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#### Reason for Report:

**Earnings Announcement** 

Changes	Previous	Current						
Rating		Overweight						
Price Tgt		\$12.00						
FY10E Rev (mil)		\$0.0						
FY11E Rev (mil)		\$0.0						
FY10E EPS	(\$1.57)	(\$1.76)						
FY11E EPS	(\$2.01)	(\$1.97)						
Price:		\$7.00						
52 Week High:		\$8.55						
52 Week Low:	\$6.50							
12-Month Price Tar	\$12.00							
Proj EV of \$288M + mid'11E cash of \$4M								
Shares Out (mil):	23.8							
Includes impact of recent IPO								
Market Cap. (mil):	\$166.6							
Avg Daily Vol (000):		NM						
Book Value/Share:		\$2.22						
Cash Per Share:		\$2.55						
Debt to Total Capita	al:	0%						
Est LT EPS Growth	:	NA						
P/E to LT EPS Grov	vth (FY10):	NA						
Est Next Rep Date:		08/08/2010						
Fiscal Year End:		Dec						
Incl partial exercise of over allotment								

Rev (mil)	2009A	2010E	2011E					
Mar	\$0.0A	\$0.0A	\$0.0E					
Jun	\$0.0A	\$0.0E	\$0.0E					
Sep	\$0.0A	\$0.0E	\$0.0E					
Dec	\$0.0A	\$0.0E	\$0.0E					
FY	\$0.0A	\$0.0E	\$0.0E					
CY	\$0.0A	\$0.0E	\$0.0E					
FY RM	NM	NM	NM					
CY RM	NM	NM	NM					
EPS	2009A	2010E	2011E					
Mar	(\$2.57)A	(\$0.48)A	(\$0.58)E					
Jun	(\$2.22)A	(\$0.24)E	(\$0.49)E					
Sep	(\$2.40)A	(\$0.43)E	(\$0.41)E					
Dec	(\$0.98)A	(\$0.62)E	(\$0.49)E					
FY	(\$8.06)A	(\$1.76)E	(\$1.97)E					
CY	(\$8.06)A	(\$1.76)E	(\$1.97)E					
FY P/E	NM	NM	NM					
CY P/E	NM	NM	NM					
Quarterly EPS does not add to full year result								

# Anthera Pharmaceuticals Overweight

(ANTH - \$7.00)

## First Quarter as Public Company; On-track for VISTA-16 and A-623 Starts

#### CONCLUSION:

With the successful IPO, Anthera now holds pro forma cash including partial exercise of the under writers option of over \$60 million. This is sufficient to begin the 6,500-patient Phase III varespladib VISTA-16 study under an SPA agreement with the FDA this quarter and the 120-patient Phase IIb lupus study of A-623 in 3Q:10. We maintain our Overweight rating and \$12 price target ahead of these study results.

- Ends 1Q:10 with Sufficient Cash to Begin Studies. Following the recent successful IPO, Anthera holds *pro forma* cash of ~\$60.7 million, sufficient to begin these studies. We expect Anthera to either partner A-623 or varespladib overseas or raise additional capital in order to complete the studies.
- Phase III VISTA-16 Trial to Begin this Quarter. Anthera received a Special Protocol Assessment (SPA) from the FDA for a single Phase III ACS study. VISTA-16 will compare 500mg QD Varespladib to placebo on top of *Lipitor* for 16 weeks in high CRP patients treated within 96 hours of event. VISTA-16 will enroll up to 6,500 ACS patients yielding an expected 385 events powered to show a 25% improvement in MACE. We expect VISTA-16 will begin this quarter with data in late 2011 or early 2012. If successful, we anticipate U.S. launch in 2013 with U.S. and EU sales of \$830 million in 2020E.
- Phase II Biomarker Data Gives Confidence in Pivotal Study. There is a growing body of evidence that inflammation plays an important role in cardiovascular disease (CVD) and heart attack. Varespladib is an sPLA2 inhibitor that acts by lowering cardiac inflammation. The Phase II PLASMA and FRANCIS studies showed varespladib in combination with statins reduced target sPLA2, C-Reactive Protein (CRP) and LDL cholesterol. These results give us confidence that varespladib can successfully prevent recurrent Major Adverse Coronary Events (MACE) in a larger Phase III study.
- A-623 Potential Blockbuster in Lupus. Based on the success of Human Genome Sciences' *Benlysta*, Anthera has accelerated development of A-623. This peptibody also targets BLyS, but is an injectable drug versus Benlysta's monthly i.v. infusion. Anthera intends to initiate a Phase II lupus study in 3Q:10 providing a data milestone next year for potential value appreciation.

#### **INVESTMENT RECOMMENDATION:**

We reiterate our Overweight rating and \$12 price target. We value varespladib at \$288M by applying a standard 5x multiple to 2015E U.S. sales of \$307M discounted back at 45% annually. To this we add mid'11E cash of \$4M. At present, we assign no value for European sales of varespladib or A-623 in lupus providing potential upside. See our 12 April 2010 note for more varespladib sales detail.

#### **RISKS TO ACHIEVEMENT OF TARGET PRICE:**

Risks include clinical, regulatory and commercial. Varespladib and/or A-623 may fail in the clinic. Anthera may require additional cash from the capital markets.

#### **COMPANY DESCRIPTION:**

Anthera is a biopharmaceutical company developing varespladib and A-623.

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#### PROMISING CARDIAC INFLAMMATION AND LUPUS PLAY

Anthera is a biopharmaceutical company developing novel drugs to treat life—threatening inflammatory and autoimmune diseases. The company's lead drug, *varespladib*, is a first-in-class secretory phospholipase A2 (sPLA2) inhibitor. sPLA2 is a family of enzymes that cause inflammation. Varespladib works through a dual mechanism by reducing cardiac inflammation and LDL cholesterol (LDLc). The Phase II PLASMA and FRANCIS studies showed varespladib in combination with statins reduced target sPLA2, C-Reactive Protein (CRP) and LDLc. We see varespladib as a novel cardiovascular agent that may lower Major Adverse Coronary Events (MACE) in patients with coronary artery disease (CAD).

Under a Special Protocol Assessment (SPA), Anthera is preparing to initiate the Phase III VISTA-16 trial of varespladib in Acute Coronary Syndrome (ACS) patients. This single 16-week pivotal study will compare 500mg once daily (QD) Varespladib to placebo on top of *Lipitor* (atorvastatin) in high CRP patients (>10 mg/L) treated within 96 hours of event. The VISTA-16 trial will enroll up to 6,500 ACS patients yielding an expected 385 events powered to show a 25% improvement in MACE. We expect VISTA-16 will begin this summer with data in late 2011 or early 2012. There is an interim biomarker futility analysis after the first 1,000 patients have completed 16 weeks of therapy, likely to take place in 1H:11, which could reassure investors on the progress of the pivotal study. If VISTA-16 is successful, we anticipate Anthera will partner varespladib for significant financial terms. We anticipate U.S. launch in 2013 with ACS sales reaching \$830 million in 2020E. Ultimately we foresee blockbuster opportunity for chronic varespladib in CAD.

Anthera is also developing A-623 for lupus, a peptibody that targets BLyS. Based on the success of Human Genome Sciences' (HGSI) *Benlysta*, Anthera has accelerated development of A-623. A-623 is an injectable drug versus Benlysta's monthly i.v. infusion. Anthera intends to initiate Phase II studies in 3Q:10 providing a data milestone for potential value appreciation by mid-2011. If successful, A-623 represents a potential blockbuster drug with potential applicability beyond lupus.

We reiterate our Overweight rating and \$12 price target. We look for Anthera to create value by reporting Phase II A-623 lupus data in 2011 and Phase III varespladib ACS data by early 2012, as well as potentially partnering either drug in the interim. We value varespladib at \$288 million by applying a standard 5x multiple to 2015 U.S. sales of \$307 million discounted back at 45% annually. To this we add mid'11E cash of \$4 million. At present, we assign no value for European varespladib sales or A-623 in lupus providing potential upside.

#### **Expected Upcoming Events:**

- Initiate Phase III trial of varespladib in ACS under an SPA this quarter
- Commence Phase II study of A-623 in lupus in 3Q:10
- DSMB to conduct interim futility analysis after first 1,000 patients in ACS pivotal study likely in 1H:11
- Report Phase II A-623 lupus data by mid-2011
- Potentially partner either European rights to varespladib or A-623 retaining significant value
- Report Phase III varespladib ACS data in late 2011 or early 2012
- Potentially file an NDA for varespladib by mid-2012 with U.S. launch in 2013

#### VARESPLADIB (A-002)

*Varespladib* is a first-in-class oral sPLA2 inhibitor. Varespladib has a dual mechanism of action that both reduces cardiac inflammation as well as LDLc, total cholesterol and non-HDLc. Specifically varespladib lowers pro-atherogenic LDLc particles. This is an important point of differentiation from LpPLA2 inhibitors like Darapladib that have not demonstrated similar effects on lipids. The effect of Varespladib on inflammation has been demonstrated in human clinical trial by a statistically significant reduction in IL-6, CRP and sPLA2. In animal studies, Varespladib has shown synergistic reductions of plaque volume when added to statins.

#### VISTA-16 Trial

Anthera received a Special Protocol Assessment (SPA) from the FDA for a single Phase III ACS study. The VISTA-16 trial will randomize up to 6,500 ACS patients within 96 hours of event or hospitalization to either 500mg QD Varespladib or placebo for 16 weeks on top of Lipitor and background standard-of-care. The number of subjects who undergo PCI following MI and prior to randomization will be limited to <55%. Physician will determine Lipitor dose of 20mg, 40mg or 80mg QD with a one-time dose adjustment permitted after 8 weeks if LDLc remains above target 100mg/dL. The primary endpoint of the trial is reduction in MACE at week 16. All cause mortality is a key secondary endpoint. The study is expected to yield a minimum of 385 events and is powered to show a 25% improvement in MACE. We expect VISTA-16 will begin this summer with data in late 2011 or early 2012.

An independent Data Safety Monitoring Board (DSMB) will conduct safety reviews and one interim biomarker efficacy analysis. The interim analysis will occur when at least 1,000 patients have completed treatment and 50% of the number of target events has occurred, which we expect will occur in 1H:11. The DSMB may also assess futility. The survival status for all subjects who have not withdrawn consent will be measured at the end of the study and 6 months after they complete the study.

#### Varespladib Sales Forecast

CAD is the leading cause of death in the developed world and ACS is a major cause of emergency medical care and hospitalization. Annual incidence of ACS in the U.S. based on hospital discharges is approximately 1.3 million with 41% of the admissions due to Unstable Angina, 36% due to STEMI and 40% due to NSTEMI. (*Circulation* Jan. 2009) An estimated 15% of ACS patients have congestive heart failure (CHF) or other co-morbidities that are excluded from VISTA-16 enrollment criteria and thus may not be included on the Varespladib label.

We expect VISTA-16 will begin this summer with pivotal data in late 2011 or early 2012. Based on positive pivotal data, we expect NDA filing in 2012 and U.S. approval in 2013 and in Europe by 2014. Shionogi retains rights in Japan. Assuming modest 15% penetration of the U.S. ACS market with a selling price of ~\$1,700 and 10% penetration of the European ACS market with a lower selling price of less than \$1,400, we forecast global sales of \$438 million in 2015. We forecast global Varespladib sales will grow to \$830 million by 2020 and exceed \$1 billion in 2023.

We expect Anthera will enter into a major Varespladib distribution alliance bringing in significant capital and a cardiology sales force. Importantly, we ultimately believe that a partner may explore use of varespladib more broadly in CAD much like darapladib representing significant upside to our forecast.

#### A-623 CLINICAL DATA AND DEVELOPMENT PLAN

A-623 is a peptibody antagonist against BlyS. Anthera in-licensed A-623 from Amgen in December 2007 and holds worldwide rights. A-623 offers several benefits over Benlysta. Most importantly, A-623 has shown proof-of-concept clinical data when formulated as both an intravenous (IV) infusion and a subcutaneous injection while Benlysta will only be available as a less convenient IV infusion that requires a monthly visit to a doctor's office. A-623 also targets both soluble and receptor bound BLyS while Benlysta only binds soluble BLys, a difference that may increase efficacy.

In two Phase I studies of 107 lupus patients, A-623 showed anti-BLys activity and statistically significant reductions in B cells using either single IV or single subcutaneous administration (p<0.001). A Phase Ib study of 63 lupus patients investigated IV doses of A-623 0.3, 1.0, and 3.0 mg/kg and an subcutaneous dose 6.0 mg/kg and demonstrated significant and selective decreases in B-cells as early as 15 days.

Anthera is planning a Phase II study of subcutaneous A-623 in 120 serologically active lupus patients on top of standard of care, which could provide a value inflection point in 2011. The trial will randomize patients with a SELENA SLEDAI > 6 who are ANA+ or dsDNA positive to one of three undisclosed doses of A-623 or placebo. The primary endpoint of the Phase II study will be percent changes in B-cell counts, as well as other relevant immunological biomarkers, such as changes in double-stranded DNA, IgG and IgM levels. A key secondary endpoint will mimic the composite response endpoint used in the Benlysta trials after 4 months of treatment. Following the 4 month treatment phase of the trial, patient will be followed for an additional 2 months for further safety assessments.

The size of the lupus market is the subject of some controversy. The Lupus Foundation of America estimates there are 1.5 million patients with SLE in the U.S. and 5 million worldwide, although many question the methodology used to arrive at these figures. In our opinion, the most reliable recent estimates come from a meta-analysis of available national surveys done in 2008 by the National Arthritis Data Workgroup (Helmick et al. (2008), *Arthritis and Rheumatism*, **58**: 15-25.) According to the Workgroup's analysis, 161,000 Americans have definitive SLE and up to 322,000 people have definitive or probable SLE. We conservatively estimate the addressable systemic lupus erythmatosus (SLE) population was ~200,000 in the U.S. in 2007, 70% of whom are seropositive and therefore eligible for A-623. Assuming a price of \$25,000 annually and modest peak penetrations of 30% of the addressable SLE market, we forecast A-623 sales could reach \$1.2 billion by 2020. We point out that we do not include any potential sales of A-623 outside of Lupus or in territories outside of the U.S. in our current estimates. Importantly, we do not include potential A-623 sales in our current price target valuation providing potential upside.

#### **VALUATION:**

We are reiterating our Overweight rating and \$12 price target. We value varespladib at \$288 million by applying a standard 5x multiple to 2015 U.S. sales of \$307 million discounted back at 45% annually. We believe this discount rate is on the high side (30-45%) for Phase II-ready drugs. To this we add mid'11E cash of \$4 million. At present, we assign no value for European varespladib sales or A-623 in lupus providing potential upside.

## Anthera Pharmaceuticals Quarterly Earnings Estimates

(\$ in thousands except per share)

	1QA	2QA	3QA	4QA	2009A	1QE 1	2QE	3QE	4QE	2010E	1QE	2QE	3QE	4QE	<u>2011E</u>
Total Revenues	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Operating Expenses:															
R&D Expense	2,915	2,286	2,526	688	8,415	\$5,242	4,000	8,500	13,000	30,742	12,000	10,000	8,000	10,000	40,000
SG&A Expense	<u>846</u>	999	<u>885</u>	<u>695</u>	3,425	1,224	1,700	1,800	2,000	6,724	2,000	2,000	2,000	2,000	8,000
Total Operating Expenses	\$3,761	\$3,286	\$3,411	\$1,383	11,841	\$6,466	\$5,700	\$10,300	\$15,000	37,466	\$14,000	\$12,000	\$10,000	\$12,000	48,000
Operating Loss	(\$3,761)	(\$3,286)	(\$3,411)	(\$1,383)	(\$11,841)	(\$6,466)	(\$5,700)	(\$10,300)	(\$15,000)	(\$37,466)	(\$14,000)	(\$12,000)	(\$10,000)	(\$12,000)	(\$48,000)
Interest and Other Income	13	9	(0)	2	24	25	50	45	35	155	45	50	40	35	170
Interest Expense	(37)	(59)	(193)	(96)	(385)	0	<u>0</u>	<u>0</u>	<u>0</u>	0	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	0
Total Other Income (Expense)	(24)	(50)	(193)	(94)	(362)	25	50	45	35	155	45	50	40	35	170
Pre-Tax Loss	(\$3,785)	(\$3,336)	(\$3,604)	(\$1,477)	(\$12,203)	(\$6,441)	(\$5,650)	(\$10,255)	(\$14,965)	(\$37,311)	(\$13,955)	(\$11,950)	(\$9,960)	(\$11,965)	(\$47,830)
Income Tax Expense	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net Loss	(\$3,785)	(\$3,336)	(\$3,604)	(\$1,477)	(\$12,203)	(\$6,441)	(\$5,650)	(\$10,255)	(\$14,965)	(\$37,311)	(\$13,955)	(\$11,950)	(\$9,960)	(\$11,965)	(\$47,830)
Net Loss per Share	(\$2.57)	(\$2.22)	(\$2.40)	(\$0.98)	(\$8.06)	(\$0.48)	(\$0.24)	(\$0.43)	(\$0.62)	(\$1.76)	(\$0.58)	(\$0.49)	(\$0.41)	(\$0.49)	(\$1.97)
Shares Outstanding	1,471	1,500	1,500	1,500	1,514	13,344	23,750	23,850	24,000	21,236	24,100	24,200	24,300	24,500	24,275

Source: Company reports and Piper Jaffray estimates.

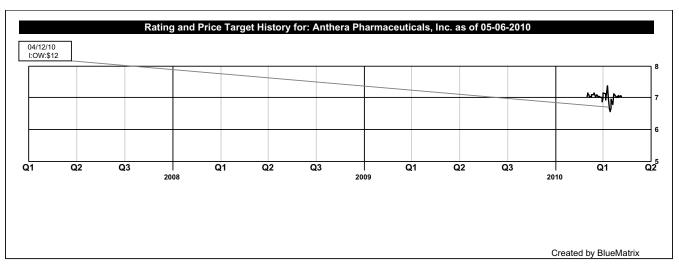
Note: CY:09A results include adjusted primary share count excluding preferred stock. As a result, quarterly EPS does not add to full year result.

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Anthera Pharmaceuticals, Inc.

<sup>1. 1</sup>Q:10 R&D expense includes \$3.5 million non-cash milestone payment in IPO stock to Lilly and Shinogi.

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Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

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			IB Serv./Past 12 Mos.				
Rating	Count	Percent	Count	Percent			
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HOLD [N]	268	39.70	15	5.60			
SELL [UW]	74	11.00	0	0.00			

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