

# Clovis Oncology, Inc. (CLVS)

FORECAST INCREASE

# LEAP readout remains on track for Q4'12

- CLVS reported Q2 earnings before the market opened yesterday -Results were uneventful. CLVS posted operating expenses that were essentially in line with CS estimates. CLVS has maintained its guidance on cash burn (\$67-72M) and end-of-year cash balance (\$140M).
- LEAP readout for CO-101 in hENT1-low remains on track. CLVS confirmed that top-line overall survival (OS) data from the pivotal LEAP PIII trial is still expected in Q4'12. As a reminder, this study is intended to show that CO-101 is superior to gemcitabine in hENT1-low patients with metastatic pancreatic cancer in OS. If the LEAP data is positive, then CLVS will likely file for approval in H1'13 and could launch CO-101 in 2014.
- Pipeline updates. CLVS confirmed that the PI/II "proof-of-concept" data for CO-1686 in Tarceva/Iressa-failed T790M+ NSCLC is still expected to read out in H2'13 and reiterated plans to go from IND to NDA for CO-1686 in four years. CLVS also disclosed plans to expand the ongoing PI/II trial evaluating rucaparib in patients with breast and ovarian cancer associated with germline mutations, with the intention to start a pivotal study in 2013. In addition, CLVS has already initiated a two-part PI trial evaluating CO-101 + Cisplatin in NSCLC; we could see early efficacy of this combo in H1'13.
- Valuation. We have updated our model post Q2 earnings, raised pricing for CO-101 to reflect the current pricing environment in oncology, and included royalty payments to Clavis for CO-101. We have kept our TP of \$21 and reiterate our Outperform rating. Our TP is derived using a DCF valuation of CO-101 (only), assuming 50% probability of success, U.S. and EU launch in Q1'14, worldwide peak sales of ~\$900M for CO-101, cash flows until 2021, 10% discount rate, and no terminal value.
- Recent pullback in CLVS stock provides good buying opportunity. We do not see any fundamental reason for the recent weakness in CLVS stock. A 100% probability of success for CO-101 implies a valuation of ~\$36 per share; the current ~\$16 per share implies a ~35% probability of success.

•	•	•	•	
Financial and valuation metrics				
Year	12/11A	12/12E	12/13E	12/14E
EPS (CS adj.) (US\$)	-14.42	-2.91	-3.54	-1.65
Prev. EPS (US\$)	_	-3.62	-3.36	-1.83
P/E (x)	-1.1	-5.4	-4.5	-9.6
P/E rel. (%)	-7.7	-40.5	-37.3	-89.1
Revenue (ÚS\$ m)	_	_	_	135.5
EBITDA (ÚS\$ m)	-54.4	-72.2	-101.7	-51.5
OCFPS (US\$)	-10.33	-2.38	-3.07	-1.11
P/OCF (x)	-1.4	-6.6	-5.1	-14.2
EV/EBITDA (current)	-7.6	-5.7	-4.1	-8.0
Net debt (US\$ m)	-138	-151	-142	-107
ROIC (%)	847.63	615.67	618.88	233.38
Number of shares (m)	26.13	IC (current, US\$ m	1)	-6.44
BV/share (Next Qtr., ÚS\$)	_	EV/IC (x)	,	_
Net debt (Next Qtr., US\$ m)	_	Dividend (Next Qtr., US\$)		_
Net debt/tot cap (Next Qtr., %)	_	Dividend yield (%)	• • •	_
Source: Company data: Credit Suisse estimates				

Rating **OUTPERFORM\*** Price (08 Aug 12, US\$) Target price (US\$) 15.76 21.00<sup>1</sup> 26.50 - 11.70 52-week price range Market cap. (US\$ m) 411.79

\*Stock ratings are relative to the relevant country benchmark.

Enterprise value (US\$ m) <sup>1</sup>Target price is for 12 months.

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On 08/08/12 the S&P 500 INDEX closed at 1402.22

Quarterly EPS	Q1	Q2	Q3	Q4
2011A	_	_	_	-1.30
2012E	-0.86	-0.61	-0.67	-0.79
2013E	_	_	_	

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**Exhibit 1: Changes to CLVS Model** 

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(In thousands except EPS)	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Total Revenues										
Current	0	0	135,513	255,388	382,380	516,810	659,010	789,921	859,521	899,209
Prior	0	0	97,015	182,835	273,749	369,989	471,791	565,511	615,339	643,752
Difference	-	-	40%	40%	40%	40%	40%	40%	40%	40%
Operating Income										
Current	(72,462)	(102,000)	(51,832)	30,771	117,391	202,589	295,236	378,372	416,008	441,512
Prior	(83,040)	(93,500)	(60,149)	31,791	114,975	203,494	292,510	378,893	424,584	457,064
Difference	13%	-9%	14%	-3%	2%	0%	1%	0%	-2%	-3%
Net Income										
Current	(72,811)	(101,858)	(51,725)	30,920	117,671	174,631	236,767	303,532	333,922	354,624
Prior	(82,295)	(92,468)	(59,705)	32,269	116,275	177,782	238,472	310,022	349,324	378,263
Difference	12%	-10%	13%	-4%	1%	-2%	-1%	-2%	-4%	-6%
Diluted EPS (With Options)										
Current	(2.91)	(3.54)	(1.65)	0.96	3.64	5.36	7.19	9.10	9.86	10.29
Prior	(3.62)	(3.36)	(1.83)	0.98	3.47	5.22	6.87	8.72	9.55	10.00
Difference	20%	-5%	10%	-2%	5%	3%	5%	4%	3%	3%
Number of Basic Shares										
Current	25,019	28,767	31,396	32,083	32,312	32,590	32,930	33,345	33,851	34,468
Prior	21,701	26,582	31,481	31,604	31,753	31,936	32,158	32,430	32,761	33,165
Difference	15%	8%	0%	2%	2%	2%	2%	3%	3%	4%
Number of Diluted Shares										
Current	25,019	28,767	31,396	32,083	32,312	32,590	32,930	33,345	33,851	34,468
Prior	22,702	27,531	32,639	33,017	33,477	34,039	34,724	35,560	36,580	37,824
Difference	10%	4%	-4%	-3%	-3%	-4%	-5%	-6%	-7%	-9%

Source: Company data, Credit Suisse estimates



**Exhibit 2: CLVS Quarterly Income Statement 2012** 

Exhibit 2: CLVS Quarterly Income Statement 2012					
Clovis Quarterly Income Statement					
(Dollars in thousands, except share and per share amounts)					
	Q1 2012A	Q2 2012A	Q3 2012E	Q4 2012E	FY 2012E
CO-101	0	0	0	0	0
Revenues	0	0	0	0	0
Cost of Goods Sold	0	0	0	0	0
Gross Profit	0	0	0	0	0
Oneveting expenses:					
Operating expenses: Research and Development	12,562	10 500	14 470	17,374	57,005
· ·	,	12,590	14,479	,	,
General, and Administrative Acquired IPRD	2,425 4,000	2,680 250	2,948 0	3,154 0	11,207 4,250
Total Operating Expenses	18,987	15,520	17,427	20,529	72,462
Total Operating Expenses	10,907	13,320	17,427	20,329	72,402
Operating Income (Loss)	(18,987)	(15,520)	(17,427)	(20,529)	(72,462)
Other Income / (Expense)	(4)	(172)	(100)	(100)	(376)
Pre-Tax Profit/(Loss)	(18,991)	(15,692)	(17,527)	(20,629)	(72,838)
Provision for Income Tax	8	(35)	0	0	(27)
Effective Tax Rate	0%	ò%´	0%	0%	Ò%´
Consolidated Net Income/(Loss)	(18,999)	(15,657)	(17,527)	(20,629)	(72,811)
Basic EPS	(0.86)	(0.61)	(0.67)	(0.79)	(2.91)
Diluted EPS	(0.86)	(0.61)	(0.67)	(0.79)	(2.91)
			` '		` '
Basic Share Outstanding	22,041	25,744	26,126	26,165	25,019
Diluted Share Outstanding	22,041	25,744	26,126	26,165	25,019
PRO-FORMA EARNINGS:					_
Option Expense	900	1,200	1,394	1,642	5,136
Ex-Option Net Income (Loss)	(18,099)	(14,457)	(16,132)	(18,986)	(67,675)
E. Outing FDO Davis	(0.00)	(0.50)	(0.00)	(0.70)	(0.70)
Ex-Option EPS, Basic	(0.82)	(0.56)	(0.62)	(0.73)	(2.70)
Ex-Option EPS, Diluted	(0.82)	(0.56)	(0.62)	(0.73)	(2.70)

Source: Company data, Credit Suisse estimates

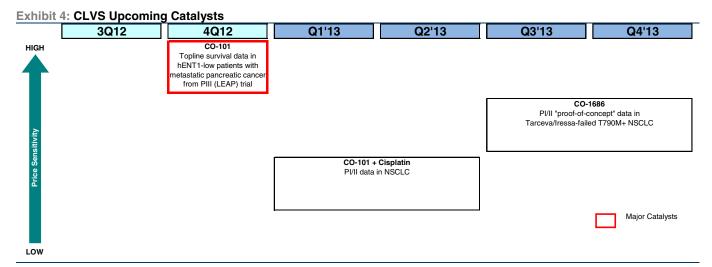


Exhibit 3: CLVS Annual Income Statement 2012

Clovis Annual Income Statement										
(Dollars in thousands, except share and p		5)								
	FY 2012E	FY 2013E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E
CO-101	0	0	135,513	255,388	382,380	516,810	659,010	789,921	859,521	899,209
Revenues:	0	0	135,513	255,388	382,380	516,810	659,010	789,921	859,521	899,209
COGS	0	0	36,589	68,955	107,066	149,875	197,703	244,875	275,047	287,747
Gross Profit	0	0	98,925	186,433	275,314	366,935	461,307	545,045	584,474	611,462
Operating Expenses:		-			-,-	,	, , , , , , , , , , , , , , , , , , , ,		,	
Research and Development	57,005	75,000	83,000	65,000	53,533	50,647	47,449	45,025	43,836	44,061
Selling, General, and Administrative	11,207	27,000	67,757	90,663	104,390	113,698	118,622	121,648	124,631	125,889
Acquired IPRD	4,250	27,000	07,757	90,663	104,390	113,696	110,022	121,046	124,031	125,669
Total Operating Expenses	72,462	102,000	150,757	155,663	157,923	164,345	166,070	166,673	168,466	169,951
Operating Income (Loss)	(72,462)	(102,000)	(51,832)	30,771	117,391	202,589	295,236	378,372	416,008	441,512
Other Income / (Expense)	(376)	142	107	149	280	470	723	1,043	1,395	1,768
(p)	(0.0)							1,010	1,000	1,1.00
Pretax Income (Loss)	(72,838)	(101,858)	(51,725)	30,920	117,671	203,059	295,959	379,415	417,403	443,280
Provision For Income Taxes	(27)	0	0	0	0	28,428	59,192	75,883	83,481	88,656
Effective Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	14.0%	20.0%	20.0%	20.0%	20.0%
Net Income (Loss)	(72,811)	(101,858)	(51,725)	30,920	117,671	174,631	236,767	303,532	333,922	354,624
Basic EPS	(\$2.91)	(\$3.54)	(\$1.65)	\$0.98	\$3.73	\$5.51	\$7.44	\$9.49	\$10.37	\$10.93
Diluted EPS	(\$2.91)	(\$3.54)	(\$1.65)	\$0.96	\$3.64	\$5.36	\$7.19	\$9.10	\$9.86	\$10.29
Basic Shares Outstanding	25,019	28,767	31,396	31,474	31,568	31,683	31,823	31,994	32,203	32,457
Diluted Shares Outstanding	25,019	28,767	31,396	32,083	32,312	32,590	32,930	33,345	33,851	34,468
Cash/Share (Diluted)	\$6.03	\$4.94	\$3.41	\$4.65	\$8.67	\$14.42	\$21.95	\$31.28	\$41.20	\$51.29
PRO-FORMA EARNINGS:										
Option Expense	5,136	8,218	10,684	12,286	13,515	14,461	15,184	15,640	15,952	16,271
Ex-Option Net Income (Loss)	(67,677)	(93,640)	(41,041)	43,206	131,186	187,068	248,915	316,044	346,684	367,641
Ex-Option EPS, Basic	(\$2.71)	(\$3.26)	(\$1.31)	\$1.37	\$4.16	\$5.90	\$7.82	\$9.88	\$10.77	\$11.33
Ex-Option EPS, Diluted	(\$2.71)	(\$3.26)	(\$1.31)	\$1.35	\$4.06	\$5.74	\$7.56	\$9.48	\$10.24	\$10.67

Source: Company data, Credit Suisse estimates





Sources: Clovis Oncology, Credit Suisse

Companies Mentioned (Price as of 08 Aug 12)

Clovis Oncology, Inc. (CLVS, \$15.76, OUTPERFORM, TP \$21.00)

# **Disclosure Appendix**

# **Important Global Disclosures**

I, Ravi Mehrotra PhD, certify that (1) the views expressed in this report accurately reflect my personal views about all of the subject companies and securities and (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

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3-Year Price, Target Price and Rating Change History Chart for CLVS

CLVS	Closing Price	Target Price		Initiation/	07				
Date	(US\$)		Rating	Assumption	27			<b>♦</b> R	
1/5/12	14.5	21	0	Х				1A 1	
3/23/12	26.5		R		23			WV	1
4/27/12	18.24		0		21			21 ■	1
5/10/12	19.03		R		19				· R
6/11/12	18.89		0		17			I ♠I O	Ŋ
6/18/12	19.95		R					·	
					15			<b>.</b> ◆ 0	-
					13			-W/	- 1
					US\$1			1/5/12 ♦	
						3,0810, 51810, 51810, 41810, 881,	9840, 10840, 21840, 318,	In "Buy Bay, Bay, "Bay, "Bay, Say, "Bay, Bay,	
						Closing Price	■ Target Price	♦ Initiation/Assumption ♦ Rating	

 $O=Outperform;\ N=Neutral;\ U=Underperform;\ R=Restricted;\ NR=Not\ Rated;\ NC=Not\ Covered$ 

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Price Target: (12 months) for (CLVS)

Method: Our target price of \$21 for CLVS is derived using a discounted cash flow (DCF) methodology, assuming a discount rate of 10%, annual cash flows on CO-101 until 2021, 50% probability of success for CO-101, and no terminal value.

**Risks:** Key risks to our \$21 target price for CLVS are (1) CO-101 is not approved in the U.S. and/or EU, (2) Launch of CO-101 is significantly delayed, (3) Readout from the pivotal LEAP trial is worse than expected, (4) Clovis fails to raise funds in 2013 to continue operations, (4) Dilution from anticipated financing in 2013 is worse than expected, and (5) CO-101 could underperform our expectations commercially.

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The analyst(s) involved in the preparation of this report have not visited the material operations of the subject company (CLVS) within the past 12 months.

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