

## Anthera Pharmaceuticals (ANTH)

### Phase IIb A-623 Trial On Hold Due to Cracked Vials; Program Remains Attractive Despite Modest Delay

• **PEARL-SC study halted due to vial problem.** Anthera announced yesterday that the ongoing A-623 PEARL-SC study in Lupus has stopped enrollment and dosing after the company discovered that the vials containing the study drug were prone to cracking. According to ANTH, a single cracked vial was discovered by a study investigator, but upon further inspection it was found problem was not isolated to the one center. Although patient safety did not appear to be compromised (no adverse events related to drug administration could be attributed to the problem), the company immediately suspended enrollment and dosing in order to investigate the problem.

• **Next steps still unclear but we expect a delay of 6-8 months at most.** As the investigation into the problem has just begun, management does not yet have a clear understanding of how long it will take to resolve. That said, we expect that the trial will have to be re-started from scratch, as patients currently enrolled will likely have to miss several of their scheduled weekly doses. Anthera noted that less than 30 patients are currently in the study (target enrollment of 600 patients), which began enrollment less than two months ago. Should the currently supply of A-623 be deemed unfit for use, the company believes it can obtain a new stock of drug in 6-8 months, and commence enrollment shortly afterwards. Therefore, we are pushing back our estimate for the trial launch to Q3:2011. Consequently, the interim B-cell biomarker data which we had expected in Q2:11 will likely now be reported in Q2:12.

• **Upcoming milestones should provide initial look into Anthera's key clinical trials.** We expect approval of HGSI/GSK's lupus drug Benlysta on December 9, which we believe will increase investor awareness of A-623. Upcoming catalysts for ANTH include: (1) interim biomarker data from the Phase III data for A-002 in Q1:11; (2) additional clarity on A-623 Phase IIb trial hold in Q4:10-Q1:11; (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).

• **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. Based on two compelling later-stage drug candidates each with blockbuster potential, we strongly reiterate our OUTPERFORM rating.

• **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.

November 17, 2010

Price (Close 11/16/10)

**\$5.67**

Rating

**OUTPERFORM**

Fair Valuation

**\$8**

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#### Company Information

52-Week Range	\$2.82 - \$8.55
Shares Outstand.	38.9 million
Avg. daily volume	97,600
Market Cap.	\$220 million

ST / LT Debt	\$0 M / \$0 M
Debt/Capital	N/A
ROE	(44.6%)
Cash & Inv/Share	\$1.88
Book Value/Share	\$2.56

#### Company Description

Anthera Pharmaceuticals is a biopharmaceutical company focused on developing products to treat inflammatory disorders, including cardiovascular and autoimmune diseases. Anthera currently has one Phase 3 clinical program, A-002, as well as two Phase 2 clinical programs, A-623 and A-001.



Source: Nasdaq.com

	2009A	2010E			2011E		
REV. (\$m)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar		\$0.0A			\$0.0E		
Q2 Jun		0.0A			0.0E		
Q3 Sep		0.0A			0.0E		
Q4 Dec		0.0E		\$0.0E	0.0E		
Year	\$0.0	\$0.0E		\$0.0E	\$0.0E		\$0.0E
	2009A	2010E			2011E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar		(\$0.83)A			(\$0.34)E	(\$0.37)E	
Q2 Jun		(0.36)A			(0.38)E	(0.40)E	
Q3 Sep		(0.36)A			(0.44)E	(0.42)E	
Q4 Dec		(0.31)E	\$(0.31)E	\$(0.45)E	(0.47)E	(0.47)E	
Year	(\$8.06)	(\$1.64)E	(\$1.64)E	\$(1.99)E	(\$1.63)E	(\$1.65)E	\$(1.80)E

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## UPCOMING MILESTONES

We estimate the following near-term milestones for Anthera:

<b>2010</b>	Q4:2010	Release of full Phase II IMPACTS data of A-001 in Acute Chest Syndrome
	December 9	Expected approval of Benlysta in Lupus (GSK and HGSi)
	YE:2010	Expect 1,000 patients enrolled in VISTA-16 Study
<b>2011</b>	Q1:2011	Biomarker data from interim analysis of VISTA-16 in late Q1:2011
	February 1	Data Safety Monitoring Board (DSMB) meeting for VISTA-16
	Q1:2011	Update on A-623 Phase IIb program
	Q3:2011	Expect restart of A-623 Phase IIB study in Lupus
	H1:2011	Initiate Phase IIb Study of A-001

## VALUATION

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 \$73 million in cash in our valuation on the assumption that these funds will be used for continued clinical development.

# **Anthera Pharmaceuticals (NASDAQ: ANTH)**

**Wedbush PacGrow LifeSciences**
**Duane Nash, MD JD MBA**

## **Historical and Projected Income Statement**

*(In thousands except per share data)*
*(Fiscal Year Ends on December 31)*

	2009A	2010					2011E	2012E
	FY:09A	Q1A	Q2A	Q3A	Q4E	FY:10E	FY:11E	FY:12E
<b>Revenues:</b>								
Royalties on Product Sales	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
A-002 in Acute Coronary Syndrome - Acute Therapy	-	-	-	-	-	-	-	-
A-002 in Acute Coronary Syndrome - Chronic Therapy	-	-	-	-	-	-	-	-
A-001 in Acute Chest Syndrome (Sickle Cell Disease)	-	-	-	-	-	-	-	-
A-623 in Systemic Lupus Erythematosus	-	-	-	-	-	-	-	-
Collaboration Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Milestones	-	-	-	-	-	-	-	-
<b>Total Revenues</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Operating Expenses</b>								
Cost of Goods								
R&D	8,415	5,242	6,438	6,885	8,429	26,994	46,664	32,229
Sales, General and Administrative	3,425	1,224	1,510	1,510	1,831	6,075	8,910	12,122
Other	-	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>11,840</b>	<b>6,466</b>	<b>7,948</b>	<b>8,395</b>	<b>10,260</b>	<b>33,069</b>	<b>55,574</b>	<b>44,351</b>
Operating Income (Loss)	(11,840)	(6,466)	(7,948)	(8,395)	(10,260)	(33,069)	(55,574)	(44,351)
Interest income	24	3	12	62	78	154	251	158
Interest expense	(386)	(4,641)	-	-	-	(4,641)	-	-
Beneficial conversion feature	-	-	-	-	-	-	-	-
<b>Income Before Income Taxes</b>	<b>(12,203)</b>	<b>(11,104)</b>	<b>(7,936)</b>	<b>(8,334)</b>	<b>(10,183)</b>	<b>(37,556)</b>	<b>(55,323)</b>	<b>(44,193)</b>
Other comprehensive income (loss)								
Provision for Income Taxes (benefit)	-	-	-	-	-	-	-	-
<b>Net Income (Loss)</b>	<b>\$ (12,203)</b>	<b>\$ (11,104)</b>	<b>\$ (7,936)</b>	<b>\$ (8,334)</b>	<b>\$ (10,183)</b>	<b>\$ (37,556)</b>	<b>\$ (55,323)</b>	<b>\$ (44,193)</b>
EPS ( Basic & Diluted)	(8.06)	(0.83)	(0.36)	(0.36)	(0.31)	(1.64)	(1.63)	(1.27)
Shares Outstanding (Basic)	1,514	13,344	22,224	22,964	33,225	22,939	33,850	34,850
Fully Diluted Shares Outstanding (Pro forma)	10,190	14,953	23,664	24,604	38,900	25,530	39,150	39,550
<b>Net Cash</b>	<b>\$3,803</b>	<b>\$56,662</b>	<b>\$51,038</b>	<b>\$73,088</b>	<b>\$62,133</b>	<b>\$62,133</b>	<b>\$8,342</b>	<b>(\$38,421)</b>

Source: Company reports, Wedbush Securities estimates

We use multiples to account for clinical and regulatory risk at various stages of development.		Today:	11/17/10	Stock	MktCap (\$000)	Upside
		Wedbush Current Fair Value for ANTH				
<b>NOVEL DRUGS</b>		Current Full Pipeline Value:				
1: In preclinical testing		Cash:				
2: passed preclinical		ANTH Total Value:				
3: IND filing		Current ANTH Stock:				
4: Phase I data		ANTH Shares Outstanding (000):				
5: Phase II data						

## **Anthera Product Pipeline Valuation**

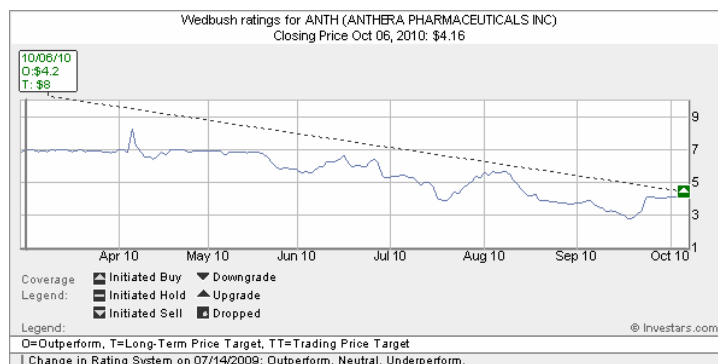
Product		Indication	Eligible # Annual WW Treatments Est	Pricing \$ per Patient per Year Est/Actual	Peak Penetration Est	Gross WW Peak Sales Est (\$000)	ANTH Net Peak Revs Est WW (\$000)	Est/Actual Launch	Multiple	Annual Discount Rate	Wedbush MktCap Fair Value (\$000)	Wedbush Stock Fair Value
sPLA2 Antagonists	A-002	Acute Therapy	3,500,000	\$2,114	15%	\$1,110,000	\$194,250	7/1/2013	6	30%	\$205,111	\$5.27
		Chronic Therapy	10,000,000	\$2,363	5%	\$1,181,250	\$206,719	6/1/2015	5	30%	\$109,978	\$2.83
	A-001	Sickle Cell Crisis	175,000	\$22,143	20%	\$775,000	\$135,625	1/1/2017	4	30%	\$49,458	\$1.27
BLyS Antagonist	A-623	Systemic Lupus Erythematosus	600,000	\$17,083	10%	\$1,025,000	\$205,000	5/1/2015	5	30%	\$111,521	\$2.87

Source: Company reports, Wedbush Securities estimates

## **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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**OUTPERFORM** – Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

**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.

**UNDERPERFORM** – Expect the total return of the stock to underperform relative to 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 provided investment banking services to Anthera Pharmaceuticals (ANTH), Heartware (HTWR), Rockwell Medical (RMTI) and World Heart (WHRT) within the last 12 months.

WS expects to receive compensation for investment banking services from Anthera Pharmaceuticals (ANTH) and World Heart (WHRT) within the next 3 months.

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

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