

Biotechnology — Company Update

AMAG Pharmaceuticals (AMAG)

Ferumoxytol — a Product and a Pipeline

June 9, 2008

Recommendation: BUY

Price Target: \$62.00

Analyst Name Phone Number



Source: StockCharts.com

Stock Data – (NASDAQ: AMAG)

Price: \$39.73
52-wk high: \$72.95
52-wk low: \$33.00
Shares out: \$16.9MM
Shares short: \$4.21MM
Avg vol (10-day): 3.19MM

Valuation Metrics

Market cap: \$675M
Enterprise value: \$390M

Financial Highlights (Mar:08)

Cash/equivalents: \$276MM
Debt: None

	06A	07A	Q1:08	08E
Revs	\$1.5M	\$2.5M	\$0.6M	\$1.8M
Prior	NA	--	--	--
EPS	\$(2.31)	\$(2.15)	\$(0.54)	\$(2.57)
Prior	NA	--	--	--

Company Description

Advanced Magnetics is a developer of super magnetic particles that improve imaging agents and therapeutics. Two products are approved as diagnostics agents. The company's lead product, ferumoxytol, is a more convenient IV iron supplement. The company is located in Cambridge, Massachusetts.

e-mail

- **Ferumoxytol's initial market is over 1.5+ MM chronic kidney disease patients (CKD) with IDA (iron deficiency anemia).** The current IV iron market is primarily CKD and was estimated at \$518MM in 2007 growing at 8% annually. AMAG expects ferumoxytol's convenient and safe profile will drive usage in the dialysis market and expand significantly the pre-dialysis market beginning early next year. At an estimated \$350/ 1000 gm treatment, well over a \$1B market opportunity.
- **Phase III studies in abnormal uterine bleeding (AUB) to begin shortly.** AUB occurs in 10-30% of women of childbearing years and an estimated 3MM women have IDA. The 2 pivotal studies will enroll 1200 women. One study will examine ferumoxytol efficacy in oral iron failure patients vs. an IV placebo. The second will compare ferumoxytol to oral iron in treatment-naïve patients. AMAG estimates as much as a \$1.4B commercial opportunity.
- **Additional ferumoxytol pivotal studies in oncology, inflammatory bowel disease (IBD) and IDA to begin in 2008.** There are an estimated 4.8M Americans with IDA. Many patients are not able to tolerate oral iron and have not been treated with IV iron due to the inconvenient dosing (8-10 IV infusions) and/or the perception that IV iron is dangerous due to infusion reactions. Ferumoxytol is in the unique position of having safe and convenient dosing for treatment in a physician's office once label expansions are obtained.
- **A phase II imaging study with ferumoxytol to start in Q3 in CKD patients with peripheral arterial disease (PAD).** AMAG estimates there are approximately 5M patients with PAD and CKD. Existing iodinated contrast agents, such as Gadolinium, are associated with risk of acute renal failure. Ferumoxytol's safety has been demonstrated in 1500 CKD patients, and CKD patients are at increased risk to develop PAD. Three doses will be studied in about 100 patients.
- **AMAG will be ready to launch ferumoxytol in H1:09.** AMAG is on track with staffing and expects 80% of commercial hiring to be complete by Q3:08. Manufacturing is also on track with 40K grams of ferumoxytol in vials by the end of this month and 200K grams in vials by YE:08. A second source supplier will contribute starting in H2:09 to meet worldwide demand.
- **We reiterate our BUY rating and YE:08 price target of \$62.** We use a 30x multiple and a 25% discount rate on our fully diluted 2012 EPS estimate of \$5.05 as the basis of our \$62 price target and BUY rating. An enterprise value of <\$500MM is inexpensive for a company 6 months away from approval.

Important Disclosures and Disclaimers Appear on Page 4 of This Report.

REPORT SUMMARY

Ferumoxytol's initial market is comprised of 1.5+ MM chronic kidney disease patients (CKD) with IDA (iron deficiency anemia). The current IV iron market, primarily CKD patients, was estimated at \$518MM in 2007, growing at 8% annually. Phase III studies in abnormal uterine bleeding (AUB) should begin shortly. AMAG estimates as much as a \$1.4B commercial opportunity. Additional ferumoxytol pivotal studies in oncology, inflammatory bowel disease (IBD) and IDA are to begin in 2008. A phase II imaging study with ferumoxytol should start in Q3 in CKD patients with peripheral arterial disease (PAD). AMAG will be ready to launch ferumoxytol in H1:09. We reiterate our BUY rating and YE:08 price target of \$62. We use a 30x multiple and a 25% discount rate on our fully diluted 2012 EPS estimate of \$5.05 as the basis of our \$62 price target and BUY rating. An enterprise value of <\$500MM is inexpensive for a company 6 months away from approval.

INVESTMENT THESIS

AMAG Pharmaceuticals' lead product candidate, ferumoxytol, has the potential to be a convenient IV iron therapy that is well suited for outpatient treatment for iron deficiency anemia (IDA), the most common nutritional deficiency worldwide. US ferumoxytol sales could begin in H1:09; we expect US sales of \$340MM and worldwide sales of \$413MM in 2012. We believe ferumoxytol has the potential to expand the \$500MM CKD US IV iron market significantly beyond dialysis-dependent (DD) CKD patients and has significant potential beyond CDK in women's health, oncology and inflammatory bowel disease.

Figure 1. AMAG Catalysts

Milestones	Timing	
Initiate Phase III abnormal uterine bleeding (AUB) study	H2:08	2008
Initiate Phase II imaging study in CKD patients w/ PAD	Q3:08	
Initiate Phase III in iron deficiency anemia (all comers)	Q4:08	
Initiate Phase III IDA studies in oncology patients	H2:08	
Hire a 80 person sales force	H2:08	
FDA advisory panel meeting (possible)	Q3:08	
Ferumoxytol US approval for CKD PDUFA	Oct. 19	
Ferumoxytol data at ASN in Philadelphia (may include repeat txt.)	Nov. 4-9	
US ferumoxytol CKD launch	H1:09	2009 +
Additional ROW partners and strategy	2009	
Results of several ferumoxytol IDA trials	2009	
Ferumoxytol approval in non CKD indications	2010	
Competitive milestones	Timing	
Ferrlicit and Venofer loose patent protection	2008	
Rockwell Medical phase IIb trial results with dialysate enriched with iron	by YE:08	
Injectafer US approval (1,00 mg iron 15 min IV)	2010?	
Source: Company Reports and SSRP research		

Figure 2. AMAG Pharmaceuticals Model

AMAG Pharmaceuticals Revenue Model (\$ in thousands)	2004	2005	2006	Q1:07	Q2:07	Q3:07	Q4:07	2007	Q1:08	Q2:08E	Q3:08E	Q4:08E	2008E	Q1:09E	Q2:09E	Q3:09E	Q4:09E	2009E	2010E	2011E	2012E	
Product sales:																						
Ferumoxtyl sales in US	-	-	-	-	-	-	-	-	-	-	-	-	-	3,000	12,000	22,000	35,000	72,000	159,881	242,079	340,005	
Ferumoxtyl sales ex-US (20% royalty)	-	-	-	-	-	-	-	-	-	100	200	300	600	-	-	-	-	821	4,331	9,593	14,525	
Feridex	432	378	619	-	-	-	-	-	-	180	195	210	585	-	-	-	-	750	800	800	850	
GastroMARK	336	428	729	159	150	150	150	609	-	-	-	-	-	-	-	-	-	750	800	800	850	
Combixid	-	85	101	135	-	-	-	135	-	-	-	200	200	-	-	-	-	200	750	1,000	1,500	
Total Product Sales	768	890	1,449	294	150	150	150	744	612	425	395	710	1,385	3,000	12,000	22,000	34,000	71,000	166,562	254,272	357,730	
Revenues:																						
License fees	2,748	1,281	907	542	520	-	-	1,062	-	175	225	250	650	150	175	225	250	800	800	800	800	
Royalties	240.0	274	317	77	75	-	-	152	-	100	100	125	325	75	100	100	125	400	400	400	400	
Milestones (exUS partnership)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5,000	5,000	5,000	5,000	5,000	
Product sales	769	890	1,449	294	150	150	150	744	612	425	395	710	1,425	3,000	12,000	22,000	34,000	71,000	166,562	254,272	357,730	
Total Revenues	3,757	2,445	2,673	913	745	503	391	2,552	612	425	475	525	1,425	3,225	12,275	22,325	39,375	77,200	172,762	260,472	363,930	
Operating expenses:																						
Cost of goods sold	117	204	273	157	101	39	23	320	44	84	119	213	460	-	-	-	-	7,200	15,988	24,208	34,001	
Research and development expenses	6,084	12,038	21,294	6,141	5,115	5,776	7,203	24,236	4,823	5,000	5,500	6,000	21,323	7,000	8,000	9,500	10,500	35,000	42,000	50,400	60,480	
S.G&A expenses	2,220	3,338	8,011	2,791	5,083	5,841	6,682	20,396	8,385	8,500	9,500	10,000	36,385	11,000	11,500	12,000	12,500	47,000	61,100	79,430	103,259	
Total operating expenses	8,421	15,579	29,578	9,089	10,299	11,656	13,908	44,952	13,252	13,584	15,119	16,213	58,168	18,000	19,500	21,500	23,000	89,200	119,088	154,038	197,740	
Loss/profit from operations	(4,664)	(13,134)	(26,905)	(8,176)	(9,554)	(11,153)	(13,517)	(42,400)	(12,640)	(13,159)	(14,644)	(15,688)	(56,743)	(14,775)	(7,225)	825	16,375	(12,000)	53,674	106,434	166,190	
Interest and other income:																						
Interest and dividend income, net	170	419	1,575	1,973	2,619	4,121	3,793	12,506	3,339	3,100	2,900	2,800	12,139	2,700	2,600	2,500	2,400	10,200	8,140	10,382	20,000	
Litigation settlement	-	-	-	(4,000)	-	-	-	(4,000)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pre-tax net loss	(4,494)	(12,715)	(25,330)	(10,203)	(6,935)	(7,032)	(9,724)	(33,894)	(9,301)	(10,059)	(11,744)	(12,888)	(44,604)	(12,075)	(4,625)	3,325	18,775	(1,800)	61,814	116,816	186,190	
Income taxes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	23,363	65,167	
Tax rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	20%	35%	
Net income	(4,494)	(12,715)	(25,330)	(10,203)	(6,935)	(7,032)	(9,724)	(33,894)	(9,301)	(10,059)	(11,744)	(12,888)	(44,604)	(12,075)	(4,625)	3,325	18,775	(1,800)	61,814	93,453	121,024	
GAAP Basic net loss per share	(0.57)	(1.47)	(2.31)	(0.72)	(0.46)	(0.42)	(0.57)	(2.15)	(0.54)	(0.58)	(0.67)	(0.73)	(2.57)	(0.68)	(0.26)	0.18	1.02	(0.10)	3.17	4.52	5.53	
Basic shares	7,818	8,634	10,964	14,160	15,150	16,838	16,916	15,777	17,085	17,256	17,429	17,603	17,343	17,779	17,957	18,136	18,318	18,384	19,487	20,656	21,895	
GAAP Diluted net loss per share	(0.57)	(1.47)	(2.31)	(0.72)	(0.46)	(0.42)	(0.57)	(2.15)	(0.55)	(0.58)	(0.67)	(0.73)	(2.57)	(0.68)	(0.26)	0.18	1.02	(0.09)	2.99	4.28	5.24	
Diluted shares	7,818	8,634	10,964	14,160	15,150	16,838	16,916	15,777	16,970	17,256	17,429	17,603	17,343	17,779	17,957	18,136	18,318	19,575	20,678	21,847	23,086	

Note: Operating expenses include employee stock option expenses

Source: SSRP Research and Company reports.

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Investment Rating Distribution for the Period 1/1/08 through 3/31/08:

Rating	Count	Percentage
BUY	19	58%
NEUTRAL	13	41%
SELL	1	1%
Companies under coverage at 3/31/08	33	100%

We have assigned an investment rating for at least one year for the following subject companies mentioned in this report:

AMAG

Ratings History

Date	Rating	Share Price	Price Target
6/21/07	NEUTRAL	\$60.88	NA
4/10/08	BUY	\$37.02	\$62.00

AMAG Investment Risks

- **Clinical/Regulatory:** Our rating is based on assumption that ferumoxytol is approved by FDA. Safety, efficacy and study design will be key issues of focus for FDA when evaluating BLA package.
- **Competition/Commercial/Reimbursement:** Ferinject (Vit-45) will likely be approved by YE:07 and will have ~1yr head start in market. Reimbursement is uncertain, physicians will need to be educated on IV iron, and new markets will need to be developed.
- **Manufacturing:** Company states they have manufacturing capacity ~\$175-225MM (depending on pricing assumptions). AMAG is in process of securing more capacity.

Valuation Method for Price Target: NA

