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Anthera Pharmaceuticals (ANTH – OUTPERFORM): Phase IIb A-623 Trial to Restart in January, Six-Months Ahead of Expectations

Price: $4.85 (Close 12/14/10) **Fair Value: $8**

- **Enrollment in A-623 trial had been halted due to problem with cracked vials.** Recall that Anthera announced on November 16, 2010 that the PEARL-SC Phase IIb study of A-623 in Lupus was placed on hold after a study investigator discovered a single cracked vial of drug, which upon further inspection was found to be a more widespread issue. While the vial problem did not lead to any reported adverse events, enrollment in the trial was halted in order to investigate the issue. At the time, Anthera noted that a worst case scenario requiring the manufacturing of new drug would result in the trial being restarted in Q3:2011. As discussed below, Anthera announced today that it has resolved the vial problem and expects to restart enrollment next month.
- **On track to restart enrollment in January.** After an extensive review of the cracked vials, the company determined that the fractures occurred at temperatures substantially colder than -20C, such as the dry-ice lined containers used to send the drug to clinical sites. Future shipments will be made under different conditions in order to avoid cracking. Anthera expects to restart enrollment in the PEARL-SC study next month, although the 12 patients enrolled in the trial prior to the halt will be excluded. Meanwhile, the 39 patients who were screened but not yet randomized may be eligible for inclusion. Despite the one-to-two month delay, management now expects to meet its initial timeline of releasing interim B-Cell biomarker data in Q2:11 and top-line results in H1:2012, based on the current expectation that the trial will enroll more rapidly than initially thought. We are encouraged that Anthera was able to rectify the problem quickly, particularly as we previously believed it might take until early Q3:2011 to restart the trial.
- **Supply deal signed for large scale Phase 3 and pre-commercial supply of A-**623. Anthera also announced that the company has signed a deal with the Merck BioManufacturing Network in the UK to manufacture the large supply of A-623 required for Phase 3 studies and in preparation for commercial launch. Anthera had previously guided to announce a manufacturing supplier by the end of 2010 and we are encouraged that the company was able to meet this goal.
- **Reiterate OUTPERFORM rating and fair value of $8 per share.** Our fair value is calculated using a sum-of-parts analysis, applying a 30% annual discount to our peak annual sales estimate for A-002 in ACS, and A-623 in SLE, incorporating a 1-10 multiple for each based on stage of clinical risk.
- **Upcoming milestones should provide initial look into Anthera's key clinical trials.** Upcoming catalysts for ANTH include: (1) interim biomarker data from the Phase III data for A-002 in Q1:11; (2) B-cell biomarker data for PEARL-SC in Q2:11; (3) initiation of a Phase IIb program of A-001 in Acute Chest Syndrome in H1:11; and (4) DSMB meeting for VISTA-16 on February 1, 2011 (this will likely be a go/no-go decision with few details expected).
- **Risks to the attainment of our fair value include risks that**: Anthera's products obtain disappointing clinical trial results and or fail to obtain regulatory approval; Physicians are not be impressed with the products' clinical profiles; Anthera or a partner fails to effectively commercialize Anthera's drug candidates; third-party patents prevent the timely commercialization; superior clinical results are obtained by a third-party competitor; Anthera is unable to raise needed capital.

objectivity of this report. Investors should consider this report as only a single factor in making their investment decision.

ANALYST CERTIFICATION

I, Duane Nash, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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NEUTRAL – Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

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