Aegerion Pharmaceuticals

Collins Stewart
Independent thinking

US | Biotechnology | AEGR

September 28, 2011

Lomitapide U.S. and E.U. HoFH Filings Now On-Tap for 1Q12

Recommendation	**BUY**
Price	**$15.08**
Target	**$27.00**

■ **Investment Thesis - Lomitapide filings on tap for 1Q12, post inclusion of longer-term stability data:**
This morning, AEGR reiterated its E.U. filing strategy for lomitapide in HoFH following discussions with the EMA regarding the acceptability of the single-arm P3 29-patient study. However, the company has delayed its expected E.U. filing timeline to 1Q12 (vs. YE11 previously) following a request by E.U. authorities for additional stability data on the lomitapide bulk drug substance. AEGR has also decided to push its U.S. filing to 1Q12 (vs. YE11) to ensure the quality of the NDA filing with the goal of securing a first-round approval. Following discussions with management, we view the need for additional stability data as a check-the-box event (*see below for details*). We currently model for 4Q12 and YE12 lomitapide approvals in the U.S. and E.U., respectively. With the possibility of a 6-month priority review in the U.S., we believe AEGR can still meet these approval timelines. In the near-term, the potential receipt of a Temporary Authorization for Use (ATU) in France by YE11 with the announcement of higher-than-expected pricing (we model for $225K/year in the E.U.) could provide upside for AEGR shares.

■ **AEGR negotiates a stability package with the EMA:**
While the EMA typically requires 12-month stability data on 3 different drug batches, AEGR management noted that the agency has approved some orphan drugs with less data. AEGR does not yet have data to meet the EMA 12-month/3-batch requirement but has come to agreement with the EMA on a satisfactory data point (AEGR has the agreement in writing), which requires additional lomitapide data to what is currently in-hand. Given that the company has 36-month stability data on one batch of lomitapide, which demonstrates that the drug maintains its efficacy over time, AEGR does not view the additional stability data as a risk, calling it a "clock watching exercise". AEGR also noted that the FDA stability requirements are less stringent than the EMA.

■ **Additional details on lomitapide HoFH regulatory filings:**
AEGR continues to be on-track to complete the required pre-clinical lomitapide studies by YE11, in time for the 1Q12 regulatory submissions (includes a tQT study, a drug-drug interaction study, etc.). The lomitapide P3 78-week data continues to be expected by YE11 and will be submitted separately to U.S. and E.U. regulatory authorities at some point after the NDA and MAA fillings.

See Page 2 for Valuation & Risks

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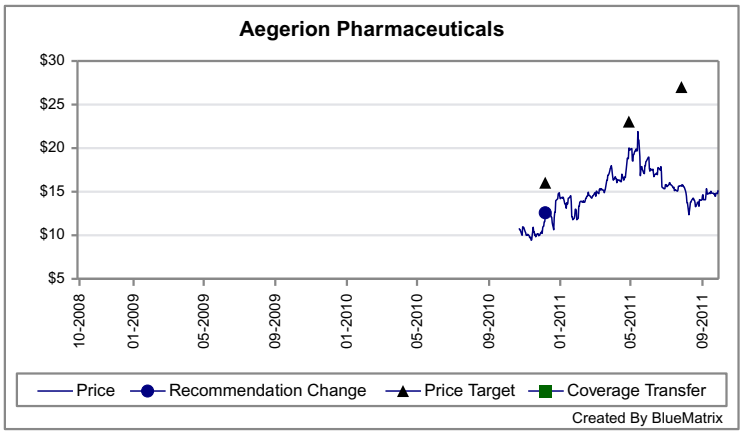
Valuation & Risks

Our 12-month PT of $27 is based on 35x our fully taxed, fully diluted FY15 GAAP EPS estimate of $1.90 discounted back to YE12 at 30%. The primary investment risks for AEGR include: 1) lomitapide clinical development risk (particularly regarding potential new safety signals in the ongoing Phase 3 trial); 2) lomitapide regulatory risk; 3) commercial risk, including the possibility that lomitapide does not achieve peak commercial revenue estimates in our model (due to market size, penetration rates, and/or pricing); 4) potential product competition; and 5) financing risk.

Important Disclosure / Disclaimer Information

Other Public Companies Mentioned in this Report

Company	Ticker	Price	Recommendation
Aegerion Pharmaceuticals	AEGR	$15.08	BUY



Ticker	Date	Action	Prior Rating	Current Rating	Price	Target Price
AEGR	2011-07-27	Raising Target Price	BUY	BUY	$15.76	$27.00
AEGR	2011-04-28	Raising Target Price	BUY	BUY	$20.00	$23.00
AEGR	2010-12-6	Initiation of Coverage	NA	BUY	$12.57	$16.00

Collins Stewart LLC Ratings

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BUY: Improving fundamentals and/or identifiable catalysts in place expected to cause stock to outperform its industry

NEUTRAL: Company's fundamental backdrop suggest stock should perform in line with industry

SELL: Deteriorating fundamentals and/or identifiable catalysts in place expected to cause stock to underperform its industry

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Hold	42%	0%
Sell	4%	0%

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