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Duane Nash, MD JD MBA (415) 263-6650 **Akiva Felt (415) 263-6648**

Anthera Pharmaceuticals (ANTH - OUTPERFORM): Expect A-002 VISTA-16 Interim Data in 4-6 Weeks

Price: $5.37 **Fair Value Estimate: $8**

- **Anthera expects to report findings of the VISTA-16 biomarker analysis in the next 4-6 weeks; resulting outcome will be a go/no-go decision for continuing enrollment.** Anthera held a conference call yesterday to discuss the mechanics of the upcoming biomarker analysis for the Phase III VISTA-16 study of A-002 (varespladib) in Acute Coronary Syndrome (ACS). The interim analysis will examine 4 biomarkers and 1 composite endpoint, comparing A-002 vs. placebo: (1) sPLA2, (2) LDL-C, (3) CRP, (4) IL-6, and (5) a composite endpoint of the percentage of patients with LDL-C < 70 mg/dl and CRP < 1 mg/ml. In order for enrollment to continue, all 5 endpoints must demonstrate a positive trend in favor of A-002, with statistical significance ($p<0.05$) required for sPLA2, LDL-C and the composite endpoint, as well as statistical significance for either IL-6 or CRP. If the above pre-specified endpoints are not met, the VISTA-16 study will be terminated. Should the biomarker analysis succeed, Anthera will be notified that the trial should continue as planned, but management will not be provided with specific data regarding the endpoints. In sum, the outcome of this analysis will be a binary go or no-go decision regarding the trial's continuation.

- **We are optimistic that the biomarker hurdle will be cleared and remove a significant overhang to the A-002 program.** Although the biomarker analysis appears daunting at first blush (all markers must show a positive trend, 4/5 must reach statistical significance) we believe that the results seen in the Phase IIb FRANCIS study bode well for VISTA-16 meeting the biomarker endpoints. As discussed in this note, the FRANCIS study demonstrated a statistically significant reduction in 4/5 of the endpoints under consideration for the VISTA-16 interim analysis, with fewer patients (n=625 vs. n=1,000) and less powering.

- **Upcoming catalysts include interim looks at A-002 and A-623 trials.** We anticipate the following near term milestones for ANTH: (1) interim biomarker data from the A-002 Phase III VISTA-16 trial in late March or early April 2011; (2) interim B-cell reduction data in A-623 Phase IIb trial in Q2:11; (3) initiation of a Phase IIb program of A-001 in Acute Chest Syndrome currently anticipated in H2:11; (4) interim efficacy analysis of VISTA-16 in late Q3:11 or early Q4:11; and (5) March 10 PDUFA date for HGSI's Benlysta in Lupus.

- **Reiterate OUTPERFORM rating and fair value of $8 per share.** Our fair value of $8 per share is calculated using a sum-of-parts analysis of Anthera's clinical pipeline. A 30% annual discount is applied to our estimate of peak annual sales for each clinical stage product/indication and a 1-10x multiple is applied to our current value based on stage of clinical development to reflect risk. While we list fair value estimates for each product in the pipeline, our overall fair value for the stock only includes fair value estimates for product candidates/indications which, in our view, have at least positive clinical proof-of-concept data. As a result, this fair value does not yet include A-002 in stable coronary artery disease, or A-001 and A-003 in any indications. Because Anthera is not yet profitable, we do not include the company's $63 million in cash in our valuation on the assumption that these funds will be used for continued clinical development. We currently estimate Anthera's cash runway through YE:2011, which is well past the upcoming interim analyses for A-002 and A-623 anticipated in H1:2011.

- **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.

PRIOR PHASE IIB FRANCIS STUDY OF A-002 GUIDES EXPECTATIONS FOR BIOMARKER DATA

Recall that in July 2008, Anthera initiated a Phase IIb study (FRANCIS) designed to evaluate the safety and efficacy of A-002 (varespladib) when co-administered with 80 mg of atorvastatin in patients with high levels of inflammation and dyslipidemia. The study was structured as a randomized, double-blind, placebo-controlled trial, and enrolled 625 acute coronary syndrome patients across 35 centers in three countries.

Because of the FRANCIS study's similarity to the ongoing VISTA-16 study, believe that the former provides a valuable preview of what we can expect from the interim biomarker data:

Table 1: Trial design of VISTA-16 and FRANCIS studies

	VISTA-16	FRANCIS
Phase	III	IIB
Number of patients	6,500 (1,000 for biomarker analysis)	625
Enrollment Criteria	• Diagnosis of UA, NSTEMI or STEMI • Less than 96 hours since hospital admission or 96 hours since event diagnosis	
	• Any one of the following risk factors: diabetes, metabolic syndrome, history of stroke or TIA, history of peripheral vascular disease, previous CABG, previous MI, previous coronary revascularization	• Presence of metabolic syndrome • Any one of the following risk factors: diabetes, BMI ≥ 25 kg/m2, CRP ≥ 2 mg/L (NSTEMI/STEMI) or CRP ≥ 3 mg/L (UA)
Treatment	20, 40 or 80 mg/day atorvastatin (physician's choice) +/- 500 mg/day varespladib for 16 weeks	80 mg/day atorvastatin +/- 500 mg/day varespladib for 24 weeks
Primary Endpoint	Reduction in MACE at 16 weeks	Reduction in LDL-C at 8 weeks
Secondary Biomarker Endpoints	Reduction in LDL-C, CRP, sPLA2, and IL-6; percentage of patients with LCL-C < 70 mg/dL and CRP < 1 mg/L	Reduction in LDL-C, CRP, and sPLA2; percentage of patients with LCL-C < 70 mg/dL and CRP < 1 mg/L

Source: Rosenson RS, JACC 2010; clinicaltrials.gov

As shown above the design of the two trials very similar, with the most notable differences being VISTA-16's larger enrollment size as well as its allowance for 3 different doses of atorvastatin (20, 40 or 80 mg/day at the physician's discretion). Of note, Anthera believes that the lower allowable doses of atorvastatin in VISTA-16 may magnify the effect of varespladib as the contribution from the statin will be minimized. We find this hypothesis to be plausible and but do not expect any such benefit to make-or-break the trial.

Table 2: Results of FRANCIS biomarker analysis

Biomarker or Composite Endpoint	P-value at week #				
	2	4	8	16	24
sPLA2	p<0.0001	p<0.0001	p<0.0001	p<0.0001	p<0.0001
LDL-C	p=0.0024	p=0.0011	p=0.0021	p=0.0071	p=0.0269
CRP	p=0.1791	p=0.3076	p=0.0913	p=0.0021	p=0.0185
IL-6	p=0.18	p=0.69	p=0.90	n/a	n/a
LCL-C < 70 mg/dL and CRP < 1 mg/L	p=0.3581	p=0.0207	p=0.6128	p=0.0130	p=0.0117

Source: Rosenson RS, JACC 2010; Company reports;

Recall that in order for the ongoing VISTA-16 trial to continue, all 5 endpoints must demonstrate a positive trend in favor of A-002, with statistical significance (p<0.05) required for sPLA2, LDL-C and the composite endpoint, as well as statistical significance for either IL-6 or CRP. Fortunately, as shown above the FRANCIS study easily achieved statistical significance in 4 of the 5 endpoints being examined in the biomarker study, with the exception of IL-6 (which did demonstrate a positive trend).

We believe that the larger sample size in VISTA-16, as well as the ability to measure IL-6 as early as 96 hours, should significantly improve the chance that this endpoint will be met with statistical significance. Indeed, in order for the biomarker results to be deemed successful, statistical significance is required only at one point in time for each biomarker. Considering that three of the four consistently achieved statistical significance throughout multiple measurements, we find it very unlikely (<20% chance) that the biomarker results will not be favorable.

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Company	Disclosure
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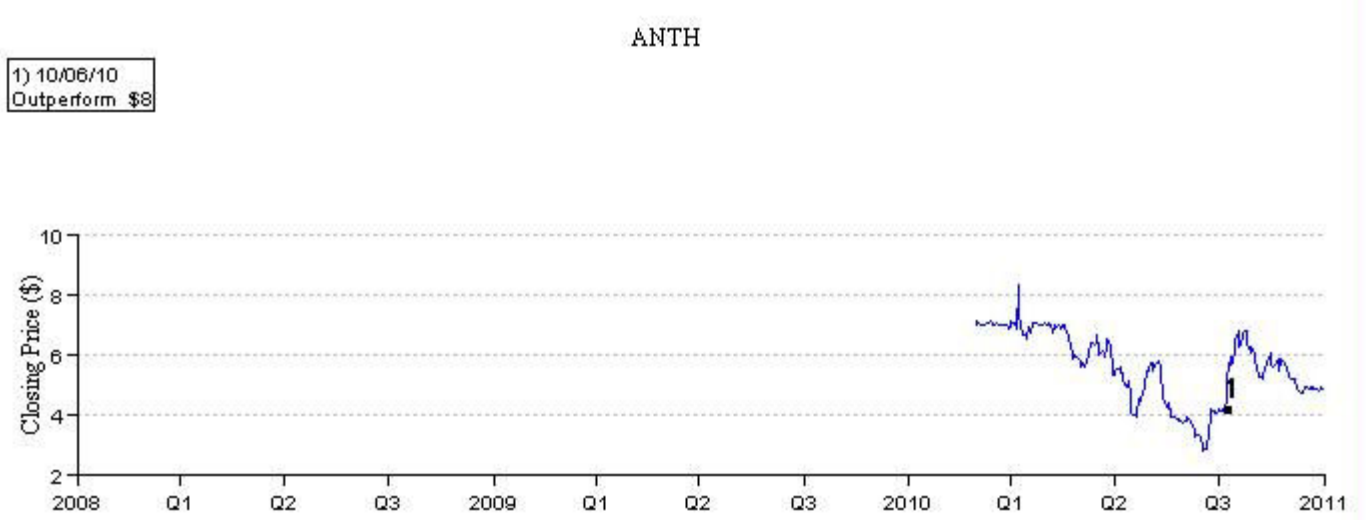

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EQUITY RESEARCH DEPARTMENT
(213) 688-4529

DIRECTOR OF RESEARCH
Mark D. Benson (213) 688-4435

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Rommel T. Dionisio (212) 938-9934
Kurt M. Frederick, CFA CPA (213) 688-4459

E-Commerce
Edward Woo, CFA (213) 688-4382
Nick McKay (213) 688-4343

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Nick McKay (213) 688-4343

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John Garrett (213) 688-4523

Camilo Lyon (212) 938-9924
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Specialty Retail: Sporting Goods
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Gabriella Santaniello (213) 688-4557

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Suhail Chandy (213) 688-4380

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Christopher N. Marai, Ph.D. (415) 274-6861

Y. Katherine Xu, Ph.D. (212) 938-9955

Cardiovascular, Devices and Regenerative
Duane Nash, MD JD MBA (415) 263-6650
Akiva Felt (415) 263-6648

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