Reason for report:

COMPANY UPDATE

Marko Kozul, M.D. (415) 905-7221 Marko.Kozul@Leerink.com

Irene Lau (415) 905-7256 Irene.Lau@Leerink.com



HEALTHCARE EQUITY RESEARCH

(NASDAQ:CLVS)

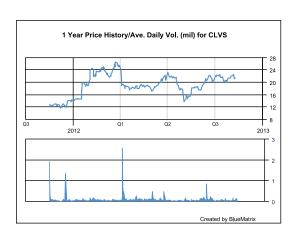
Key Stats:

CLOVIS ONCOLOGY, INC. Reiterate OP & New \$15 DCF based on CO-1686 in NS

Reiterate OP & New \$15 DCF based on CO-1686 in NSCLC; Weakness Overdone

- Bottom Line: We previously estimated CO-1686 worth \$15/share and are not surprised the CO-101 Phase IIb LEAP trial failed based on our diligence leading a 17% probability of success estimate. We also believe CO-1686 has not drawn enough Street attention despite it being a more valuable compound to CLVS. 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; 3) KOL feedback, and; 4) successes and in the NSCLC space. On potential negative CO-101 LEAP data we expected an overreaction to the downside and we recommend taking advantage of weakness below \$15. We reiterate an Outperform (OP) rating and new \$15 DCF.
- CO-1686 for NSCLC worth \$15/share: CO-1686 was always more valuable to us (est. 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. CLVS will also have preliminary 2nd-line T790M Phase II efficacy data in 2H13 with full Phase II data at ASCO-2014. In 1H13, after reaching a Maximum Tolerated Dose (MTD) in the Phase I trial, CLVS also plans to initiate a Phase II front-line (FL) trial in treatment naïve NSCLC patients. In if Phase II 2nd-line NSCLC data are positive, CLVS could initiate a pivotal NSCLC trial in this relapsed setting in 1H14. In 2H14, CLVS would also have preliminary Progression Free Survival (PFS) data from the FL NSCLC trial which if positive could lead to a pivotal trial start in this indication in 2015. 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 (i.e., FL) would lead to upside to our estimates.
- Negative CO-101 LEAP Trial: While we were hopefully, based on previous diligence leading us to estimate a 17% probability of success, we are not surprised the CO-101 Phase IIb LEAP trial failed. CLVS announced 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. We have now removed CO-101 completely from our model while previous and based on a 17% probability of success, it was worth \$10/share in our previous \$25 valuation.
- Reiterate Outperform: We reiterate our OP rating and are introducing our \$15 DCF based valuation based solely on potential for CO-1686. We would take advantage of shares if they trade significantly below \$15 in an over-reaction to the downside based on the failure of the CO-101 LEAP trial.

| ney otats. | (NAODAQ:OLVO) |
|------------------------------|----------------|
| 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 |
| Book Value/Share: | \$6.50 |
| Cash Per Share: | \$6.27 |
| Dividend (ann): | \$0.00 |
| Dividend Yield: | 0.0% |
| Valuation: | \$15 from \$25 |
| | |



| Dec Yr | 1Q | 2Q | 3Q | 4Q | FY Rev | 1Q | 2Q | 3Q | 4Q | FY EPS | P/E |
|-------------|------|------|------|-----|--------|-----------|-----------|-----------|----------|-----------|-----|
| 2011A | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | (\$0.97) | (\$2.15) | (\$1.22) | (\$1.30) | (\$14.42) | NM |
| 2012E | 0.0A | 0.0A | 0.0A | 0.0 | 0.0 | (\$0.86)A | (\$0.61)A | (\$0.71)A | (\$0.77) | (\$2.93) | NM |
| 2013E - New | | | | | 0.0 | | | | | (\$3.37) | NM |
| 2013E - Old | | | | | 0.0 | | | | | (\$5.51) | NM |

Source: Company Information and Leerink Swann LLC Research

GAAP EPS presented; note: quarterly EPS do not sum to annual total due to changes in shares outstanding.



INVESTMENT THESIS

We rate CLVS Outperform. We previously estimated CO-1686 worth \$15/share and are not surprised the CO-101 Phase IIb LEAP trial failed based on our diligence leading a 17% probability of success estimate. We also believe CO-1686 has not drawn enough Street attention despite it being a more valuable compound to CLVS. 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; 3) KOL feedback, and; 4) successes and in the NSCLC space. On potential negative CO-101 LEAP data we expected an overreaction to the downside and we recommend taking advantage of weakness below \$15. We reiterate an Outperform (OP) rating and new \$15 DCF.

Change in Estimates

We adjusted our model based on today's negative outcome on the CO-101LEAP study. As a result, we removed CO-101 potential revenues from our model. We also decreased R&D and G&A projections due to failure of CO-101. Our 2013E R&D expense decreased from \$75M to \$62M. Our 2013E G&A expense decreased from \$35M to \$18M. As a result, our 2013E EPS increased from (\$5.51) to (\$3.37) due to decrease in operating expense projections.

Milestones

| Product: | Partner: | Indication: | Timing: | Milestone: | |
|---------------|-------------|---------------------|-----------|---|--|
| CO-101: | Proprietary | NSCLC | 2013 | Data from Asia Phase I-II study in combo with Cisplatin | |
| CO-1686: | Proprietary | NSCLC | 2013 | Initiate Phase I in Japan (informed dose + tablet) | |
| | | (1st or 2nd line) | 1H13 | Initiate Phase II Front-Line NSCLC trial | |
| | | | ASCO-2013 | Data from Phase I (started March-2012) | |
| | | | 2H13 | Data from Phase II (started March-2012) | |
| | | | 1H14 | Pivotal trial start in 2 nd -line NSCLC | |
| | | | 2H14 | Data (PFS) from Front-Line NSCLC trial | |
| | | | 2015 | Initiate Front-Line pivotal NSCLC trial | |
| | | | 2016 | NDA (goal 4 years from IND) | |
| | | | 2017 | FDA Approval and Launch (in T790M patients) | |
| Rucaparib | Proprietary | Breast Cancer (BC), | 2013 | Data from Phase I-II monotherapy trial | |
| (CO-338): | | Ovarian Cancer (OC) | | Initiate global registration trial in plat-sensitive OC | |
| KIT Inhibitor | ARRY | GIST | TBD | Identify clinical candidate | |

Source: Company Reports, Leerink Swann LLC estimates

VALUATION

Our New \$15 Valuation (\$25 previously): We calculate a \$15 fair value estimate for CLVS based on a discounted cash flow (DCF) analysis that is probability adjusted for CO-1686. If successful, our model assumes CO-1686 for NSCLC with T790M mutations. Earlier line use would lead to upside to our estimates.

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 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.

| CLVS ANNUAL P&L (\$M, except per share data) | | | | | | | | | | | | |
|---|-----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| | 2011A | 1Q12A | 2Q12A | 3Q12A | 4Q12E | 2012E | 2013E | 2014E | 2015E | 2016E | 2017E | 2018E |
| Total CO-1686 Sales | | | | | | | | | | | \$212 | \$467 |
| Probability of Success | | | | | | 29% | 29% | 29% | 29% | 29% | 29% | 29% |
| CO-1686 Probability Adjusted U.S. sales (\$M) | | | | | | \$0 | \$0 | \$0 | \$0 | \$0 | \$62 | \$136 |
| Other Revenue | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 | \$0.0 |
| Total Revenue (\$M) | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$62 | \$136 |
| Y/Y | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | #DIV/0! | 120% |
| cogs | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$14 | \$33 |
| % Sales | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | 18% | 20% | 22% | 24% |
| R&D | 41 | 13 | 13 | 15 | 17 | 58 | 62 | 70 | 80 | 90 | 100 | 100 |
| % Rev | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M |
| G&A | 7 | 2 | 3 | 3 | 4 | 12 | 18 | 22 | 26 | 32 | 45 | 50 |
| % Rev | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | 37% |
| Amortization of intangible asset | | | | | | | | | | | | |
| Acquired in-process R&D/milestones | 7 | 4 | 0 | - | - | 4 | 30 | 40 | - | 50 | 50 | 50 |
| Operating Expenses | 55 | 19 | 16 | 18 | 21 | 74 | 110 | 132 | 106 | 172 | 209 | 233 |
| Interest/other income | (1) | (0) | (0) | (0) | 1 | 1 | 3 | 6 | 7 | 9 | 15 | 20 |
| Interest rate | 1% | | | | | 2% | 3% | 3% | 3% | 3% | 3% | 3% |
| Pretax income/(loss) | (56) | (19) | (16) | (18) | (20) | (73) | (107) | (126) | (99) | (163) | (132) | (77) |
| Accretion of preferred stock | | | | | | | | | | | | |
| Taxes | 0 | 0 | (0) | - | - | - | - | - | - | - | - | - |
| Rate | 0% | | | | | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Net income(/loss) | (\$56) | (\$19) | (\$16) | (\$18) | (\$20) | (\$73) | (\$107) | (\$126) | (\$99) | (\$163) | (\$132) | (\$77) |
| EPS/(Loss per share) | (\$14.42) | (\$0.86) | (\$0.61) | (\$0.71) | (\$0.77) | (\$2.93) | (\$3.37) | (\$3.34) | (\$2.04) | (\$2.87) | (\$2.31) | (\$1.34) |
| Y/Y | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | N/M | -19% | -42% |
| Shares | 4 | 22 | 26 | 26 | 26 | 25 | 32 | 38 | 48 | 57 | 57 | 57 |

Source: Company reports and Leerink Swann estimates

| DCF Calculation | |
|-----------------------|-------|
| Discount Rate | 10% |
| Terminal Growth Rate | 1% |
| NPV of Free Cash Flow | \$320 |
| Valuation / Share | \$15 |

Source: Leerink Swann estimates

| CLOVIS DCF VALUATION ANALYSIS | | | | | | | | |
|-------------------------------|---------------|------------------------------|------|------|------|------|--|--|
| | Discount Rate | | | | | | | |
| | <u></u> | 9.5% 10.0% 10.5% 11.0% 11.5% | | | | | | |
| | 0.0% | \$15 | \$13 | \$12 | \$10 | \$9 | | |
| le e | 0.5% | \$16 | \$14 | \$12 | \$11 | \$9 | | |
| Terminal Multiple | 1.0% | \$17 | \$15 | \$13 | \$11 | \$10 | | |
| ĒĒ | 1.5% | \$18 | \$15 | \$13 | \$12 | \$10 | | |
| | 2.0% | \$19 | \$16 | \$14 | \$12 | \$11 | | |

Source: Leerink Swann estimates



Disclosures Appendix Analyst Certification

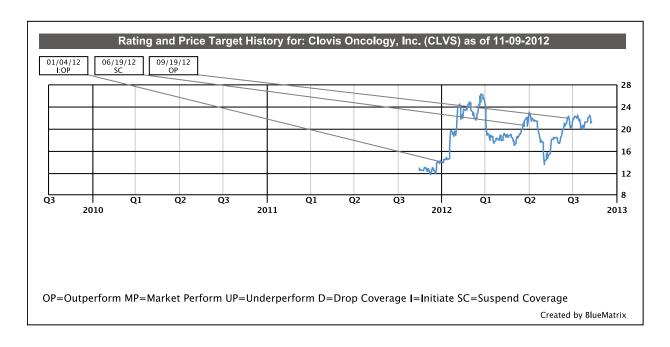
I, Marko Kozul, M.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

Our New \$15 Valuation (\$25 previously): We calculate a \$15 fair value estimate for CLVS based on a discounted cash flow (DCF) analysis that is probability adjusted for CO-1686. If successful, our model assumes CO-1686 for NSCLC with T790M mutations. Earlier line use would lead to upside to our estimates.

Risks to Valuation

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| | Distribution of Ratings/Investment Bank | ing Services (IB | , | erv./Past 12 Mos. |
|-----------------------|---|------------------|---------|----------------------|
| Rating | Count | Percent | Count | Percent |
| BUY [OP] HOLD [MP] | 102 73 | 58.30 41.70 | 29 3 | 28.40 4.10 |
| SELL [UP] | 0 | 0.00 | Ŏ | 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:

Outperform (Buy): 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.



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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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| Leerink Swann LLC Equity Research | | | | | | | | |
|---|--|----------------------------------|---|--|--|--|--|--|
| | Leerink Swann LLC | Equity Research | | | | | | |
| Director of Equity Decemb | John I. Cullivan CEA | (647) 040 4075 | iaha aulliyaa @laariak aam | | | | | |
| Director of Equity Research | John L. Sullivan, CFA | (617) 918-4875 | john.sullivan@leerink.com | | | | | |
| Associate Director of Research | Alice C. Avanian, CFA | (617) 918-4544 | alice.avanian@leerink.com | | | | | |
| Healthcare Strategy | John L. Sullivan, CFA | (617) 918-4875 | john.sullivan@leerink.com | | | | | |
| | Alice C. Avanian, CFA | (617) 918-4544 | alice.avanian@leerink.com | | | | | |
| | | | | | | | | |
| Biotechnology | Howard Liang, Ph.D. | (617) 918-4857 | howard.liang@leerink.com | | | | | |
| | Joseph P. Schwartz | (617) 918-4575 | joseph.schwartz@leerink.com | | | | | |
| | Marko Kozul, M.D. | (415) 905-7221 | marko.kozul@leerink.com | | | | | |
| | Michael Schmidt, Ph.D. | (617) 918-4588 | michael.schmidt@leerink.com | | | | | |
| | Irene Lau | (415) 905-7256 | Irene.lau@leerink.com | | | | | |
| | Gena Wang, Ph.D. | (212) 277-6073 | gena.wang@leerink.com | | | | | |
| | | | | | | | | |
| Life Science Tools & | Dan Leonard | (212) 277-6116 | dan.leonard@leerink.com | | | | | |
| Diagnostics | John L. Sullivan, CFA | (617) 918-4875 | john.sullivan@leerink.com | | | | | |
| | | (0.17) 0.10 1011 | | | | | | |
| Pharmaceuticals/Major | Seamus Fernandez | (617) 918-4011 | seamus.fernandez@leerink.com | | | | | |
| | Kathryn Alexander | (617) 918-4568 | kathryn.alexander@leerink.com | | | | | |
| | Swati Kumar | (617) 918-4576 | swati.kumar@leerink.com | | | | | |
| Specialty Pharmaceuticals, | Jason M. Gerberry, JD | (617) 918-4549 | jason.gerberry@leerink.com | | | | | |
| Generics | | | | | | | | |
| Madical Davison Cardialogy 8 | Daniella Antalffy | (212) 277 6044 | denialle entelffy@learink.com | | | | | |
| Medical Devices, Cardiology & Orthopedics | Danielle Antalffy Richard Newitter | (212) 277-6044 (212) 277-6088 | danielle.antalffy@leerink.com richard.newitter@leerink.com | | | | | |
| | Robert Marcus | (212) 277-6084 | robert.marcus@leerink.com | | | | | |
| | Kathleen McGrath | (212) 277-6020 | kathleen.mcgrath@leerink.com | | | | | |
| | Talling of the Country of the Countr | (= :=) =: : 00=0 | | | | | | |
| Healthcare Services | Jason Gurda, CFA | (212) 277-6023 | jason.gurda@leerink.com | | | | | |
| | Jason Twizell | (212) 277-6049 | jason.twizell@leerink.com | | | | | |
| | George Villarina | (212) 277-6012 | george.villarina@leerink.com | | | | | |
| Healthcare Technology | David Larsen, CFA | (617) 918-4502 | david.larsen@leerink.com | | | | | |
| & Distribution | Christopher Abbott | (617) 918-4010 | chris.abbott@leerink.com | | | | | |
| | • | , , | | | | | | |
| Sr. Editor/Supervisory Analyst | Mary Ellen Eagan, CFA | (617) 918-4837 | maryellen.eagan@leerink.com | | | | | |
| Supervisory Analysts | Robert Egan | | bob.egan@leerink.com | | | | | |
| - | Amy N. Sonne | | amy.sonne@leerink.com | | | | | |
| | | | | | | | | |

New York 1251 Avenue of Americas, 22nd Floor New York, NY 10020 (888) 347-2342 Boston One Federal Street, 37th Floor Boston, MA 02110 (800) 808-7525

San Francisco 201 Spear Street, 16th Floor San Francisco, CA 94105 (800) 778-1164