# Aegerion Pharmaceuticals Collins Stewart

Independent thinking

US | Biotechnology | AEGR

## **Lomitapide 1Q12 Filings On-Track**

Fiscal Year Ends: Dec		2010A	2011E	2012E	
Revenue (MM)		\$0	\$0	\$3	
Previous Revenue (MM)				\$8	
GAAP Earnings per Share					
	Q1	-	(0.39)A	(0.58)	
	Q2	-	(0.49)A	(0.56)	
	Q3	(3.61)	(0.48)A	(0.60)	
	Q4	(0.92)	(0.65)	(0.54)	
Year		(5.07)	(2.00)	(2.37)	
Previous GAAP EPS			(1.96)	(1.90)	
P/E GAAP		NM	NM	NM	
Diluted Shares (MM)		4.5	19.4	21.5	

#### ■ Investment Thesis - All eyes on NDA and MAA filings in 1Q12:

This morning, AEGR reported 3Q11 EPS of \$(0.48), in-line with our estimate and below Street consensus of \$(0.43), primarily due to higher-than-expected R&D expense associated with the lomitapide P3 study, preparations for regulatory filings and inventory build. The company remains on-track to file both its NDA and MAA for lomitapide in HoFH in 1Q12 (pending conclusion of the ongoing stability testing for the E.U.). In the U.S., management expects an FDA advisory panel review and launch by YE12 (publication of P3 56-week data to coincide with launch). We currently model for 4Q12 and 2Q13 (prev. 4Q12) lomitapide approvals in the U.S. (assume standard review, but 6-month priority review likely) and E.U. (assume 15-month review), respectively. In the near term, we believe pricing and commercialization of lomitapide in France by YE11, pending discussions with authorities in 4Q11 and receipt of ATU (we model for \$225K/patient/year in France and E.U.) and the lomitapide P3 78-week data by YE11 (not part of the initial filing) could serve as a catalyst for AEGR shares.

#### ■ New timelines for FC and pediatric HoFH:

AEGR expects to initiate the FC study in 2012, following FDA and EMA feedback on the finalized protocol (likely similar design to adult HoFE P3; ~30-40 patients). In 2012, AEGR also expects to develop a spray/liquid formulation of lomitapide for use in the pediatric HoFH trial to accommodate young patients unable to swallow capsules (as per EMA feedback), with study initiation now expected in late 2012/early 2013.

#### ■ 3Q11 financial results and changes to model:

AEGR reported 3Q11 GAAP R&D expense of \$7.1M, above our estimate of \$6.0M, while GAAP SG&A expense was \$3.5M, below our estimate of \$3.8M. AEGR exited 3Q11 with \$82.9M in cash, and reiterated its FY11 cash burn guidance of \$29.5M-\$32.5M. As a result of the delay in the pediatric HoFH trial initiation, we model for approval in the U.S. in mid-2016 and E.U. in YE16 (vs. mid-2014 and YE14 previously).

Disclaimers regarding the content of this report as well as full disclosure of Collins Stewart LLC's ratings and information on the firm's position(s) in securities mentioned herein appear on page 5 of this report.

October 27, 2011

Recommendation	BUY
Price	\$14.62
Target	\$27.00

#### **Key Data**

52-Week Range	\$25.92-\$9.00
Shares Outstanding (MM)	21.1
Market Cap (MM)	\$308
Avg. Daily Volume (000)	63
Float (MM)	14.0
% Held Institutionally	87.5%
Total Debt (MM)	\$8.7
Cash Per Share	\$3.94
Short Interest	3.50%

#### **Stock Performance**



	1m	3m	12m
Performance	-0.9%	-6.4%	44.9%

Source: Bloomberg

Aegerion is a biopharmaceutical company focused on the development and commercialization of treatments for patients with severe lipid disorders. The company's lead therapeutic is lomitapide, an oral small-molecule inhibitor of MTP, which is in a Phase 3 clinical trial for the treatment of patients with Homozygous Familial Hypercholesterolemia (HoFH). Aegerion was founded in 2005 and is headquartered in Bridgewater, New Jersey.

Please see Page 3 for price target valuation method and risks to achieving that target.

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Figure 1: 3Q11 Variance Table

(\$thousands, except per share data)

		Sep	Sep	Variance	Variance	Y/Y	Q/Q
		3Q11A	3Q11E	A-E	%	%	%
Revenue							
Lomitapide Total Revenue		-	-	-	n/a	n/a	n/a
Lomitapide HoFH - U.S.		-	-	-	n/a	n/a	n/a
Lomitapide HoFH - E.U.		-	-	-	n/a	n/a	n/a
Milestone, Contract Revenues		-	-	-	n/a	n/a	n/a
Total Revenue	\$	-	\$ -	-	n/a	n/a	n/a
cogs		-		-	n/a	n/a	n/a
Gross profit		-	-	-	n/a	n/a	n/a
Operating expense							
R&D		7,105	6,032	1,073	-85%	433%	38%
SG&A		3,456	3,898	(442)	-113%	126%	8%
Total operating expense		10,562	9,930	632	-94%	269%	27%
Operating income (loss)		(10,562)	(9,930)	(632)	-94%	269%	27%
Interest Expense		(335)	(332)	(3)	-99%	-45%	1%
Interest Income		96	140	(44)	-146%	542%	37%
Change in fair value of warrant liability		-	-	-	n/a	n/a	n/a
Other income, net		680		680	n/a	n/a	n/a
Total Other Income		441	(191)	633	43%	-118%	-269%
Income Before Income Taxes		(10,120)	(10,121)	1	-100%	91%	18%
Income Tax Provision		-	-	-	n/a	n/a	n/a
Accretion of preferred stock dividends		-	-	-	n/a	n/a	n/a
Net income (GAAP)	\$	(10,120)	\$ (10,121)	1	-100%	64%	18%
GAAP EPS (diluted)	\$	(0.48)	\$ (0.48)	(0.00)	-99%	-87%	-1%
	Ť	(0.40)	(0.40)	(0.00)	5576	07.70	170
Weighted shares outstanding							
diluted - GAAP		21,064	21,226	(162)	-101%	1133%	19%

Source: Collins Stewart LLC Research and Company Reports

**Figure 2: AEGR Upcoming Milestones** 

Product	Indication	Timing	Milestone
	HoFH	4Q11	Complete pre-clinical studies
	HoFH	1Q12	Submit U.S. regulatory filing
	HoFH	1Q12	Submit E.U. regulatory filing
	HoFH	YE11	Full Phase 3 78-week data
Lomitapide	HoFH	YE11	Potential ATU approval in France
	Pediatric HoFH	Late-2012 / 1H13	Initiation of a pivotal study
	FC	2012	Initiation of a pivotal study
	HoFH	Mid-2012	Potential FDA approval
	HoFH	YE12	Potential EMEA approval

Source: Collins Stewart LLC Research and Company Reports



Figure 3: Changes to Model

(\$thousands, except per share data) New Prio New Prio New Prio New Prio New Prio New Prior Revenue Lomitapide Total Revenue 3,082 36,798 40,074 73,057 76,740 107,074 122,860 139,407 166,075 8,236 Lomitapide HoFH - U.S. 3,082 6,940 23,882 23,882 41,813 44,087 60,945 69,247 78,456 91,817 Lomitapide HoFH - E.U. 1,296 12,916 16,192 31,244 32,653 46,128 53,613 60,950 74,258 Milestone, Contract Revenues 107.074 \$ Total Revenue 3.082 8.236 36.798 40.074 73.057 76.740 122.860 139.407 166.075 9,497 COGS 4.784 5.210 9.976 14.743 18.268 Gross profit 2,835 7,577 32,014 34,865 63,560 66,764 94,225 108,117 124.072 147,807 Operating expense 21,988 28,412 30,211 32,113 31,783 24,651 27,094 25,523 27,002 27,002 28,412 30,211 15,846 24.035 20.321 25,433 25,433 28,001 28,001 30,523 30,523 32,683 32,683 37,834 Total operating expense 51.129 45.844 52,435 56.413 56.413 60.734 60.734 64.796 64,466 39.235 52,435 (20,421) Operating income (loss) (39,235 (37,834 (48,047) (38,267 (17,570) 7,147 10,351 33,491 47,383 59,276 83,341 Interest Expense (1,108 (2,899) (2,887) (2,899) (2,887) (2,899) (2,887) (1,933) (1,925) Interest Income 334 404 97 105 126 97 127 203 253 426 523 Change in fair value of warrant liability Other income, net 680 Total Other Income (704 (2,802) (2,782 (2,815) (2,762) (2,802) (2,760) (1,730) (1,672) 523 (100 Income Before Income Taxes (38,537 31,761 45,710 59,702 83,864 (39,335) (50,849 (41,049) (23,236) (20,332 7,591 4,345 Income Tax Provision (4,193) Accretion of preferred stock dividends 45,710 \$ (39,335) \$ (38,537) \$ (50,849) \$ (23,236) 4.345 31,761 \$ 53.732 \$ Net income (GAAP) \$ (41,049) \$ (20.332) 7,591 79,671 GAAP EPS (diluted) (1.96 (2.37) (1.90 (1.06) (0.93 0.32 3.28 Weighted shares outstanding 21 62 21 841 23.814 24 053 diluted - GAAP 19 421 19 502 21 461

Source: Collins Stewart LLC Research and Company Reports

#### Valuation and Risks

Our 12-month PT of \$27 is based on 35x our fully taxed, fully diluted FY16 (prev. FY15) GAAP EPS estimate of \$2.21 (prev. \$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.

Independent thinking

# Aegerion Pharmaceuticals (NASDAQ: AEGR)

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Consolidated Income Statement (\$thousands, except per share data)

	FY 2008A	FY 2009A	FY 2010A	Mar 1Q11A	Jun 2Q11A	Sep 3Q11A	Dec 4Q11E	FY 2011E	Mar 1Q12E	Jun 2Q12E	Sep 3Q12E	Dec 4Q12E	FY 2012E	FY 2013E	FY 2014E	FY 2015E	FY 2016E
Revenue Lomitapide Total Revenue Lomitapide HoFH - U.S. Lomitapide HoFH - E.U.			:	-	:			-			:	3,082 3,082	\$ 3,082 3,082	\$ 36,798 23,882 12,916	\$ 73,057 41,813 31,244	\$ 107,074 60,945 46,128	\$ 139,407 78,456 60,950
Total Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 3,082	\$ 3,082	\$ 36,798	\$ 73,057	\$ 107,074	\$ 139,407
COGS Gross profit	:	:	:	:						:		247 2,835	247 2,835	4,784 32,014	9,497 63,560	12,849 94,225	15,335 124,072
Operating expense R&D (GAAP) SG&A (GAAP)	17,712 5,185	7,041 3,075	7,629 5,922	3,297 3,491	5,138 3,205	7,105 3,456	9,111 4,432	24,651 14,584	7,553 4,611	6,553 5,182	6,000 6,746	6,988 7,496	27,094 24,035	27,002 25,433	28,412 28,001	30,211 30,523	32,113 32,683
Total operating expense	22,897	10,116	13,551	6,787	8,343	10,562	13,543	39,235	12,164	11,735	12,746	14,484	51,129	52,435	56,413	60,734	64,796
Operating income (loss)	(22,897)	(10,116)	(13,551)	(6,787)	(8,343)	(10,562)	(13,543)	(39,235)	(12,164)	(11,735)	(12,746)	(11,402)	(48,047)	(20,421)	7,147	33,491	59,276
Interest Expense Interest Income Change in fair value of warrant liability Other income, net Total Other Income	(1,127) 533 91 (1,635) (2,138)	(2,083) 177 (174) - (2,080)	(2,404) 109 (416) 215 (2,496)	(113) 68 - - (45)	(332) 70 - - (262)	(335) 96 - 680 441	(335) 101 - - (234)	(1,114) 334 - 680 (100)	(335) 86 - - (248)	(335) 73 - - (262)	(335) 64 - - (271)	(335) 50 - - (284)	(2,899) 97 - (2,802)	(2,899) 84 - (2,815)	(2,899) 97 - - (2,802)	(1,933) 203 - - (1,730)	- 426 - - 426
Income Before Income Taxes Income Tax Provision	(25,035)	(12,196)	(16,047) 1,793	(6,832)	(8,605)	(10,120)	(13,777)	(39,335)	(12,412)	(11,997)	(13,017)	(11,687)	(50,849)	(23,236)	4,345 -	31,761	59,702 (5,970)
Accretion of preferred stock dividends  Net income (GAAP)	(6,242) \$ (31,277)	(3,287)	(8,751)	- \$ (6,832)	\$ (8,605)	\$ (10,120)	\$ (13,777)	\$ (39,335)	- \$ (12,412)	\$ (11,997)	\$ (13,017)	\$ (11,687)	\$ (50,849)	\$ (23,236)	\$ 4,345	s 31.761	\$ 53,732
GAAP EPS (diluted)	\$ (20.92)	\$ (9,35)		\$ (0,39)			\$ (0.65)	\$ (2.00)	\$ (0.58)	\$ (0.56)					\$ 0.18	\$ 1,32	\$ 2.21
Weighted shares outstanding diluted - GAAP	1,495	1,657	\$ <b>(5.07)</b> 4,537	17,642	17,729	21,064	21,248	19,421	21,354	21,461	21,568	\$ (0.54) 21,676	\$ (2.37) 21,461	\$ (1.06) 21,893	23,866	24,105	24,346
Margin Analysis: Cost of product sales Product gross margin RAD (non-GAAP) SC&A (non-GAAP) Stok-based compensation expense Total operating expense Operating margin Income tax provision Net margin (GAAP)	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	8% nm nm nm nm nm nm	8% 92% 879% 780% 258% 1659% -1559% 0%	13% 87% 73% 69% 24% 142% -55% 0%	13% 87% 39% 38% 14% 77% 10% 0%	12% 88% 28% 29% 10% 57% 31% 0%	11% 89% 23% 23% 8% 46% 43% 10% 39%
YY change: Total revenue R&D SC&A SC&A SC&C Stock-based compensation expense Total operating expense Operating income Net income (GAAP) GAAP EPS (diluted) Shares outstanding - GAAP	nm 31% -15% -30% 17% 31% 9% 20%	nm -60% -41% -25% -56% -56% -55% 11%	nm 8% 93% 125% 34% 34% 49% -46%	nm nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm 223% 146% 208% 190% 71% -61% 328%	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm	nm nm nm nm nm nm nm	nm 10% 65% 23% 30% 22% 29% 18%	1094% 0% 6% 12% 3% -57% -54% -55%	99% 5% 10% 11% 8% -135% -119% -117%	47% 6% 9% 9% 8% 369% 631% 624%	30% 6% 7% 9% 7% 77% 69% 68% 1%

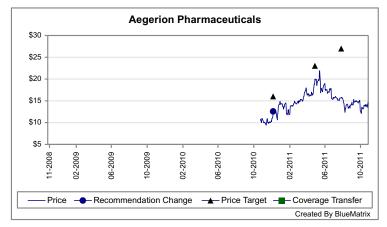
Source: Collins Stewart LLC Research and Company Reports



## **Important Disclosure / Disclaimer Information**

Other Public Companies Mentioned in this Report

CompanyTickerPriceRecommendationAegerion PharmaceuticalsAEGR\$14.62BUY



Ticker	Date	Action	Prior Rating	<b>Current Rating</b>	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

#### Valuation and Risks

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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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	% of CSTI Universe with this rating	% of rating tier for which CSTI provided IB services
Buy	54%	0%
Buy Hold	42%	0%
Sell	4%	0%

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