November 12, 2012

OUTPERFORM

Reason for report: FLASH NOTE

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HEALTHCARE EQUITY RESEARCH

Key Stats: (NASDAQ:CLVS)

S&P 600 Health Care Index:	790.49
Price:	\$21.49
52 Week High:	\$27.55
52 Week Low:	\$11.45
Shares Outstanding (mil):	26.1
Market Capitalization (mil):	\$560.9

CLOVIS ONCOLOGY, INC.

CO-1686 Worth \$15 in Our DCF; LEAP Failure Not Unexpected; Reiterate OP

- Bottom Line: Based on our previous due diligence leading to a 17% probability of success, we are not surprised that CLVS announced the CO-101 Phase IIb LEAP trial failed to meet primary or secondary end points and showed no difference from gemcitabine. With CO-101 removed from the story, we reiterate that CO-1686 is worth \$15 in our DCF valuation and expect that CLVS shares may trade down beyond this level in an over-reaction as the Street begins to focus more on CO-1686's prospects and value. CO-1686 was always more valuable to us (with 28% chance of success) vs. CO-101 (17%) based on: 1) longer IP (out to 2028); 2) mechanism of action (MOA); 3) key opinion leader (KOL) feedback; and 4) successes in the NSCLC space. We would take advantage of the shares if they trade significantly below \$15.
- Negative CO-101 LEAP Trial: While we were hopeful, based on previous due diligence leading us to estimate a 17% probability of success, we are not surprised the CO-101 Phase IIb LEAP trial failed. Last night, CLVS announced that CO-101 showed no overall survival (OS) benefit vs. gemcitabine in either the primary analysis of hENT1-low patients or in the overall intent-to-treat (ITT) population. The hENT1 biomarker was determined to be not predictive for gemcitabine outcomes. Median survival for each arm in the trial was ~6 months with a hazard ratio (HR) of 0.99. In terms of safety, there were no differences in any subgroup analyses between the arms, and the trial was balanced in terms of key prognostic variables. As a result, CLVS will suspend all further development of CO-101 and focus on its remaining pipeline. Based on a 17% probability of success, CO-101 was worth \$10/share in our \$25 valuation (currently under review).
- CO-1686 for NSCLC worth \$15/share: CO-1686 was always more valuable to us (estimated 28% chance of success) vs. CO-101 (17%) based on: 1) longer IP (out to 2028); 2) MOA; 3) KOL feedback; and 4) successes of other Epidermal Growth Factor Receptor (EGFR) inhibitors in the NSCLC space. Proof of concept (POC) Phase I data remain on track for presentation at ASCO 2013 with CLVS guiding to having early evidence of efficacy in 2H13 vs. our estimate for Phase II data at ASCO-2014. Based on positive POC Phase I data, CLVS also plans to initiate a Phase II in front-line (FL) treatment naïve non small cell lung cancer (NSCLC) patients. Based on available data, CLVS believes it could initiate a pivotal NSCLC trial in 1H14. Based solely on potential in NSCLC patients post Iressa or Tarceva therapy with T790M mutations, we estimate CO-1686 is worth \$15/share in our valuation. Earlier line use would lead to upside to our estimates.
- Reiterate Outperform: We reiterate our OP rating on CLVS and would take advantage of the shares if they trade significantly below \$15 in an over-reaction to the downside based on failure of the CO-101 LEAP trial. CLVS will hold a conference call today at 8:30 A.M. EST (Dial-in: US 866.730.5766, International 857.350.1590; Passcode 99196369) to discuss events.

VALUATION

We calculated a \$25 fair value estimate for CLVS based on a discounted cash flow (DCF) analysis that is probability-adjusted for CO-101 and CO-1686. Our model assumed CO-101 use only in hENT-1 low pancreatic patients and assumes use of CO-1686 for NSCLC with T790M mutations. Earlier line use would lead to upside to our estimates. Our valuation is under review.

RISKS TO VALUATION

An investment in CLVS is fundamentally a high-risk, high-reward investment, in our opinion. CLVS may face significant pipeline clinical, regulatory, and commercial risks. Most important is risk associated with clinical failure of CO-101 in pancreatic cancer and subsequent potential clinical failure of CO-1686 for patients with NSCLC. CO-1686 could also face commercial competition from compounds such as afatinib (Boehringer Ingelheim) and other late stage development-stage candidates. Finally, defense of its Intellectual Property (IP) portfolio is also a risk.

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Disclosures Appendix Analyst Certification

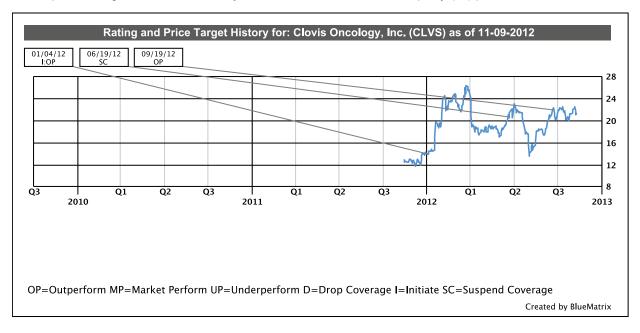
I, Marko Kozul, M.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

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	Distribution of Ratings/Investment Banking Services (IB) as of 09/30/12 IB Serv./Past M					
Rating	Count	Percent	Count	Percent		
BUY [OP]	102	58.30	29	28.40		
HOLD [MP]	73	41.70	3	4.10		
SELL [UP]	0	0.00	0	0.00		

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

From October 1, 2006 through January 8, 2009, the relevant benchmarks for the above definitions were the Russell 2000® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

Definitions of Leerink Swann Ratings prior to October 1, 2006 are shown below:

<u>Outperform (Buy):</u> We expect this stock to outperform its benchmark by more than 10 percentage points over the next 12 months.

<u>Market Perform (Hold/Neutral)</u>: We expect this stock to perform within a range of plus or minus 10 percentage points of its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark by more than 10 percentage points over the next 12 months.

For the purposes of these definitions, the relevant benchmark were the Russell 2000® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Index for issuers with a market capitalization over \$2 billion.



Important Disclosures

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Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to Clovis Oncology, Inc.

Leerink Swann LLC makes a market in Clovis Oncology, Inc.

Leerink Swann LLC has acted as a co-manager for a public offering of Clovis Oncology, Inc. in the past 12 months.

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