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#### Reason for Report:

Company Update

Changes	Previous	Current					
Rating	-	Overweight					
Price Tgt		\$12.00					
FY10E Rev (mil)		\$0.0					
FY11E Rev (mil)		\$0.0					
FY10E EPS		(\$1.76)					
FY11E EPS		(\$1.97)					
Price:		\$5.10					
52 Week High:		\$8.55					
52 Week Low:		\$3.76					
12-Month Price Tar	get:	\$12.00					
Proj EV of \$288i	M + mid'11E ca	sh of \$4M					
Shares Out (mil):		23.8					
Includes impact	of recent IPO						
Market Cap. (mil):		\$121.4					
Avg Daily Vol (000)	:	22					
Book Value/Share:		\$2.22					
Cash Per Share:		\$2.55					
Debt to Total Capita	al:	0%					
Est LT EPS Growth	n:	NA					
P/E to LT EPS Grov	wth (FY10):	NA					
Est Next Rep Date:	į	08/08/2010					
Fiscal Year End:		Dec					
Incl partial exercise of over allotment							

moi partiai c	ACIOISC OI OV	or anouncin							
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	<u>\$0.0A</u>	<u>\$0.0E</u>	\$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 - \$5.10)

# Revised: Begins Phase IIb PEARL SC Trial in Lupus; Valuation is Compelling

#### **CONCLUSION:**

This morning, Anthera announced the initiation of the Phase IIb PEARL SC trial of A-623 for the treatment of lupus. The study is larger and longer than initially envisioned and begins ahead of schedule. Clinical validation of modulating B-cells and a clarified regulatory path makes A-623 an exciting program that could in our view differentiate from *Benlysta*. We look for an interim safety look in the Phase III VISTA-16 trial after the first 1,000 ACS patients are treated with varespladib to be the next value driver. ANTH shares appear cheap trading at an enterprise value of only \$65 million for 2 late-stage, unpartnered potential blockbuster drugs.

Note: corrects Phase IIb trial design on page 3

- Anthera Initiates Larger and Longer Lupus Study. Anthera has begun the Phase IIb PEARL SC trial of A-623 for the treatment of lupus. PEARL-SC will randomize up to 600 SLE patients to one of three doses of A-623 or placebo for 24 weeks. The primary endpoint will be the approvable SLE responder index used by HGS in the *Benlysta* studies. Anthera will also measure several secondary endpoints including safety, SLEDAI and BILAG scores, fatigue, steroid utilization and time to flare. A blinded interim biomarker look will measure B-cells and potentially remove any inactive arm(s). PEARL SC is both larger (600 vs. 120 SLE patients) and longer (6 vs. 4 months) than envisioned at the time of the IPO in our view dramatically increasing the likelihood of success.
- A-623 Potential Blockbuster in Lupus. Based on the success of *Benlysta* and a clarified regulatory path, we are increasingly excited about the market opportunity for A-623. While Piper Jaffray analysts are positive on the approvability and market potential of Benlysta as the first new lupus therapy in decades, we believe there is room for A-623 to differentiate and compete. Unlike Benlysta, A-623 is a peptibody that targets both soluble and membrane bound BLyS, which could offer an efficacy advantage. Further, A-623 is an injectable drug versus Benlysta's monthly intravenous infusion. We see ANTH as an attractive hedge for any HGSI holder trading at only a fraction of HGSI's almost \$5 billion market cap.
- **Healthy Cash Position.** Anthera holds *pro forma* cash of ~\$61 million, sufficient to progress the Phase III VISTA-16 ACS trial of varespladib and the expanded Phase IIb PEARL SC lupus study of A-623. We expect Anthera to either partner A-623 or varespladib overseas or raise additional capital to complete the studies.

#### **INVESTMENT RECOMMENDATION:**

We reiterate our Overweight rating and \$12 price target. We value varespladib at \$288 million by applying a standard 5x multiple to 2015E 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.

### 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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#### SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

SLE is a chronic autoimmune disease in which an individual's immune system attacks the body's own tissues. Lupus is a debilitating disease that affects multiple tissues including the skin, joints, and multiple organ systems including the lungs, kidneys, and blood. Lupus causes inflammation, atherosclerosis, organ damage/failure, and can potentially result in death. Lupus has been a particularly difficult disease to treat due to the heterogeneity of disease. This complex autoimmune disease targets organs in each individual differently and unpredictably, making drug development and clinical trial design challenging.

The CDC estimates lupus affects approximately 1.5 million Americans and at least 5 million people worldwide. The death rate from lupus remains relatively low at 52 people per million with a total of 22,861 deaths reported from 1979-1998. Approximately 36% of deaths occur under the age of 45 and are caused by active SLE, organ failure, infection, or heart disease related to accelerated atherosclerosis. Lupus predominantly affects women (5x) and especially those of African descent (3x). It is estimated that 1 in 250 African-American women between the ages of 18 and 65 are affected by the disease.

No new therapies for the treatment of lupus have been approved by the FDA over the last 40 years, presenting a massive unmet clinical need. Today, most treatments for lupus only provide symptomatic relief including NSAIDs, corticosteroids, and immunosuppressants. The FDA states that current treatments for SLE remain inadequate as many patients have incompletely controlled the disease, progression to end-stage organ involvement continues, and current therapies carry potential risks of debilitating side effects. Lupus can be extremely difficult to diagnose as patients do not display identical symptoms. Often, different symptoms occur over a period of time, and it may take years for a definitive diagnosis.

Physical symptoms of SLE are often accompanied by elevated concentrations of antinuclear antibodies (ANA). An immunoflorescent test is available to measure concentrations of ANA and to confirm SLE when other symptoms are seen. Almost 97% of lupus patients have elevated concentrations of ANA. However, the test is not definitive as elevated ANA concentrations are associated with numerous ailments such as rheumatoid arthritis, thyroid disease, viral infections, autoimmune diseases and certain drug use. Further, an ANA test will be weakly positive in approximately 20% of healthy individuals. Difficulty in diagnosing the disease is further complicated by the fact that lupus can enter periods of inactivity or remission and can quickly "flare up" due to some external stimuli.

Several potentially fatal diseases are associated with SLE as a result of increased inflammatory response and cellular damage. These include increased risk of atherosclerosis and inflammation of the heart (myocarditis, endocarditis, and pericarditis), kidney (nephritis), the lungs (pleuritis), blood (vasculitis), and central nervous system. During periods of flare, many of these organ systems are susceptible to damage, which can accumulate over years and eventually lead to organ failure. Flares are treated with increased immunosuppressive therapy, which in turn has additional toxicities. The most commonly studied organ-specific manifestation of lupus is lupus nephritis, which can lead to end-stage renal disease and death.

#### BLYS TARGETING IS THE NEXT BIG ADVANCE IN LUPUS THERAPY

B-Lymphocyte Stimulator (BLyS) is a highly specific B-cell growth factor that causes progenitor cells to differentiate into B-lymphocytes. B-cells are immune cells that play a central role in the inflammatory component of lupus. Plasma B cells produce antibodies that act as the first line of defense for the body's immune system. In lupus and certain other autoimmune diseases, elevated levels of BLyS are believed to contribute to the production of auto-antibodies that attack and destroy the body's own healthy tissues. The presence of auto-antibodies appears to correlate with disease severity. Extensive preclinical studies have demonstrated that BLyS promotes B-cell count, as well as production of the serum immunoglobulin IgA, IgG, and IgM.

BLyS is a clinically validated lupus target, as evidenced by the recent success of Human Genome Science's *Benlysta*. Benlysta is a fully human monoclonal antibody directed against soluble BLyS which has completed two Phase III trials. HGS and partner GSK intend to file a BLA for 10mg/kg Benlysta in the U.S. this quarter. Importantly, BLys targeting agents may have applicability in other autoimmune diseases such as rheumatoid arthritis and multiple sclerosis.

In two Phase III trials, BLISS-52 and BLISS-76, SLE patients with confirmed antinuclear antibodies (ANA+) were randomized to one of three treatment groups: 10 mg/kg Benlysta (in BLISS-52, n=290), 1 mg/kg Benlysta (BLISS-52, n=288), or placebo (BLISS-52, n=287). Patients were dosed intravenously on Days 0, 14 and 28, then every 28 days thereafter for the duration of the study. All receive standard of care therapy in addition to the study medication.

In the Phase III BLISS-52 study, Benlysta met the composite primary endpoint of response at 52 weeks. Benlysta also significantly reduced SLE disease activity versus placebo based on the SELENA SLEDAI and Physician's Global Assessment scores. The composite primary endpoint was defined by 1.) a reduction in baseline SELENA SLEDAI score of at least 4 points, 2.) no worsening in the Physician's Global Assessment (PGS) score, 3.) no new BILAG-A severe organ domain score, and 4.) no >1 new BILAG-B moderate organ domain score from baseline. Benlysta showed a composite response of 57.6% for 10 mg/kg (p=0.0006), 51.7% for 1

mg/kg (p=0.013) vs. 43.6% for placebo. Benlysta response was driven by a significant 4-point reduction in SLEDAI at both 10mg/kg (p=0.0024) and 1mg/kg (p=0.019). Benlysta delayed time to first SLE Flare with median 119 days for 10 mg/kg (p=0.0055), 126 days for 1 mg/kg (p=0.1342) vs. 84 days for placebo. On Physician's Global assessment (PGA), Benlysta showed a 45.7% improvement at 10mg/kg (p<0.0001) and 39.3% at 1mg/kg (p=0.004) vs. 27.8% for placebo. Steroid dose reduction trended at 10mg/kg, but was not statistically significant. Both Benlysta doses did significantly improve fatigue (p<0.05) and Health Related Quality of Life as measured by SF36 (p=0.025 and p=0.027, respectively). Benlysta was generally well tolerated, with rates of overall adverse events, comparable between Benlysta and placebo treatment groups. Serious infection was 6.2% in Benlysta patients vs. 5.9% with placebo.

The BLISS-76 study reported patient response of 43.2% for 10 mg/kg (p=0.021), 40.6% for 1 mg/kg (p=0.10) versus 33.8% for placebo. While these results came in below the first BLISS-52 trial, 10mg/kg was statistically significant and supports approval. BLISS-76 has precisely the same design as BLISS-52, however is slightly smaller with 826 SLE ANA+ patients primarily recruited in the developed world - in U.S., Canada and Europe, and only 5-10% from and Mexico and Costa Rica. Benlysta response was driven by a significant 4-point reduction in SLEDAI at the 10mg/kg (p=0.0062) with a non-significant trend at 1mg/kg (p=0.087). On the secondary PGA endpoint, Benlysta showed non-significant trends at both doses with a 0.49 point improvement at 10mg/kg and 0.55 point improvement at 1mg/kg vs. 0.46 point improvement for placebo. Steroid dose reduction also trended at 10mg/kg in BLISS-76, but reached significance when pooled with BLISS-56.

#### 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 after either a single IV or subcutaneous dose (p<0.001). A Phase Ib study of 63 lupus patients investigated IV doses of A-623 at 0.3, 1.0, and 3.0 mg/kg and an subcu dose 6.0 mg/kg demonstrating a significant and selective decreases in B-cells as early as 15 days.

Anthera has begun a Phase IIb study of A-623 in 600 serologically active lupus patients on top of standard of care. 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 is the approvable SLE responder index used by HGS in the *Benlysta* studies. Anthera will measure several secondary endpoints including safety, SLEDAI and BILAG scores, fatigue, steroid utilization and time to flare. A blinded interim biomarker look will measure B-cells and potentially remove any inactive arm(s). PEARL SC is both larger (600 vs. 120 SLE patients) and longer (6 vs. 4 months) than envisioned at the time of the IPO, in our view, dramatically increasing the likelihood of success.

#### A-623 MARKET FORECAST

Based on the success of *Benlysta* and a clarified regulatory path, we are increasingly excited about the market opportunity for A-623. While Piper Jaffray analysts are positive on the approvability and market potential of Benlysta as the first new lupus therapy in decades, we believe there is room for A-623 to differentiate and compete. Unlike Benlysta, A-623 is a peptibody that targets both soluble and membrane bound BLyS, which could offer an efficacy advantage. Further, A-623 is an injectable drug versus Benlysta's monthly intravenous infusion. We see ANTH as an attractive hedge for any HGSI holder trading at a fraction of HGSI's market cap.

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 reiterate our Overweight rating and \$12 price target. We value varespladib at \$288 million by applying a standard 5x multiple to 2015E U.S. sales of \$307 million discounted back at 45% annually. We believe this discount rate is on the high side (30-45%) for a Phase III drug. 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.

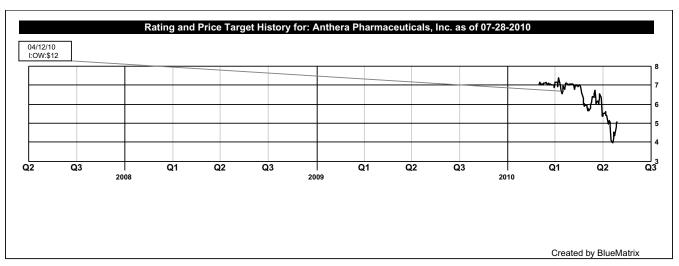
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Anthera Pharmaceuticals, Inc.

<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.

Legend:

I: Initiating Coverage

R: Resuming Coverage

T: Transferring Coverage

D: Discontinuing Coverage

S: Suspending Coverage

OW: Overweight

N: Neutral

UW: Underweight

B: Buy (Piper Jaffray discontinued use of the B, N, and S ratings on June 30, 2009)

N: Neutral

S: Sell

OP: Outperform (Piper Jaffray discontinued use of the OP, MP and UP ratings on November 15, 2007)

MP: Market Perform UP: Underperform

AL On/AL Off: Placed on/removed from the Alpha List maintained by Piper Jaffray (AL use discontinued March 2010)

NA: Not Available UR: Under Review

Distribution of Ratings/IB Services Piper Jaffray							
			IB Serv./Past 12 Mo				
Rating	Count	Percent	Count	Percent			
BUY [OW]	360	51.90	83	23.06			
HOLD [N]	268	38.60	21	7.84			
SELL [UW]	66	9.50	1	1.52			

Note: Distribution of Ratings/IB Services shows the number of companies currently in each rating category from which Piper Jaffray and its affiliates received compensation for investment banking services within the past 12 months. FINRA rules require disclosure of which ratings most closely correspond with "buy," "hold," and "sell" recommendations. Piper Jaffray ratings are not the equivalent of buy, hold or sell, but instead represent recommended relative weightings. Nevertheless, Overweight corresponds most closely with buy, Neutral with hold and Underweight with sell. See Stock Rating definitions below.



# **Important Research Disclosures**

# Analyst Certification — Edward A. Tenthoff, Sr Research Analyst

— Chad J. Messer, Ph.D., Research Analyst

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- Neutral (N): Anticipated to perform in line relative to the median of the group of stocks covered by the analyst.
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