Aegerion Pharmaceuticals

AEGR : NASDAQ : US$14.88

BUY

Target: US$24.00

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COMPANY STATISTICS:

Market Cap (M):	US$313.43
52-week Range:	US$9.00 - 25.92

EARNINGS SUMMARY:

FYE Dec		2010A	2011E	2012E
Revenue:		0.0	0.0	195.1
EPS:		(5.07)	(2.09)	6.97
Revenue:	Q1	-	0.0A	-
	Q2	0.0	0.0A	-
	Q3	0.0	0.0	-
	Q4	0.0	0.0	-
Total		0.0	0.0	195.1
EPS:	Q1	-	(0.39)A	-
	Q2	(2.77)	(0.49)A	-
	Q3	(3.61)	(0.53)	-
	Q4	(0.92)	(0.50)	-
Total		(5.07)	(1.92)	5.90

SHARE PRICE PERFORMANCE:

Source: Interactive Data Corporation

COMPANY DESCRIPTION:

Aegerion Pharmaceuticals is an emerging biopharmaceutical company focused on novel therapeutics to treat severe but rare genetic lipid disorders. The company's lead drug, lomitapide, is currently in pivotal development for homozygous familial hypercholesterolemia, characterized by very high LDL levels that do not respond well to statin therapy.

All amounts in US$ unless otherwise noted.

Life Sciences -- Biotechnology

NOTES FROM THE ROAD

Investment recommendation

Reiterate BUY, $24 target on lomitapide potential as best-in-class HoFH drug. Lomitapide is AEGR's Phase 3 drug for HoFH, a rare genetic disease that causes high LDLs. We think lomitapide is the best-in-class HoFH drug vs. ISIS/SNY's Phase 3 mipomersen with tolerability and efficacy. AEGR will submit an NDA/MAA in Q4/11 for H2/12 approval. Our $24 target is based on a pNPV analysis.

Investment highlights

- **AEGR September EMA, Netherlands rappateur meetings to give clarity on EU filing strategy; we estimate MAA filing in Q1/12.** While lomitapide does not have orphan status in the EU, it has new EU method of use patent coverage to 2025. We think lomitapide will be approved in the EU near the end of 2012.
- **SNY/ISIS mipomersen ESC extension data highlights complex safety, tolerability issues – we think worse than lomitapide's.** Mipo extension data from the HoFH, HeFH and severe HeFH Phase3 trials showed interim ~50% discontinuation rate, but little granularity on side effects. We think this highlights mipo's problematic vs. lomitapide's superior tolerability.
- **We think mipo is ahead in EU, but both drugs neck and neck in race to the US; drug with best profile will win the market.** SNY expects to submit mipo's NDA in Q4/11. We think AEGR will file its NDA by the end of Q1/12 and expect that FDA will give the drugs back-to-back advisory committee meetings and approve them around the same time. We think any lead mipo has in the US will have no impact on lomitapide's US sales, but an EU head start may slow lomitapide's EU uptake.

AEGR EU REGULATORY STRATEGY AND FRENCH ATU ON TRACK

September meetings with EMA and Rappateur scheduled. Aegerion management noted yesterday in investor meetings that they already have meetings scheduled in September with EMA and its MAA rappateur country The Netherlands to discuss European regulatory strategy for lomitapide. Drug background dossiers due at least 30 days before the meeting have already been submitted. Aegerion plans to submit a centralized application for Europe followed by country by country pricing dossiers after approval. We believe that Aegerion will file the lomitapide for EU regulatory approval by the end of Q1/12, relatively concurrent to its US NDA filing. While Aegerion is targeting Q4/11 filing in the US and EU, we think the company is willing to slightly delay filing in order to ensure the highest possibly quality filing.

75 potential patients for French ATU already identified. Aegerion has already identified 75 patients in France that meet their expected lomitapide label requirement. They have also liased with the four appointed lipidologist experts that will manage the lomitapide ATU program, including determining the drug price. Aegerion indicated that conversations with this group have already suggested that they can charge between $200,000 and $400,000 per patient per year. We note that this range was higher than the $150,000 to $300,000 that Aegerion previously estimated and may be in part because apharesis is more widely used in Europe than in the US. As a result, lomitapide may have strong pharmaco-economic arguments in the EU as a result of apharesis sparing.

We expect European approval in late 2012, likely after mipomersen approval. Mipomersen is a Phase 3 antisense treatment for HoFH that was first developed by ISIS and partnered with Genzyme, now a division of Sanofi. Sanofi submitted the mipo MAA at the end of July, and we expect mipo to be approved in mid 2012, likely about six months ahead of lomitapide. We believe that European HoFH patient groups are better organized and that European HoFH patient registries are better established. A European head start for mipo could slow lomitapide's adoption in Europe. However, Aegerion plans to have at least 1000 HoFH potential patients identified in the EU by the time of lomitapide's EU launch.

MIPO LONG TERM EXTENSION STUDY: 50% DROPOUTS SO FAR REFLECT LIKELY POOR TREATMENT TOLERABILITY

We think mipo's long-term extension interim ~50% discontinuation rate reveals serious tolerability issues. The extension study enrolled 141 patients with mixed FH disease types from three mipo Phase 3 trials (HoFH, HeFH, and severe HeFH). ISIS reported at ESC that 69 of the 141 (49%) have discontinued treatment (Figure 1) to date in the first year of follow-up. We think this rate is unusually high given the dropouts occurred during a study extension phase and that study patients suffered from a life-threatening orphan disease (HoFH) with no good drug treatment options and have high mortality rates. Two year efficacy data show durable statistically singificant ~30% LDL-C and ApoB reduction and 15-20% Lp(a) reduction, though we note LDL-C and ApoB reduction error bars are quite wide (Figure 2) and that no mean baseline values were given. We think that breakout of efficacy measures by patient population may also be important to consider.

Little detail on discontinuations provided; we think many were likely related to LFTs elevations and and injection site reactions. ISIS provided little detail on discontinuations or adverse events, except to suggest side effects are expected when patients are rolled over from placebo to 200 mg mipo. We note that the placebo controlled blinded portions of the Phase 3 trials have shown significant discontinuations due to LFT elevations as well as injection site reactions. Mipo investigators we have spoken to have also noted that injection site reactions in particular have made it difficult for patients to continue on the drug and have led to a significant number of dropouts. The extension trial design did not allow for dose titration, which would likely be done in a clinical setting and may have improved tolerability. We expect ISIS to release more data detail including additional data on the 72 patients remaining in the long term extension study.

Peak median change in liver fat for mipo 12% vs. 5.6% (HoFH alone) for lomitapide. Extension data suggests mipo peak median change in liver fat from baseline of 12% at week 52 (Figure 3). No baseline liver fat levels were disclosed. Keeping in mind the lomitapide Phase 3 trial was in HoFH patients only, we note lomitapide median change from baseline in liver fat was lower at 5.6% at week 26 and 4.4% at week 56. ISIS argues that data detail suggest liver fat elevation in mipo-treated patients is related to and mediated by ApoB-mediated reduction. However, ISIS has not yet released data showing a mathematical correlation between Apo-B mediated LDL-C reduction and elevation in liver fat percentages. ISIS noted there still not have been any mipo discontinuations due to Hy's law or bilirubin elevations.

We think that mipo may prove to have worse treatment related liver fat elevations than lomitapide. We would expect that the mixed patient population would have had a lower baseline LDL than the HoFH population in the lomitapide pivotal study. Given overall treatment effect trends, we would also expect the absolute and percentage relative LDL reduction in the lomitapide patients to be higher than that seen in mipo extension data. If this is the case and mipo patients still show meaningfully higher liver fat elevations, we think mipo treatment will generally be associated with worse liver fat elevations than lomitapide.

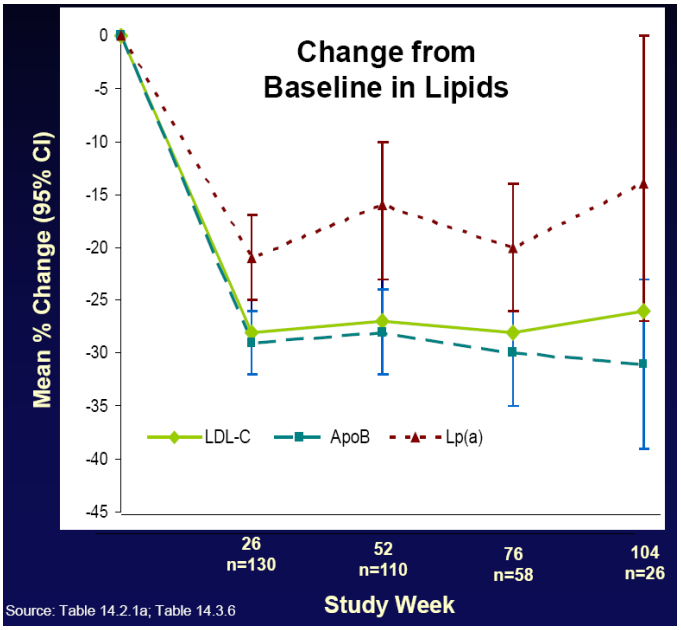
We also note inconsistent rise in patient counts between week 52 and 76 measures. The number of patients completing 76 weeks of mipo treatment was 37, an increase from the 30 patients completing 30 weeks of treatment. We would expect all 37 patients completing 76 weeks of treatment to have also completed 52 weeks of treatment. While decreases in the liver fat percent change from baseline were observed between weeks 52, 76 and 104, we think this data may be confounded by drop out bias.

Figure 1: ISIS mipomersen long term extension in HoFH, HeFH, and severe HeFH: interim patient data

	n	%
Enrolled	141	--
Discontinued	69	49%
Completed	17	12%
Continuing treatment	55	39%

Source: Kastelein, J. [University of Amsterdam] ISIS webcast. 12 September 2011. "Will Further Therapies Help to Further Lower LDL Cholesterol?"

Figure 2: ISIS mipomersen long term extension in HoFH, HeFH, and severe HeFH: interim efficacy data



Source: Kastelein, J. [University of Amsterdam] ISIS webcast. 12 September 2011. "Will Further Therapies Help to Further Lower LDL Cholesterol?"

Figure 3: ISIS mipomersen long term extension in HoFH, HeFH, and severe HeFH: interim liver fat data

Percent Change from Baseline in Liver Fat		
Week	n	Median (IQR)
26	60	5 (1, 17)
52	30	12 (2, 22)
76	37	6 (2, 13)
104	22	5 (3, 14)

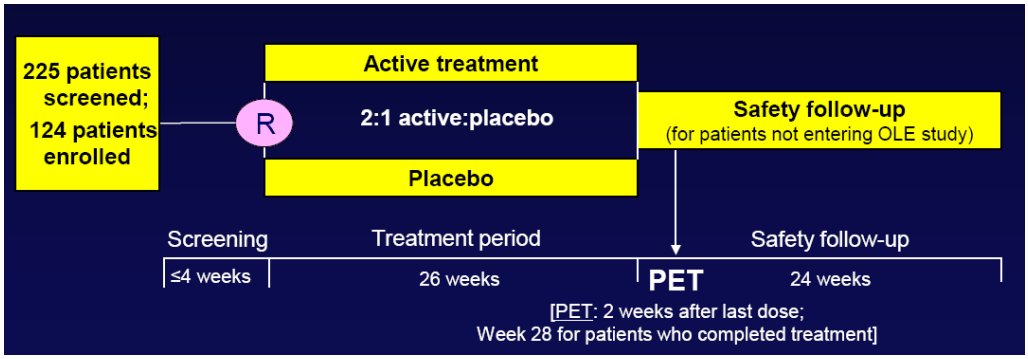
Source: Kastelein, J. [University of Amsterdam] ISIS webcast. 12 September 2011. "Will Further Therapies Help to Further Lower LDL Cholesterol?"

Mipomersen Phase 3 data in HeFH patients

Incremental Phase 3 HeFH mipomersen (mipo) data at ESC shows consistent response but with notable outliers (Figure 4). ISIS also presented incremental data from its Phase 3 mipo trial in HeFH last week at the European Society of Cardiology (ESC) meeting. Recall the mipo Phase 3 HeFH trial was a randomized, placebo-controlled study enrolling 124 patients. The trial hit its primary endpoint, with mipo-treated patients experiencing an average 28% LDL-C reduction vs. 5% increase for placebo ($p<0.001$, Figure 5). Mipo-treated patients had an average 150 mg/dL LDL-C level at baseline and experienced an average 46 mg/dL LDL-C reduction. We note a handful of mipo-treated patients had markedly elevated LDL-C at 28 weeks (Figure 6).

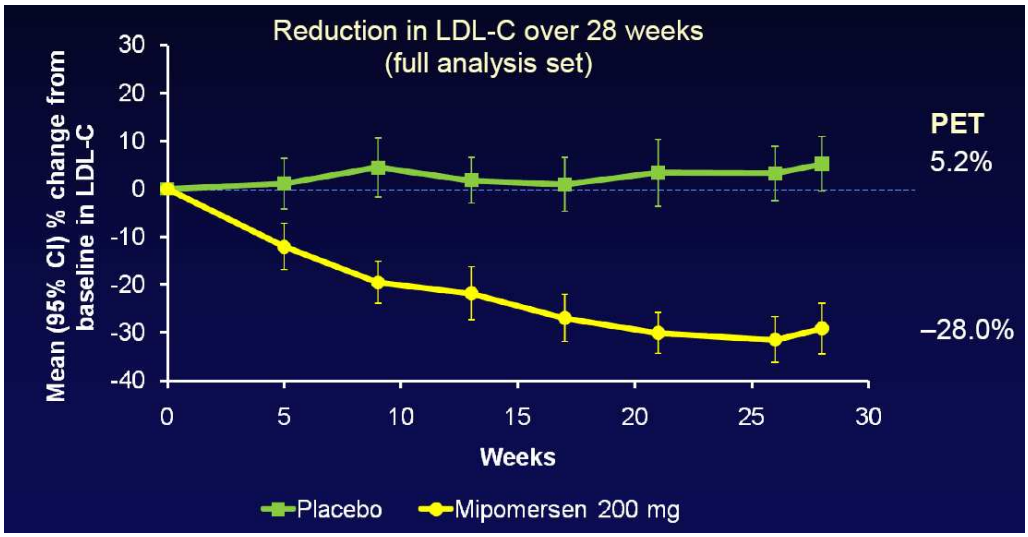
We think the ~12% discontinuation rate seen in the Phase 3 HeFH mipo trial may be misleadingly low (see previous discussion on long term extension data). Of the mipo-treated patients, 10 (12%) discontinued treatment. All but one discontinuation was related to adverse events. Adverse events leading to the discontinuations included elevations in liver transaminases (3), injection site reactions (2), non-cardiac chest pain (2), injection site reactions and flu-like symptoms (1), and constipation (1).

Figure 4: ISIS mipomersen Phase 3 in HeFH trial design



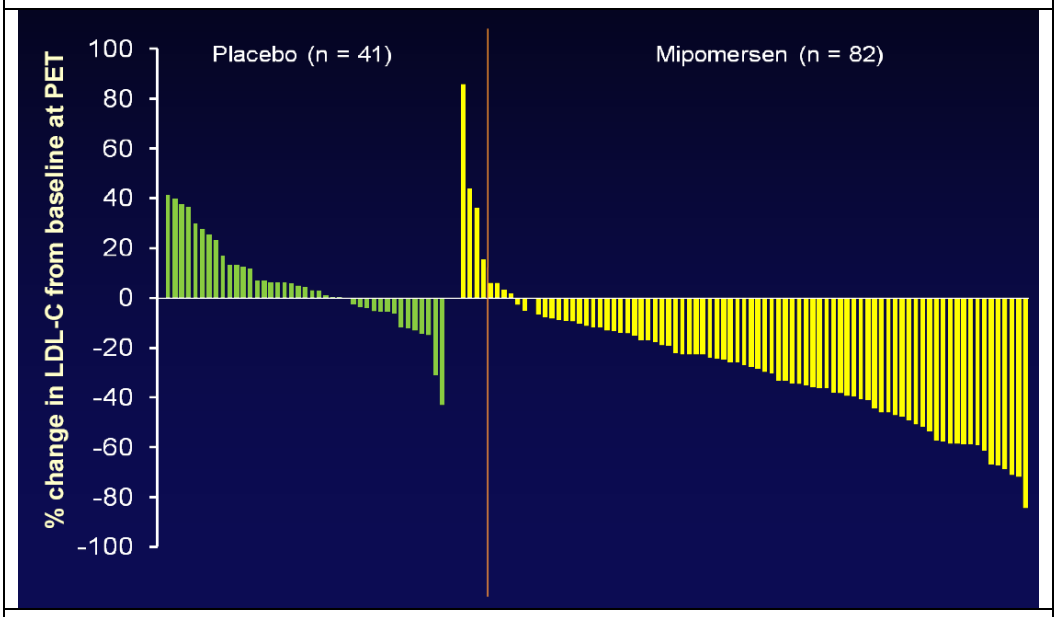
Source: Company reports

Figure 5: ISIS mipomersen Phase 3 in HeFH trial: mean LDL-C % change from baseline. PET = primary efficacy endpoint, 2 weeks after final dose.



Source: Company reports

Figure 6: ISIS mipomersen Phase 3 in HeFH trial: Distribution of LDL-C % change from baseline. PET = primary efficacy endpoint, 2 weeks after final dose.



Source: Company reports

Figure 7: AEGR upcoming catalysts

Expected date	Drug/Program	Item	Impact
Q3/11	Lomitapide in HoFH	78-week safety data	+
Q4/11	Lomitapide in HoFH	NDA filing	+
H1/12	Lomitapide in HoFH	Advisory committee meeting	++

Source: Company reports, Canaccord Genuity estimates

Figure 8: AEGR pNPV

Drug name	Indication	Status	Launch	Success	Sales (US$m)	Royalty	Profitability	NPV (US$)
lomitapide	HoFH - genotype diagnosis	Phase 3	2012	70%	89.0	90%	75%	6.72
lomitapide	HoFH - phenotype diagnosis	Phase 3	2012	60%	187.3	90%	75%	12.12
lomitapide	HoFH - functional diagnosis	Phase 3	2012	33%	140.5	90%	75%	5.00
							Total	**23.85**

Source: Canaccord Genuity estimates

Figure 9: AEGR P&L

	2010A	Q1/11A	Q2/11A	Q3/11E	Q4/11E	2011E	2012E	2013E
Lomitapide - US	-	-	-	-	-	-	98.5	169.7
Lomitapide - EU/SA	-	-	-	-	-	-	96.6	164.8
Total product revenues	**-**	**-**	**-**	**-**	**-**	**-**	**195.1**	**334.5**
Revenue from royalties and royalty rights	-	-	-	-	-	-	-	3.0
Revenues from license agreements	-	-	-	-	-	-	-	0.5
Total revenues	**-**	**-**	**-**	**-**	**-**	**-**	**195.1**	**338.0**
Cost of goods sold	**-**	-	-	-	-	**-**	19.5	33.4
Gross Profit	**-**	**-**	**-**	**-**	**-**	**-**	**175.6**	**304.5**
R&D expense	7.6	3.3	5.1	5.5	7.0	20.9	20.0	20.0
SG&A expense	5.9	3.5	3.2	3.5	4.5	14.7	20.0	20.0
Other operating expense	-	-	-	-	-	-	-	-
Total operating expense	**13.6**	**6.8**	**8.3**	**9.0**	**11.5**	**35.6**	**40.0**	**40.0**
Operating income	**(13.6)**	**(6.8)**	**(8.3)**	**(9.0)**	**(11.5)**	**(35.6)**	**135.6**	**264.5**
(interest expense)	(2.4)	(0.1)	(0.3)	(0.4)	(0.6)	(1.4)	(1.6)	(1.6)
Interest income	0.1	0.1	0.1	0.0	0.1	0.2	0.2	0.2
Change in fair value warrant liability	(0.4)	-	-	(1.8)	1.1	(0.8)	-	-
Other non-operating income (expense)	0.2	-	-	0.0	0.2	0.3	-	-
Pre-tax income	**(16.0)**	**(6.8)**	**(8.6)**	**(11.2)**	**(10.7)**	**(37.4)**	**134.2**	**263.1**
Income tax expense (benefit)	(1.8)	-	-	-	-	-	1.8	6.3
Accretion of Dividends	8.8	-	-	-	-	-	-	-
Net income	**(23.0)**	**(6.8)**	**(8.6)**	**(11.2)**	**(10.7)**	**(37.4)**	**132.4**	**256.8**
Basic EPS	**(5.07)**	**(0.39)**	**(0.49)**	**(0.53)**	**(0.50)**	**(1.92)**	**5.90**	**10.90**
Diluted EPS	**(5.07)**	**(0.39)**	**(0.49)**	**(0.53)**	**(0.50)**	**(1.92)**	**5.90**	**10.90**
Basic shares outstanding	4.5	17.6	17.7	21.2	21.4	19.5	22.4	23.6
Diluted shares outstanding	4.5	17.6	17.7	21.2	21.4	19.5	22.4	23.6

Source: Company reports and Canaccord Genuity estimates

Investment risks

Development risk -- Previous clinical trials have shown problematic safety/tolerability

Previous higher dose non-titration lomitapide trials have shown rates of liver fat and liver enzyme elevations that were deemed unacceptable by clinicians for treatment of a broad patient population with moderately elevated LDL levels. Additionally, GI tolerability in these trials was very poor. Although safety and tolerability data to date is significantly better due to lower dose and titration, some patients still experience side effects that could reach problematic levels, albeit we think the data thus far suggests the drug, at its current dose and treatment schedule, will be a safe and relatively well-tolerated therapy.

Regulatory risk -- Despite unmet need, a single, open-label, uncontrolled Phase 3 trial may not be sufficient to secure FDA or European approval

The FDA normally requires two randomized placebo-controlled pivotal trials for drug approval. Aegerion plans to submit the lomitapide NDA with data from a single uncontrolled open-label Phase 3 trial with a small number of patients. Also, the company does not have a Special Protocol Assessment (SPA) from the FDA, although it has had extensive discussions with the agency as part of the SPA process.

Commercial risk -- Lomitapide may not have as large a market as estimated, since current market assumptions are relatively new and as yet unproven

While there is little dispute on the number of HoFH patients with definitive genotypic diagnosis (600-1,000 patients worldwide), there is controversy over the additional number of HoFH patients whose exact genetic mutations have not yet been identified. Lomitapide may not be approved or reimbursed for patients with LDL levels characteristic of HoFH but without genotypic, cell culture or familial history diagnosis. Furthermore, Aegerion may face pricing pressure on lomitapide's orphan pricing. As such, the exact potential patient population and market size for lomitapide is uncertain.

Competitive risk -- Lomitapide may compete with Isis' mipomersen, which is partnered with Genzyme, a large-cap biotechnology with an established orphan business unit.

We believe that lomitapide may be approved for HoFH around the same time as Isis Pharmaceuticals' mipomersen, partnered with Genzyme. We note that Genzyme has pioneered the orphan disease business model and has considerable experience at launching and commercializing orphan drugs. However, we think that lomitapide still has a very good chance at becoming the gold standard HoFH treatment based on its superior efficacy, safety and ease of use, as well as its (at worst) comparable tolerability.

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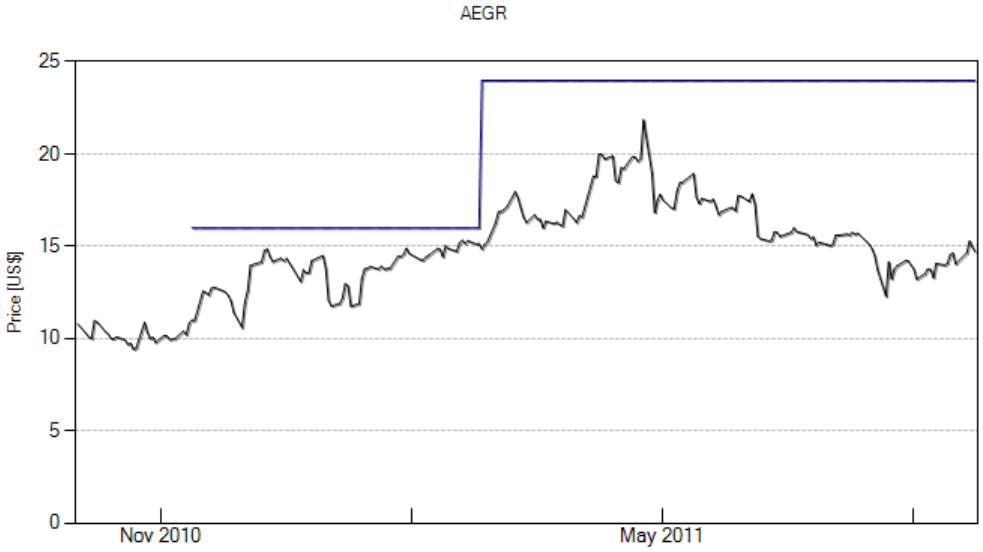
Price Chart:*



	Date	Analyst	Rating	Target Price		Date	Analyst	Rating	Target Price
1)	12/02/2010	Baral	Buy	16.00	2)	03/16/2011	Baral	Buy	24.00

*Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

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(as of 7 September 2011)

	Coverage Universe		IB Clients
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Speculative Buy	83	10.7%	62.7%
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Sell	13	1.7%	23.1%
	777	100%	

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Company	Disclosure
Aegerion Pharmaceuticals	1A, 2, 3, 5, 7

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