

Today's Changes	Annual EPS	Annual Revenue	Rating/Target
	2011E \$(1.92) from \$(2.09) 2012E \$5.21 from \$6.97	No change	No change

## Aegerion Pharmaceuticals

AEGR : NASDAQ : US\$14.62

**BUY**

**Target: US\$24.00**

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### COMPANY STATISTICS:

Shares Out (M): 21.06  
Market Cap (M): US\$307.96  
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)	(1.92)	5.21

Revenue:	Q1	-	0.0A	-
	Q2	0.0	0.0A	-
	Q3	0.0	0.0A	-
	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)	(0.48)A	-
	Q4	(0.92)	(0.56)	-
Total		(5.07)	(1.92)	5.21

### 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

## Q3/11: LOMITAPIDE NDA, MMA FILING ON TRACK FOR Q1/12

### 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 in terms of tolerability and efficacy vs. ISIS/SNY's Phase 3 mipomersen. AEGR will submit lomitapide's NDA/MAA Q1/12, and we expect FDA approval Q3/12. Our \$24 target is based on a pNPV analysis.

### Investment highlights

- **EPS of \$(0.48) misses consensus of \$(0.45), beats our estimate of \$(0.63).**
- **Positive pre-NDA, MMA meetings held; submissions on track for Q1/12.** Stability testing is the only outstanding issue for MMA filing. We expect lomitapide FDA approval Q3/12.
- **Lomitapide manufacturing detail.** AEGR currently has a single manufacturer and is in the process of finding another. Although each lomitapide manufacturing lot produces enough drug for several years, AEGR plans to run lots every few quarters to maintain manufacturer competency.
- **Upcoming lomitapide catalysts:** Q4/11E: 78-week safety data and French ATU pricing; mid-2012E: FDA advisory committee meeting; Q3/12E: FDA approval.

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**Figure 1: AEGR upcoming catalysts**

Expected date	Drug/Program	Item	Impact
Q4/11	Lomitapide in adult HoFH	78-week safety data	++
Q4/11	Lomitapide in familial chylomicronemia	Initiate Phase 3	+
Q1/12	Lomitapide for adult HoFH	NDA and MMA filing	+
Mid-2012	Lomitapide in adult HoFH	Advisory committee meeting	+++
Q3/12	Lomitapide in adult HoFH	FDA approval	+++
H1/13	Lomitapide for pediatric HoFH	Initiate Phase 3	+

Source: Company reports, Canaccord Genuity estimates

**Figure 2: 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
<b>Total</b>								<b>23.85</b>

Source: Canaccord Genuity estimates

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Figure 3: AEGR P&amp;L

	2010A	Q1/11A	Q2/11A	Q3/11A	Q4/11E	2011E	2012E	2013E
Lomitapide - US	-	-	-	-	-	-	98.5	169.7
Lomitapide - EU/SA	-	-	-	-	-	-	96.6	164.8
<b>Total product revenues</b>	-	-	-	-	-	-	<b>195.1</b>	<b>334.5</b>
Revenue from royalties and royalty rights	-	-	-	-	-	-	-	3.0
Revenues from license agreements	-	-	-	-	-	-	-	0.5
<b>Total revenues</b>	-	-	-	-	-	-	<b>195.1</b>	<b>338.0</b>
Cost of goods sold	-	-	-	-	-	-	19.5	33.4
<b>Gross Profit</b>	-	-	-	-	-	-	<b>175.6</b>	<b>304.5</b>
R&D expense	7.63	3.3	5.1	7.1	7.0	22.5	28.0	30.0
SG&A expense	5.92	3.5	3.2	3.5	4.5	14.7	28.0	30.0
Other operating expense	-	-	-	-	-	-	-	-
<b>Total operating expense</b>	<b>13.6</b>	<b>6.8</b>	<b>8.3</b>	<b>10.6</b>	<b>11.5</b>	<b>37.2</b>	<b>56.0</b>	<b>60.0</b>
<b>Operating income</b>	<b>(13.6)</b>	<b>(6.8)</b>	<b>(8.3)</b>	<b>(10.6)</b>	<b>(11.5)</b>	<b>(37.2)</b>	<b>119.6</b>	<b>244.5</b>
(interest expense)	(2.4)	(0.1)	(0.3)	0.4	(0.6)	(0.6)	(1.6)	(1.6)
Interest income	0.1	0.1	0.1	-	0.1	0.2	0.2	0.2
Change in fair value warrant liability	(0.4)	-	-	-	-	-	-	-
Other non-operating income (expense)	0.2	-	-	-	0.2	0.2	-	-
<b>Pre-tax income</b>	<b>(16.0)</b>	<b>(6.8)</b>	<b>(8.6)</b>	<b>(10.1)</b>	<b>(11.8)</b>	<b>(37.4)</b>	<b>118.2</b>	<b>243.1</b>
Income tax expense (benefit)	(1.8)	-	-	-	-	-	1.8	6.3
Accretion of Dividends	8.8	-	-	-	-	-	-	-
<b>Net income</b>	<b>(23.0)</b>	<b>(6.8)</b>	<b>(8.6)</b>	<b>(10.1)</b>	<b>(11.8)</b>	<b>(37.4)</b>	<b>116.4</b>	<b>236.8</b>
<b>Basic EPS</b>	<b>(5.07)</b>	<b>(0.39)</b>	<b>(0.49)</b>	<b>(0.48)</b>	<b>(0.56)</b>	<b>(1.92)</b>	<b>5.21</b>	<b>10.10</b>
<b>Diluted EPS</b>	<b>(5.07)</b>	<b>(0.39)</b>	<b>(0.49)</b>	<b>(0.48)</b>	<b>(0.56)</b>	<b>(1.92)</b>	<b>5.21</b>	<b>10.10</b>
Basic shares outstanding	4.5	17.6	17.7	21.1	21.3	19.4	22.3	23.5
Diluted shares outstanding	4.5	17.6	17.7	21.1	21.3	19.4	22.3	23.5

Source: Company reports and Canaccord Genuity estimates

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Figure 4: Lomitapide sales forecast

Sales forecasts	2012E	2013E	2014E	2015E
<u>US Genotype Diagnosed HoFH</u>				
# US pts	315	323	331	339
growth rate (increasing diagnosis/survival)	2.5%	2.5%	2.5%	2.5%
Estimated lomitapide market penetration	75.0%	90.0%	95.0%	95.0%
# of US HoFH patients on lomitapide	236	291	315	322
US lomitapide revenue per patient (3% yoy \$ increase)	\$150,000	\$154,500	\$159,135	\$163,909
US genotype HoFH lomitapide revenues to Aegerion	\$35,458,594	\$44,922,492	\$50,061,750	\$52,852,693
<u>EU/SA Genotype Diagnosed HoFH</u>				
# EU pts	309	314	318	323
growth rate (increasing diagnosis/survival)	1.5%	1.5%	1.5%	1.5%
Estimated market penetration	75.0%	90.0%	95.0%	95.0%
# of EU HoFH patients on lomitapide	232	282	302	307
EU lomitapide revenue per patient (3% yoy \$ increase)	\$150,000	\$154,500	\$159,135	\$163,909
EU/SA genotype HoFH lomitapide revenues to Aegerion	\$34,770,094	\$43,620,473	\$48,136,525	\$50,324,330
<u>US Inheritance Pattern/Fibroblast Assay FH</u>				
# US pts	1,051	1,077	1,104	1,131
growth rate (increasing diagnosis/survival)	2.5%	2.5%	2.5%	2.5%
Estimated lomitapide market penetration	25.0%	45.0%	55.0%	60.0%
# of US HoFH patients on lomitapide	263	485	607	679
US lomitapide revenue per patient (3% yoy \$ increase)	\$150,000	\$154,500	\$159,135	\$163,909
US Lomitapide IP/FA Revenues	\$39,398,438	\$74,870,821	\$96,610,395	\$111,268,827
<u>EU/SA Inheritance Pattern/Fibroblast Assay FH</u>				
# EU/SA pts	1,030	1,046	1,061	1,077
growth rate (increasing diagnosis/survival)	1.5%	1.5%	1.5%	1.5%
Estimated lomitapide market penetration	25.0%	45.0%	55.0%	60.0%
# of EU/SA HoFH patients on lomitapide	258	471	584	646
EU/SA lomitapide revenue per patient (3% yoy \$ increase)	\$150,000	\$154,500	\$159,135	\$163,909
EU/SA lomitapide IP/FA Revenues	\$38,633,438	\$72,700,789	\$92,895,049	\$105,945,959
<u>US Functional FH</u>				
# US pts	1,576	1,615	1,656	1,697
growth rate (increasing diagnosis/survival)	2.5%	2.5%	2.5%	2.5%
Estimated lomitapide market penetration	10.0%	20.0%	25.0%	30.0%
# of US HoFH patients on lomitapide	158	323	414	509
US lomitapide revenue per patient (3% yoy \$ increase)	\$150,000	\$154,500	\$159,135	\$163,909
US lomitapide Functional Revenues	\$23,639,063	\$49,913,880	\$65,870,724	\$83,451,620
<u>EU/SA Functional FH</u>				
# EU/SA pts	1,545	1,569	1,592	1,616
growth rate (increasing diagnosis/survival)	1.5%	1.5%	1.5%	1.5%
Estimated lomitapide market penetration	10.0%	20.0%	25.0%	30.0%
# of EU/SA HoFH patients on lomitapide	155	314	398	485
EU/SA lomitapide revenue per patient (3% yoy \$ increase)	\$150,000	\$154,500	\$159,135	\$163,909
EU/SA lomitapide IP/FA Revenues	\$23,180,063	\$48,467,193	\$63,337,533	\$79,459,469

Source: 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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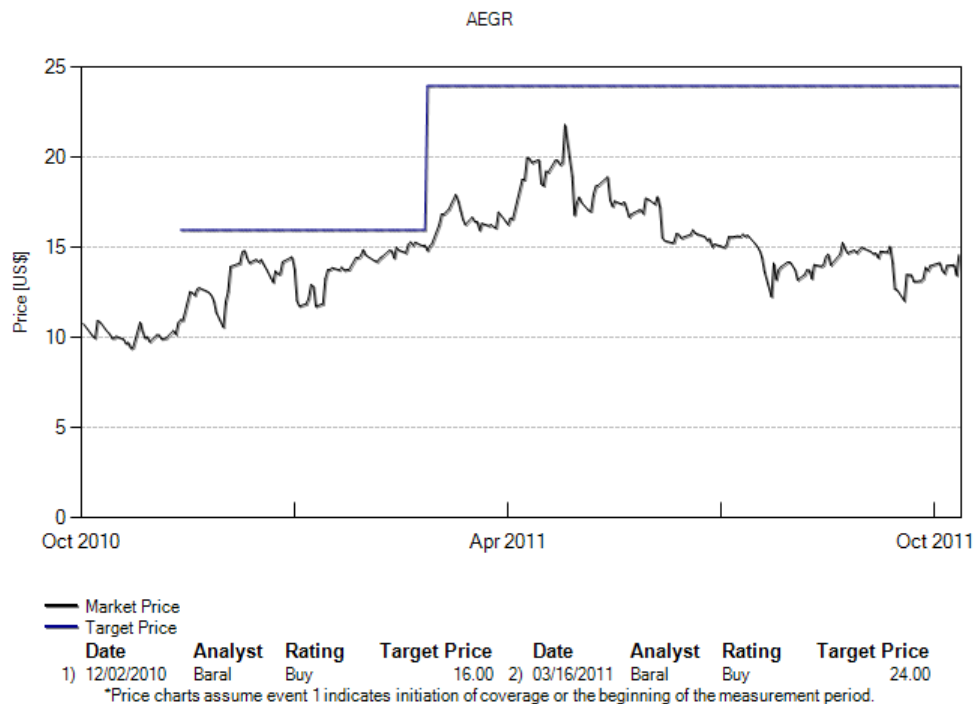
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(as of 3 October 2011)

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	801	100%			

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