February 4, 2011

HEALTHCARE/BIOTECHNOLOGY

Alimera Sciences

36-Month Iluvien Data Should Support FDA Approval

Stock Rating:

OUTPERFORM

12-18 mo. Price Target	$14.00
ALIM - NASDAQ	$10.14
3-5 Yr. EPS Gr. Rate	NA
52-Wk Range	$12.70-$6.30
Shares Outstanding	31.2M
Float	25.8M
Market Capitalization	$316.2M
Avg. Daily Trading Volume	106,429
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 IPO

EPS Diluted	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
2012E	--	--	--	--	1.86	5.5x

SUMMARY

On 2/3, ALIM reported top-line, 36-month data from the two ph.III FAME trials of Iluvien for DME. Pooled trial data showed a significant improvement in the percentage of patients with ≥15 letter BCVA improvements for Iluvien vs. control and side effects generally consistent with 24mo. results. While 36mo. efficacy results from the individual trials were not statistically significant, they were numerically consistent with the 24mo. results. Importantly, ALIM confirmed that the FDA does not require statistically significant 36mo. results for approval. ALIM should resubmit the Iluvien NDA by 1Q11 end, and we expect a 6mo. review. The 36mo. FAME results reinforce our view that Iluvien is likely to be approved, and we recommend buying ALIM on any weakness.

KEY POINTS

- **Extension data shows durable efficacy.** Iluvien demonstrated consistent efficacy at 30/33/36mos. vs 24mos. This is a robust outcome, given Iluvien's effect peaks at 30mo and the benefit of laser/off-protocol treatment was likely concentrated in the placebo pts. Although FAME A/B did not achieve 36mo. statistical significance individually, pooled results were significant due to greater powering.
- **In our view, Iluvien's safety profile remains acceptable.** There was negligible additional cataract formation beyond 24mos. Although, there was a slight increase in IOP lowering surgeries with Iluvien from 24 to 36mos, we do not believe this is overly concerning, given the incidence remained low and did not apparently accelerate in this timeframe.
- **36-month data will likely address FDA questions raised in Dec. CRL.** We believe the results generally confirm that Iluvien's long-term benefit outweighs the vision decrement from cataracts caused by the drug. Given Iluvien's chronic dosing, we believe the FDA was mainly looking for consistency between the 36mo and 24mo efficacy/safety data.
- **We continue to see a good probability of 4Q11 US approval of Iluvien.** ALIM met with the FDA on 2/2, and, based on this meeting, continues to expect a 1Q11 refiling. We view this positively. Additionally, we believe ALIM's third-party suppliers have already largely addressed cGMP issues raised in the CRL.

Stock Price Performance

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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36 Month Phase III FAME Results

Overall, we believe the efficacy data from the FAME program supports approval. In our view, a key result was the pooled ITT analysis, showing 28.7% of Iluvien patients with a >=15 letter improvement in BCVA compared to 18.9% for control at 36 months (p=0.018). For the individual trials, the increase in the percentage of responders at 36 months was not statistically significant. However, there are several reasons to expect this will not be a major issue with the FDA. First, Alimera specifically affirmed that statistical significance at the 36-month time point was not a requirement for approval, based on FDA feedback. This seems logical, as the FAME trials were designed for a primary efficacy readout at 24 months vs. 36 months. Second, Iluvien showed a statistically significant benefit up to 33 months in both FAME trials, with peak efficacy occurring at approximately 30 months. We believe this result is consistent with early PK/PD data, which predicted that fluocinolone acetonide (FA) elution from Iluvien would wane in the 30-36 month timeframe. Thirdly, the best corrected visual acuity (BVCA) in each of the individual trials is numerically similar to what is seen in the pooled data, suggesting that the drug effect at 36 months is real and that the lower patient numbers in each individual trial contributed to lack of statistical significance. Finally, there were surprising improvements in the control arm from month 24 to 32. This is likely explained by significantly more patients on the control arm receiving laser photocoagulation (48.6% vs. 30.9%), and off-protocol therapies including anti-VEGF (Lucentis/Avastin), IVTA and vitrectomy, (28.6% vs. 12.5%). We believe the complete 36-month FAME data, to be presented at AED 2011 on February 12th, will clarify some of the questions regarding the late improvement of a limited number of control patients.

Iluvien's long-term safety appears acceptable. We believe the FDA's complete response letter (CRL) to the original Iluvien NDA was likely focused on the potential for long-term side effects with the insert, including serious elevations in intraocular pressure (IOP) and cataract formation, which are known side effects of FA and other intraocular steroid treatments. Based on our conversations with ophthalmologists, we believe cataract interventions are considered very manageable. We believe the FDA is likely focused on the IOP increases seen with Iluvien, but would be surprised if the agency has a specific "line in the sand" where IOP increases/interventions become unacceptable. Based on our recent survey of ophthalmologists, we believe the 4.8% incidence of surgical correction for IOP seen with Iluvien at 36 months falls well within a clinically manageable range. Additionally, the percent of patients requiring IOP lowering surgeries increasing from 3.7% at 24 months to 4.8% at 36 months suggests a decreased annual incidence after 24 months.

Exhibit 1: Phase III Efficacy Results (Full Analysis Data Set)

	Months After Insertion				
%pts with improved BCVA*	**24**	**27**	**30**	**33**	**36**
Trial A					
Iluvien (low dose)	26.8%	25.8%	28.9%	28.4%	28.4%
Placebo	14.7%	15.8%	14.7%	16.8%	18.9%
P-value	0.029	0.076	0.011	0.042	0.106
Trial B					
Iluvien (low dose)	30.6%	31.7%	33.9%	29.6%	29.0%
Placebo	17.8%	13.3%	15.6%	17.8%	18.9%
P-value	0.030	0.001	0.002	0.046	0.086
Trial A+B					
Iluvien (low dose)	28.7%	28.7%	31.4%	29.0%	28.7%
Placebo	16.2%	14.6%	15.1%	17.3%	18.9%
P-value	0.002	<0.001	<0.001	0.004	0.018

*>=15 letter improvement on ETDRS eye chart

Source: Company Reports.

Exhibit 2: Phase III Pooled Safety Results

	Months After Insertion	
%pts with AE	**24**	**36**
Cataract Formation		
Iluvien (low dose)	80.0%	81.7%
Placebo	46.3%	50.4%
Cataract Surgery		
Iluvien (low dose)	74.9%	80.0%
Placebo	23.1%	27.3%
IOP>30mmHg		
Iluvien (low dose)	16.3%	18.4%
Placebo	2.7%	4.3%
IOP Lowering Surgery		
Iluvien (low dose)	3.7%	4.8%
Placebo	0.5%	0.5%

IOP - Intraocular pressure

Source: Company Reports.

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 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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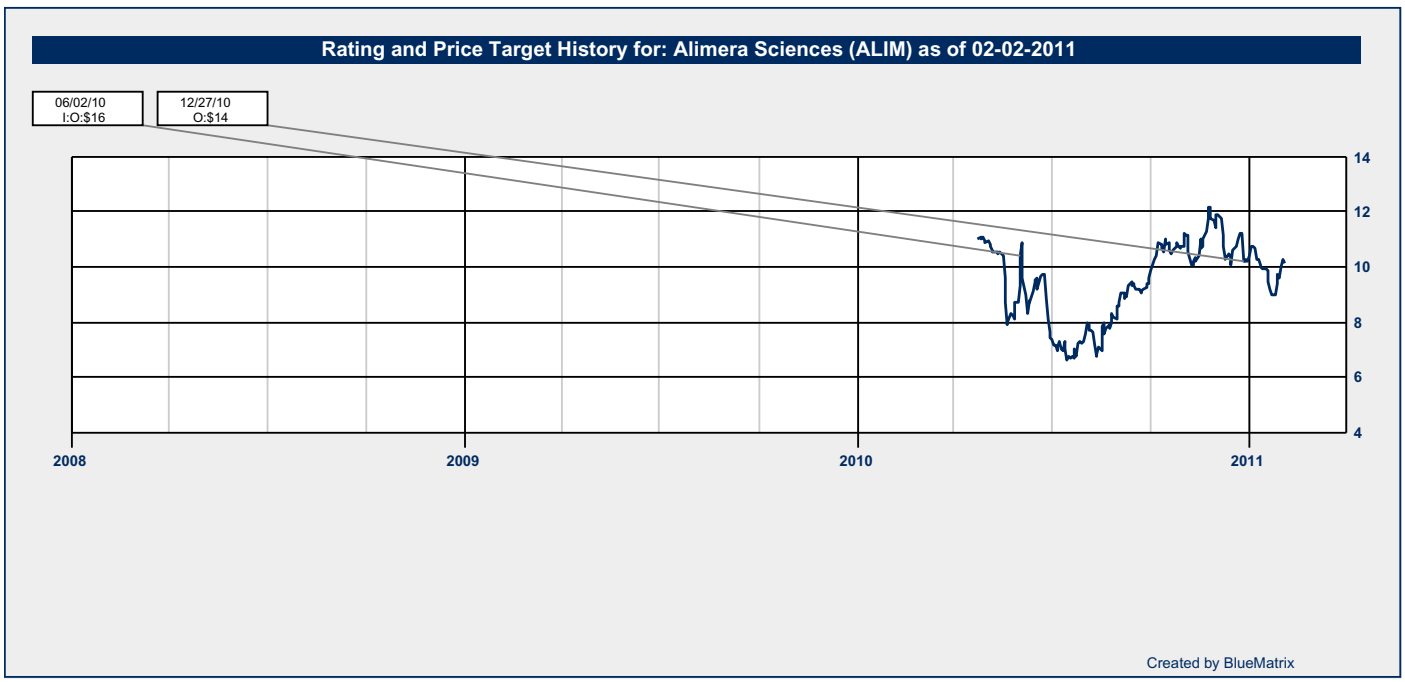

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			IB Serv/Past 12 Mos.	
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