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AMAG Pharmaceuticals, Inc.

Bullish on Intrarosa as the Next AMAG Value Driver Following Survey; Initiate OW, \$26 PT

Stock Rating | Industry View | Price Target
Overweight | In-Line | \$26.00

We are bullish on AMAG, a stock that has been pressured from concerns about the impact of Makena generics, an overhang that may be overstated. Further, our AlphaWise OB/GYN survey sees a differentiated profile for newly launched Intrarosa that appears underappreciated at current levels.

Initiating coverage on AMAG with Overweight rating, \$26 PT. AMAG

Pharmaceuticals is a biopharmaceutical company that specializes in women's health prescription drugs and services as well as hematology products. Investors have focused intensely on the company's largest current revenue driver Makena which faces the loss of orphan drug exclusivity and the potential for generic competition in February 2018. We believe the bear case for Makena is largely priced in at these levels and look toward the underappreciated aspects of AMAG's future growth including intrarosa for dyspareunia (pain during sex) related to menopause in women label expansion for Vivroner and durable revenue and valuation support from the Cord Blood Registry (CBR) service.

Winter is coming for Makena, but AlphaWise survey and proprietary scenario analysis suggest the bear case is largely priced in. Orphan drug exclusivity for intramuscular Makena a progesterone injection used to reduce the risk of recurrent preterm birth expires on February 3 2018. We anticipate at least one generic entrant into the market following exclusivity expiration as does the company. Our diligence supported by our proprietary AlphaWise survey of 108 US OB/GYNs suggests that physicians would prefer AMAG's subcutaneous auto-injector should gain approval and that there is some sense of loyalty to branded intramuscular Makena suggesting there will likely be durability for AMAG in this segment of the market. Further our proprietary scenario analysis suggests that the bear case is largely priced in with a base case NPV for the Makena franchise of ~\$10 per share a best-case scenario (2 year delay for generic Makena) value of \$26 per share and a worst-case scenario (subcutaneous Makena not approvable multiple generics in 2018) of \$5 per share.

ALPHAWISE 
Evidence-based research

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AMAG Pharmaceuticals, Inc. (AMAG.O, AMAG.US)

Biotechnology / United States of America

Stock Rating					Overweight
Industry View					In Line
Price target					\$26.00
Shr price, close (Sep 7, 2017)					\$ 8.70
Mkt cap, curr (mm)					\$65
52 Week Range					\$36.83 - 6.00
Fiscal Year Ending	12/16	12/17e	12/18e	12/19e	
ModelWare EPS (\$)	5.24	4.61	0.66	0.64	
Prior ModelWare EPS (\$)					
P/E	6.6	4.1	28.3	29.4	
Consensus EPS (\$) §	6.00	(1.38)	(1.59)	(0.35)	
Div yld (%)					

Unless otherwise noted, all metrics are based on Morgan Stanley ModelWare framework
 § = Consensus data is provided by Thomson Reuters Estimates
 e = Morgan Stanley Research estimates

QUARTERLY MODELWARE EPS (\$)

Quarter	2016	2017e Prior	2017e Current	2018e Prior	2018e Current
Q1	0.76		2.56a		
Q2	30		20a		
Q3	62		0.34		
Q4	59		0.53		

e = Morgan Stanley Research estimates, a = Actual Company reported data

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to use among OB/GYNs, suggesting launch dynamics likely to improve. In our August 2017 AlphaWise survey of 108 OB/GYNs physicians indicated that they view AMAG's ntrarosa as a positively differentiated option to treat dyspareunia (pain during sex) a market that is currently served by legacy branded intravaginal estrogen products that accounted for >\$1bn in 2016 sales. As has become the new normal for most drug launches we anticipate a gradual launch for ntrarosa with physician awareness, payor decisions and formulary access likely to be early gating factors. However, our AlphaWise survey provides confidence that ntrarosa, which does not contain a black box warning unlike alternative therapies, is poised for long-term success. Over 80% of physicians in our survey view the drug as positively differentiated and anticipate prescribing to ~25% of the relevant patients with dyspareunia at peak. With this profile we believe ntrarosa is likely to take share while growing the market. We see sales of ~\$178mn by 2022, over 40% above current consensus peak of ~\$125mn with sales in our model growing to \$330mn peak in 2030. ntrarosa is the largest piece of our AMAG valuation, accounting for NPV of ~\$12 per share in our model.

Shares also appear to be discounting label expansion for IV iron product

Feraheme. Feraheme has provided a steady backbone of revenue growth for AMAG since its initial approval in 2009. While the drug has recently faced strong competition from Vfor's njectafer, which is approved with a broad label and no black box warning, positive Phase 3 data reported in May 2017 show that Feraheme safety and efficacy in the broader iron deficiency anemia (IDA) population is similar to njectafer with some potential differentiation vs. njectafer's higher rate of hypophosphatemia. We model 15% YoY growth in 2018 while consensus implies 12.5% attrition in minimal growth to an expanded label that could double the addressable market opportunity with an IDA decision expected in February 2018, potentially doubling the addressable market opportunity. We see 2018 sales of \$126mn vs \$119mn consensus.

Cord Blood Registry business provides important durable revenue stream and NPV backbone.

CBR is the world's largest newborn stem cell collection and storage company, storing over 600k preserved umbilical cord blood and tissue stem cell units. Although we forecast modest growth for CBR with revenues rising from \$118mn in 2017 to \$129mn by 2025, we view the durability of this revenue stream favorably as the historical low attrition rates (<1% of units per year) and lack of P/exclusivity provide a stable durable revenue backbone for AMAG. The business represents ~\$10 per share in our model, providing a solid base value for AMAG shares.

Where we could be wrong. It is possible that subcutaneous Makena is not approvable and that multiple generic entrants erode the market more quickly than anticipated, even in our worst-case scenario, resulting in pressure on AMAG shares. If ntrarosa is unable to successfully gain share in the dyspareunia market, sales could lag expectations. A complete response letter (CRL) for Feraheme in February 2018 or unexpected erosion of CBR's business also represent potential downside.

Risk Reward

With the Makena bear case largely priced in, we look ahead to Intrarosa as a growth driver



Source: Thomson Reuters, Morgan Stanley Research

Price Target \$26

We derive our PT from a risk-adjusted sum-of-the-parts (SOP) analysis. We forecast expected revenue/profits for each drug/condition combination. We assume a 9% WACC and no terminal growth to derive our NPV. We then assign a probability factor for each drug/condition to reflect clinical and regulatory risks/timing, sum the risk-adjusted NPVs and add cash in excess of required investment.

Bull \$40

Risk-adjusted SOP

In a best-case scenario Makena generics are delayed by 2 or more years and AMAG is able to rapidly convert the market to subcutaneous Makena following FDA approval in Feb 2018 resulting in peak Makena sales of ~\$570mn. The Intrarosa launch exceeds expectations with quick adoption and minimal payor pushback with greater uptake and peak sales of \$450mn. Feraheme usage in broad DA drives higher-than-anticipated revenue growth.

Base \$26

Risk-adjusted SOP

Makena faces generic competition from one generic upon orphan drug exclusivity expiry in Feb 2018 followed shortly thereafter by introduction of the company's subcutaneous auto-injector. Intrarosa sees a gradual launch that starts to accelerate in 2018 driven by the drug's differentiated attributes and increased physician awareness. We see peak sales of ~\$330mn in 2030. We see peak sales Feraheme label expansion into broad DAs successful driving ~\$60mn of incremental peak revenue.

Bear \$10

Risk-adjusted SOP

In a worst-case scenario multiple Makena generics enter the market and subcutaneous auto-injector Makena never reaches the market. Intrarosa's launch is supported and/or market dynamics change (e.g. black box removed from all local estrogens) that make the product's differentiated appeal less appealing leading to peak sales of less than ~\$100mn. Feraheme does not gain broad

Investment Thesis

■ **Makena bear case is largely priced in.**

While investor focus has been on the anticipated loss of orphan drug exclusivity (ODE) and potential for life cycle extension of Makena AMAG's largest current source of revenue we believe the bear case is largely priced in. Our August 2017 AlphaWise OB/GYN survey shows physicians are positive on the auto-injector with some sense of loyalty to the branded intramuscular Makena while our proprietary scenario analysis shows NPV for the Makena franchise of \$10 per share in our base case \$5 per share in our worst case scenario and \$26 per share in our best case scenario.

■ **Intrarosa is an underappreciated growth driver, with AlphaWise OB/GYN survey showing strong positive differentiation and prescribing intentions.**

Intrarosa a vaginal steroid to treat dyspareunia (pain during sex) is viewed as positively differentiated by over 80% of OB/GYNs in our AlphaWise survey with peak usage expected in ~25% of dyspareunia patients. The lack of a black box warning is a significant positive differentiating factor which we think is likely to drive uptake in patients concerned about the long-term use of estrogen therapies and/or at moderate risk of breast cancer. We see peak sales of ~\$330mn for Intrarosa 3x higher than current consensus peak of ~\$125mn.

■ **CBR and Feraheme provide strong revenue/NPV backbone, while Feraheme label expansion represents upside.**

Cord Blood Registry (CBR) and the Feraheme base business represent a combined ~\$16 per share of NPV in our model. Feraheme label expansion into broad DAs with an FDA decision (PDU A) date in Feb 2018 represents an additional ~\$65mn of sales at peak (\$2 share NPV) which we do not believe is reflected in consensus today.

Key Value Drivers

■ The key valuation drivers are commercial

ntarosa, eraheme and the Cord Blood Registry (CBR) service, as well as pipeline advancement and business development.

Potential Catalysts

- 3Q17 earnings in late Oct/early Nov
- Weekly/monthly prescription tracking for ntrarosa
- FDA decision (PDU A) for eraheme label expansion in Feb 2018
- FDA decision (PDU A) for subcutaneous Makena in Feb 2018
- Makena orphan drug exclusivity expiry in Feb 2018

Risks to Achieving Price Target

- Makena life cycle extension strategy fails and multiple Makena IM generics are introduced, leading to faster-than-anticipated erosion and sales that are materially below expectations
- eraheme label expansion does not materialize; sales fall short of expectations
- Pipeline does not advance and business development is value destructive

Key Investment Levers for AMAG Pharmaceuticals

Overview: AMAG Pharmaceuticals is a biopharmaceutical company that specializes in women's health prescription drugs and services as well as hematology products. Primary value drivers for the company include three marketed drugs in Makena (medroxyprogesterone acetate) and recently launched ntrarosa as well as the Cord Blood Registry (CBR) stem cell collection and storage service for newborns. We believe that the bear case for Makena (AMAG's largest current revenue source which is facing the expiration of orphan drug exclusivity in February 2018) is largely reflected in shares at these levels. Supported by durable revenue streams in ntrarosa and CBR we believe that the market is overlooking a promising growth driver in ntrarosa, a non-estrogen treatment for postmenopausal women experiencing dyspareunia (pain during sex) that our AlphaWise survey suggests is highly positively differentiated and likely to take ~25% of the \$1bn market for these treatments. While we expect a gradual launch for ntrarosa as the drug gains broader awareness and formulary access we see the potential for peak sales to exceed \$300mn (approximately 3x current consensus) and would encourage investors to use any weakness around the initial launch as an entry point.

Winter is coming for Makena, but AlphaWise survey and proprietary scenario analysis suggest the bear case is already largely priced in. Orphan drug exclusivity for intramuscular Makena (a progesterone injection used to reduce the risk of recurrent preterm birth) expires on February 3, 2018. We anticipate at least one generic entrant into the market following exclusivity expiration as does the company. We believe AMAG will launch their own authorized generic intramuscular Makena sacrificing price to maintain share of the market. Our diligence supported by our proprietary AlphaWise survey of 108 US OB/GYNs suggests that physicians would prefer the Makena subcutaneous auto-injector should it gain approval and that there is some sense of brand loyalty to branded intramuscular Makena suggesting there will likely be some durability for AMAG in this segment of the market. See the [AlphaWise survey supports SC Auto-injector uptake if approved and a surprising level of branded M Makena durability](#) section of this report for more detail on the Makena portion of our AlphaWise survey.

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