

# **COMPANY UPDATE**

December 27, 2010

## **OUTPERFORM**

12-18 mo. Price Target	\$14.00
ALIM - NASDAQ	\$11.22

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range \$	12.70-\$6.30
Shares Outstanding	31.2M
Float	25.8M
Market Capitalization	\$349.9M
Avg. Daily Trading Volume	84,703
Dividend/Div Yield	NA/NM
Fiscal Year Ends	Dec
Book Value	NM
2010E ROE	NA
LT Debt	\$15.0M
Preferred	NA
Common Equity	NA
Convertible Available	No
52 WFFK I OW (\$): Range since 4/22/10 IF	20

EPS Diluted	<b>d</b> Q1	Q2	Q3	Q4	Year	Mult.
2009A					(0.86)	NM
2010E	(0.21)A	(0.20)A	(0.20)A	(0.22)	(0.82)	NM
2011E					(0.69)	NM
Prior (E)					2.30	4.9x
2012E					1.86	6.0x
Prior (E)					2.73	4.1x

HEALTHCARE/BIOTECHNOLOGY

# Alimera Sciences

Iluvien CRL a Real Setback, but Long-Term Potential Remains Intact

#### SUMMARY

On 12/23, ALIM received an FDA complete response letter (CRL), delaying approval of Iluvien for diabetic macular edema (DME). Importantly, the FDA did not request an additional trial, suggesting the agency did not find major inadequacies with the ph.III FAME trials. The agency requested full 36-mo. FAME data, and we believe these results will likely be consistent with the positive 24-mo. results. Based on our discussions with ALIM, we believe the new data analyses, and resolution of outstanding manufacturing issues, should be completed for a late 1Q11 NDA refiling. Although the CRL is a real setback, we would buy ALIM on significant weakness, as we believe Iluvien will likely be approved by 4Q11. Reducing PT to \$14 from \$16.

#### **KEY POINTS**

- The FDA is apparently looking for consistency between 24-mo. and 36-mo. FAME results. Importantly, a completers analysis showed visual acuity results improved from 24 to 30 mos. We would expect this trend to continue over 36-mos. While an ITT analysis will likely show somewhat diminished efficacy, we expect lluvien's benefit/risk profile will remain compelling.
- We expect near-term resolution of the cGMP issues raised by the FDA. According to ALIM, the company's third-party suppliers have already made initial progress toward addressing the FDA's concerns. Based on this, we believe manufacturing issues are unlikely to derail Iluvien's approval.
- ALIM expects to resubmit the Iluvien NDA late 1Q11, and we project 4Q11 approval. ALIM will meet the FDA in February to discuss the CRL, and the company expects to have the full 36-mo. FAME results available by then. Based on this, we believe a 4Q11 approval timeline is reasonable.
- Physician enthusiasm should remain high. Based on results from our recent survey, we believe ophthalmologists have a very positive stance on Iluvien. We do not believe the issues raised in the CRL would have any negative impact on physician perception, and continue to expect a strong launch following approval.

## Stock Price Performance

# 1 Year Price History for ALIM 14 12 10 8 6 4 201 Q2 Q3 2011 Created by Blockleting

#### **Company Description**

Alimera Sciences is a biopharmaceutical company focused on the research, development, and commercialization of ophthalmic pharmaceuticals. Product candidates include Iluvien, an intravitreal insert for treatment of diabetic macular edema, as well as other ophthalmic diseases, such as the wet form of age-related macular degeneration (AMD), the dry form of AMD, and retinal vein occlusion.

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# **Changes to Our Model**

Following the FDA's CRL, we have adjusted our US sales estimates to reflect a later launch. Our 2010 EPS estimate remains the same. For 2011-2017 our new EPS estimates are (\$0.69), \$1.86, \$2.55, \$3.08, \$3.96, \$5.06, and \$5.99, respectively, vs. our prior estimates of \$2.30, \$2.73, \$3.13, \$3.64, \$4.40, \$5.32 and \$6.18, respectively.

## Alimera Sciences Statement of Operations 2009A-2017E

Amounts in thousands, except per-share figures		2010														
						Prior		Prior		Prior						
	2009A	1QA	2QA	3QA	4QE	4QE	2010E	2010E	2011E	2011E	2012E	2013E	2014E	2015E	2016E	2017E
Revenues:																
Iluvien U.S. sales	-	-	-	-	-	-	-	-	6,358	139,876	149,271	215,487	283,640	369,173	465,565	554,242
Iluvien Ex-U.S. revenues	-	-	-	-	-	-	-	-	-	-	13,020	32,550	44,221	56,048	68,976	81,296
Total operating revenue	-	-	-	-	-	-	-	-	6,358	139,876	162,291	248,037	327,861	425,221	534,542	635,538
Operating expenses:																
Cost of goods	-	-	-	-	-	-	-	-	318	6,994	7,464	10,774	14,182	18,459	23,278	27,712
Payment to pSivida for Iluvien	-	-	-	-	-	-	-	-	827	18,184	24,344	42,166	59,015	76,540	96,217	114,397
Research & development	15,057	3,065	4,140	3,276	3,000	3,000	13,481	13,481	8,000	8,000	10,000	13,000	13,650	14,333	15,049	15,802
Selling, general & administrative	4,159	1,151	1,553	2,843	4,500	4,500	10,047	10,047	22,606	22,606	36,169	45,212	56,514	70,643	74,175	77,884
Total operating expenses	19,216	4,216	5,693	6,119	7,500	7,500	23,528	23,528	31,750	55,783	77,976	111,152	143,361	179,974	208,720	235,794
Income (Loss) from operations	(19,216)	(4,216)	(5,693)	(6,119)	(7,500)	(7,500)	(23,528)	(23,528)	(25,392)	84,093	84,314	136,885	184,500	245,247	325,822	399,743
Other income (expense)	(1,860)	(472)	872	37	96	96	533	533	327	988	1,027	2,749	5,520	10,803	16,034	22,722
Pretax income (loss)	(21,076)	(4,688)	(4,821)	(6,082)	(7,404)	(7,404)	(22,995)	(22,995)	(25,065)	85,080	85,342	139,634	190,020	256,050	341,856	422,466
Income tax provision (benefit)	-	-	-	-	-	-	-	-	-	-	12,801	34,909	57,006	76,815	102,557	126,740
Net income (loss)(2)	(21,076)	(4,688)	(4,821)	(6,082)	(7,404)	(7,404)	(22,995)	(22,995)	(25,065)	85,080	72,540	104,726	133,014	179,235	239,299	295,726
Basic & diluted net loss per share	(\$0.86)	(\$0.21)	(\$0.20)	(\$0.20)	(\$0.22)	(\$0.22)	(\$0.82)	(\$0.82)	(\$0.69)	\$2.30	\$1.86	\$2.55	\$3.08	\$3.96	\$5.06	\$5.99
Basic common shares outstanding (1)	22,496	22,496	24,293	31,146	33,646	33,646	27,895	27,895	36,146	36,146	38,146	40,146	42,146	44,146	46,146	48,146
Diluted common shares outstanding	22,496	22,496	24,293	31,146	33,646	33,646	27,895	27,895	37,046	37,046	39,096	41,146	43,196	45,246	47,296	49,346

<sup>(1)</sup> Pre-IPO share count for 2009 and 1Q 2010 are based on the pro-forma share count provided in ALIM's form S-1A

<sup>(2)</sup> Excludes one-time items

Ratios and Margins																
Gross Margin	NM	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%							
R&D as percent of revenue	NM	5.7%	6.2%	5.2%	4.2%	3.4%	2.8%	2.5%								
SG&A as percent of revenue	NM	16.2%	22.3%	18.2%	17.2%	16.6%	13.9%	12.3%								
Operating margin	NM	60.1%	52.0%	55.2%	56.3%	57.7%	61.0%	62.9%								
Pretax margin	NM	60.8%	52.6%	56.3%	58.0%	60.2%	64.0%	66.5%								
Profit margin	NM	60.8%	44.7%	42.2%	40.6%	42.2%	44.8%	46.5%								
Tax rate	NM	0.0%	0.0%	15.0%	25.0%	30.0%	30.0%	30.0%	30.0%							

Source: Company documents and Oppenheimer & Co. Inc.



#### **Investment Thesis**

Based on Iluvien's significant commercial potential, we believe ALIM shares are substantially undervalued. We believe Iluvien, Alimera's treatment for diabetic macular edema (DME), will likely be approved by the FDA and the EMA in late 2011. Following approval, Iluvien should become an important treatment for DME, a serious complication of diabetes that can lead to blindness. We currently estimate peak worldwide Iluvien sales of more than \$900 million.

#### **Price Target Calculation**

Our new 12-18 month price target of \$14 is based on 12x our probability adjusted 2014E EPS of \$1.83, discounted 3 years at 15%. We believe this multiple is appropriate compared to specialty pharma peer companies.

### **Key Risks to Price Target**

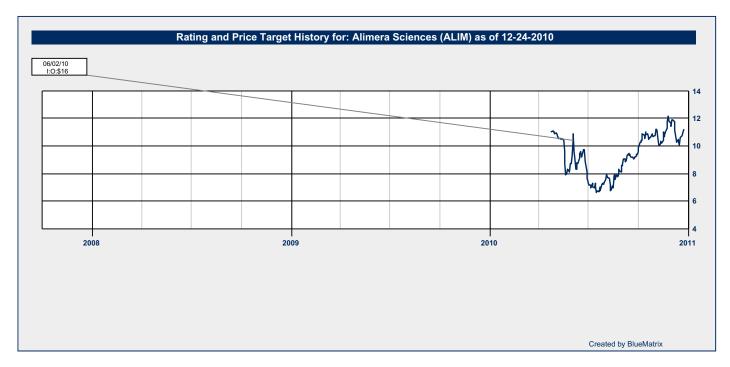
Key risks to our price target include, but are not limited to, failure to gain FDA or EMA approval of Iluvien in diabetic macular edema, difficulty commercializing Iluvien in the US following potential approval, an inability to find a partner to commercialize Iluvien in Europe, and an inability to raise additional funding if required. We also view potential competition in the DME market as an important risk to our price target.

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