

# **QUARTERLY UPDATE**

August 12, 2010

Stock Rating:
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## **OUTPERFORM**

12-18 mo. Price Target	\$16.00
ALIM - NASDAQ	\$6.80

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range \$	11.30-\$6.30
Shares Outstanding	31.1M
Float	25.8M
Market Capitalization	\$211.2M
Avg. Daily Trading Volume	59,302
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 WEEK LOW (\$): Range since 4/22/10 IF	20

EPS Diluted	<b>l</b> Q1	Q2	Q3	Q4	Year	Mult.
2009A					(0.86)	NM
2010E	(0.21)A	(0.20)A	(0.28)	(0.30)	(1.00)	NM
Prior (E)		(0.30)	(0.24)	(0.26)	(1.02)	NM
2011E					1.96	3.5x
Prior (E)					1.86	3.7x
2012E					2.74	2.5x
Prior (E)					2.63	2.6x

HEALTHCARE/BIOTECHNOLOGY

# Alimera Sciences

Reports 2Q; FDA Decision on Iluvien for DME Approaching Quickly

### SUMMARY

On 8/12, ALIM reported 2Q results. The company has made substantial progress with Iluvien for diabetic macular edema (DME), with US/EU regulatory filings in June/July, respectively. We believe results of the two ph.III FAME trials of Iluvien in this indication support both US and EU approval, based on the drug's impressive visual acuity improvements and good safety profile. Notably, we see a reasonable probability the FDA will grant Iluvien a 6-month review, likely leading to approval by YE10. We believe first-mover status will lead to rapid uptake of Iluvien in DME, and est >\$500M US peak sales. With near-term approval decisions for Iluvien serving as major catalysts, we believe ALIM is substantially undervalued at current levels.

### **KEY POINTS**

- ALIM reported 2Q10 EPS of (\$0.20) vs. our (\$0.30). The difference is primarily attributable to lower than expected expenses and a one-time gain of \$1.34M based on the recognition of interest previously accrued on retired debt. We expect expenses to be higher in 2H10, as ALIM prepares for the U.S. launch of Illuvien.
- We see a good probability of Iluvien's approval in 4Q10/1Q11. Although one of the ph.III trials narrowly missed the primary endpoint using a modified statistical analysis, both trials showed significant visual acuity improvements under an intent-to-treat analysis. We believe the FDA will focus on the intent-to-treat results, which better define likely real-world use of Iluvien.
- Accelerated FDA review a near-term catalyst. Given prior FDA action for retinal drugs, we now see priority review for Iluvien as likely, which should be announced late August. Additionally, we believe an AdCom is unlikely as Iluvien's drug component has a well-established safety profile and the FDA has not required an AdCom for other intravitreal inserts.
- We expect Iluvien to become an important chronic DME treatment. Current corticosteroid treatments have drawbacks, such as frequent injections and cataract/IOP development. Based on Iluvien's efficacy and relative safety for ~3 years following a single, convenient intravitreal insertion, at a reasonably low cost (~\$7,500/insertion), we believe the drug has substantial commercial potential.

### Stock Price Performance

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### **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**

**Based on 2Q10 results, we have adjusted our financial model.** For 3Q10/4Q10 our EPS estimates are now (\$0.28) and (\$0.30), respectively, vs. our prior estimates of (\$0.24) and (\$0.26), respectively. Our full-year 2010 EPS estimate is now (\$1.00). For 2011-2017 our new EPS estimates are \$1.96, \$2.74, \$3.35, \$3.95, \$4.76, \$5.77, and \$6.70, respectively.

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

						2010												
	_	_		Prior		Prior		Prior		Prior		Prior						
	2009A	1QA	2QA	2QE	3QE	3QE	4QE	4QE	2010E	2010E	2011E	2011E	2012E	2013E	2014E	2015E	2016E	2017E
Revenues:																		
Iluvien U.S. sales	-	-	-	-	-	-	-	-	-	-	127,160	127,160	191,598	251,591	324,227	399,100	481,019	563,761
Iluvien Ex-U.S. revenues	-	-	-	-	-	-	-	-	-	-	-	-	13,020	32,550	44,221	56,048	68,976	81,296
Total operating revenue	-	-	-	-	-	-	-	-	-	-	127,160	127,160	204,618	284,141	368,448	455,148	549,995	645,057
Operating expenses:																		
Cost of goods	-	-	-	-	-	-	-	-	-	-	6,358	6,358	9,580	12,580	16,211	19,955	24,051	28,188
Payment to pSivida for Iluvien	-	-	-	-	-	-	-	-	-	-	16,531	16,531	30,693	48,304	66,321	81,927	98,999	116,110
Research & development	15,057	3,065	4,140	3,500	3,500	4,000	3,650	4,500	14,355	15,065	19,379	21,091	19,961	20,559	21,176	21,812	22,466	23,140
Selling, general & administrative	4,159	1,151	1,553	3,500	3,950	3,500	5,000	3,500	11,654	11,651	22,725	22,137	36,360	45,451	56,813	71,017	74,567	78,296
Total operating expenses	19,216	4,216	5,693	7,000	7,450	7,500	8,650	8,000	26,009	26,716	64,993	66,117	96,594	126,894	160,521	194,710	220,083	245,734
Income (Loss) from operations	(19,216)	(4,216)	(5,693)	(7,000)	(7,450)	(7,500)	(8,650)	(8,000)	(26,009)	(26,716)	62,167	61,043	108,025	157,247	207,926	260,438	329,912	399,323
Other income (expense)	(1,860)	(472)	872	(2,270)	141	155	122	136	663	(2,450)	971	1,040	2,467	4,763	8,171	14,510	19,977	26,767
Pretax income (loss)	(21,076)	(4,688)	(4,821)	(9,270)	(7,309)	(7,345)	(8,528)	(7,864)	(25,346)	(29,166)	63,138	62,084	110,491	162,010	216,097	274,949	349,890	426,091
Income tax provision (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	16,574	40,502	64,829	82,485	104,967	127,827
Net income (loss)(2)	(21,076)	(4,688)	(4,821)	(9,270)	(7,309)	(7,345)	(8,528)	(7,864)	(25,346)	(29,166)	63,138	62,084	93,917	121,507	151,268	192,464	244,923	298,263
Basic & diluted net loss per share	(\$0.86)	(\$0.21)	(\$0.20)	(\$0.30)	(\$0.28)	(\$0.24)	(\$0.30)	(\$0.26)	(\$1.00)	(\$1.02)	\$1.96	\$1.86	\$2.74	\$3.35	\$3.95	\$4.76	\$5.77	\$6.70
Basic common shares outstanding (1)	22,496	22,496	24,293	30,501	26,293	30,501	28,793	30,501	25,469	28,500	31,293	32,501	33,293	35,293	37,293	39,293	41,293	43,293
Diluted common shares outstanding	22,496	22,496	24,293	30,501	26,293	30,501	28,793	30,501	25,469	28,500	32,193	33,401	34,243	36,293	38,343	40,393	42,443	44,493

<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	15.2%	16.6%	9.8%	7.2%	5.7%	4.8%	4.1%	3.6%									
SG&A as percent of revenue	NM	17.9%	17.4%	17.8%	16.0%	15.4%	15.6%	13.6%	12.1%									
Operating margin	NM	48.9%	48.0%	52.8%	55.3%	56.4%	57.2%	60.0%	61.9%									
Pretax margin	NM	49.7%	48.8%	54.0%	57.0%	58.7%	60.4%	63.6%	66.1%									
Profit margin	NM	49.7%	48.8%	45.9%	42.8%	41.1%	42.3%	44.5%	46.2%									
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 EMEA in late 2010 and 2011, respectively. 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 12-18 month price target of \$16 is based on 11x our probability adjusted 2012E EPS of \$1.76, discounted 1.5 years at 15%. We have chosen to use a 11x multiple based on the average multiple for specialty pharma peer companies, which is 11.4x for 2012. We chose 2012 as the year upon which to value Alimera, as it should be the first full year of US Iluvien sales. We view this as a conservative choice, as 2012 includes limited EU revenues for Iluvien, assuming a launch in 1Q12.

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

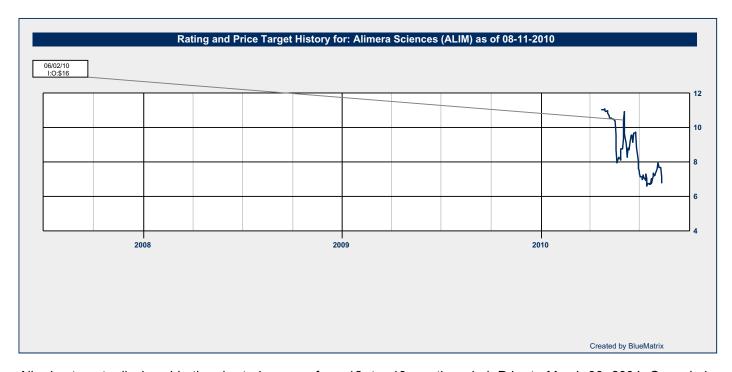
Key risks to our price target include, but are not limited to, failure to gain FDA or EMEA approval of Iluvien in diabetic macular edema, difficulty commercializing Iluvien in the U.S. following potential approval, an inability to find a partner to commercialize Iluvien in Europe, and an inability to 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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	Ī		IB Serv/Pa	st 12 Mos.			
Rating	Count	Percent	Count	Percent			
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PERFORM [P]	306	47.40	81	26.47			
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