

## **COMPANY UPDATE**

June 29, 2010

Stock Rating:

## **OUTPERFORM**

 12-18 mo. Price Target
 \$16.00

 ALIM - NASDAQ
 \$8.08

3-5 Yr. EPS Gr. Rate	NA
	.30-\$7.76
Shares Outstanding	31.1M
Float	25.8M
Market Capitalization	\$250.9M
Avg. Daily Trading Volume	NA
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 IPC	)

EPS Diluted	<b>d</b> Q1	Q2	Q3	Q4	Year	Mult.
2009A					(0.86)	NM
2010E	(0.21)A	(0.30)	(0.24)	(0.26)	(1.02)	NM
2011E				-	1.86	4.3x
2012E					2.63	3.1x

HEALTHCARE/BIOTECHNOLOGY

# Alimera Sciences

ALIM Files Iluvien NDA On Schedule, Expecting 1H11 Approval

#### SUMMARY

On 6/29, ALIM announced the submission of an NDA for low-dose Iluvien for tithe treatment of diabetic macular edema (DME). The timing of the filing is in-line with the company's prior 2Q guidance. We believe results of the two ph.III FAME trials of Iluvien for DME support approval by 1H11. Using an ITT analysis, both trials showed significant visual acuity improvements vs. placebo. Based on consultations with experts familiar with the FDA's ophthalmic drugs division, we expect the agency to focus primarily on this analysis. We est Iluvien will reach >\$500M in peak U.S. sales, with total peak WW sales of >\$900M. Based on Iluvien's significant commercial potential, we believe ALIM shares are undervalued.

#### **KEY POINTS**

- We see a good probability of Iluvien's approval. Although one ph.III trial just missed the primary endpoint of improved visual acuity (VA) under a modified statistical analysis plan, both trials showed significant VA improvements using an intent-to-treat approach. We believe the FDA will focus on the ITT analysis, which more accurately reflects real-world clinical practice.
- A priority review would accelerate our expected approval time line. Based on a lack of approved DME therapies, ALIM requested a 6-month review from the FDA, which could lead to a an approval in late 4Q/early 1Q. We believe a 10-month review is more likely, but see some chance of a priority review, given unmet medical need.
- The Iluvien NDA may not be reviewed by an FDA AdCom. The drug component of Iluvien (FA) has a well-established safety profile, and the FDA has recently approved other intravitreal inserts without an advisory committee meeting. While we believe an AdCom meeting is unlikely, were there a panel, we would anticipate a positive recommendation.
- If approved, we expect rapid adoption of Iluvien for DME. Based on the insert's efficacy and safety, coupled with convenience and likely cost advantages vs. off-label DME treatments like Lucentis/Avastin, we believe Iluvien's commercial profile is compelling. Additionally, we do not believe these treatments are mutually exclusive and see the potential for Iluvien/VEGF inhibitor combination therapy.

## Stock Price Performance

# 1 Year Price History for ALIM 12 11 10 9 8 7 7 Created by Blandarin.

#### **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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Job Taylor, Ph.D 212 667-6586 Job.Taylor@opco.com Oppenheimer & Co. Inc. does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. See "Important Disclosures and Certifications" section at the end of this report for important disclosures, including potential conflicts of interest. See "Price Target Calculation" and "Key Risks to Price Target" sections at the end of this report, where applicable.

#### **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 be approved by the FDA and the EMEA in 2011. Following approval, Iluvien should become an important treatment for DME, a serious complication of diabetes that can lead to blindness. We estimate peak worldwide Iluvien sales of more than \$900 million.

## **Price Target Calculation**

Our 12-18 month price target of \$16 is based on 12x our probability adjusted 2012 EPS of \$1.69, discounted 1.5 years at 15%. We have chosen to use a 12x 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 U.S. Iluvien sales. We view this as a conservative choice, as 2012 includes limited E.U. 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.

Stock prices of other companies mentioned in this report (as of 6/29/2010):

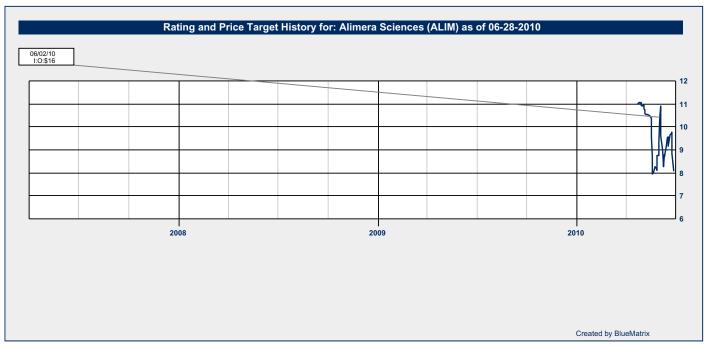
Roche (RHHBY-OTC, \$35.60, not rated)

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Distribution of Ratings/IB Services Firmwide							
			IB Serv/Pa	st 12 Mos.			
Rating	Count	Percent	Count	Percent			
OUTPERFORM [O]	331	51.60	131	39.58			
PERFORM [P]	293	45.70	77	26.28			
UNDERPERFORM [U]	17	2.70	3	17.65			

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