-	-	-	-	Gross margin	-	-	-	-
Current assets	-	-	-	-	EBIT margin	-	-	-	-
PP&E	2	1	1	1	EBITDA margin	-	-	-	-
Total assets	143	139	209	115	Tax rate	-	-	-	-
Total debt	-	-	-	-	Net margin	-	-	-	-
Total liabilities	12	9	9	9	Debt / EBITDA	-	-	-	-
Shareholders' equity	132	130	200	106	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

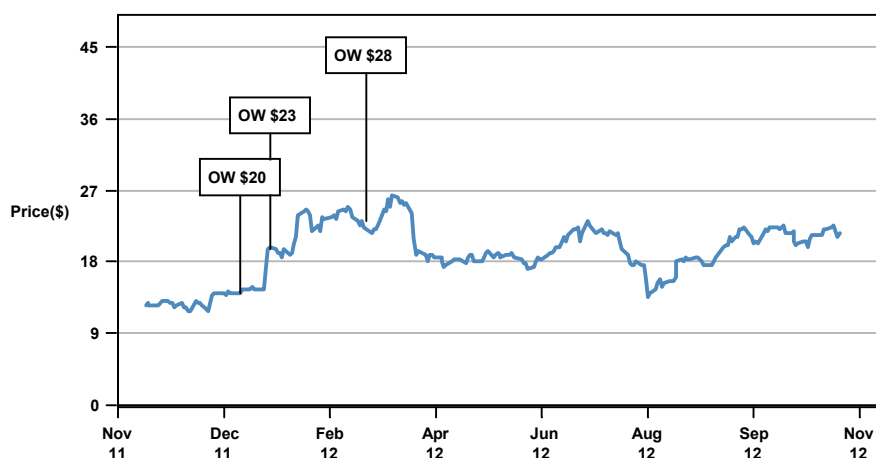
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Clovis Oncology (CLVS, CLVS US) Price Chart



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

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IB clients*	52%	46%	34%
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