

Clovis Oncology

A LEAP of Faith Ends with a Thud - ALERT

This morning, CLVS announced disappointing news that the LEAP trial for CO-101 in pancreatic cancer did not meet its primary endpoint of overall survival. We thought the outcome could go either way heading into the data (55% probability in our model), as this Phase 2 trial was essentially a proof-of-concept experiment wrapped inside of a pivotal study, and unfortunately the concept didn't pan out. We see no path forward for CO-101 in any indication. However, while this asset was the focus of investors over the past year, CLVS still has a noteworthy pipeline, in our view. So while we expect shares to take a significant hit today, once the dust settles, we see this as an opportunity to own the stock for the two remaining oncology candidates. Maintain OW.

- **CO-101 misses survival endpoint.** The LEAP trial enrolled ~360 pts with advanced pancreatic cancer and was evaluating whether CO-101 extended survival in patients who were hENT1 low. Recall the theory here was that standard of care, gemcitabine, needed to enter tumor cells via the transporter hENT1 and that CO-101 (lipid conjugated gemcitabine) got around this. Unfortunately a hazard ratio (HR) of 0.99 indicates that survival in the CO-101 arm was essentially the same as the gemcitabine arm. The median survival of 6 mos was also within expectations for gemcitabine from historical experience.
- **CO-1686 now becomes the near-term value driver, with initial data expected at ASCO 2013.** CO-1686 has similarities with ARIA's AP26113, at least on the EGFR side (inhibits mutant forms but spares wild type) and is being developed with a companion diagnostic. Dose optimization is ongoing (initial data at ASCO 2013) in a Ph1/2 trial 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 provides further backup and could also have data at ASCO.** Rucaparib is a PARP-1/2 inhibitor that has also been compared to BMRN's PARP inhibitor, BMN-673, for which promising data is expected before year end. Ph1/2 proof-of-concept is ongoing, with data also expected at ASCO 2013. A global registrational trial in platinum sensitive ovarian cancer (with germline mutations in BRCA1 and other DNA repair genes) is planned to start in 2013.
- **Balance Sheet.** As of 3Q, the company has \$163M in cash or a little over \$6/sh with no debt.
- **Conference call at 8:30 AM ET.** Mgmt will host a conference call this morning that can be accessed with the following dial-in info: US 866.730.5766, international 857.350.1590, passcode 99196369.

Overweight

CLVS, CLVS US

Price: \$21.49

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Biotechnology

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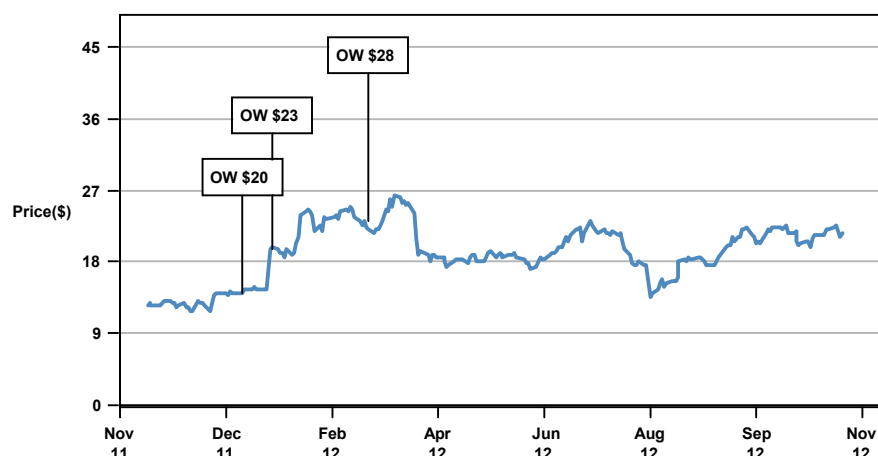
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Clovis Oncology (CLVS, CLVS US) Price Chart



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

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