



Quick Take

Alimera Sciences — Outperform (1)

ALIM: \$11.22

Quick Take: FDA's CRL Request For 36-Month Iluvien Data Not A Surprise

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After the market close on December 23rd, Alimera announced the receipt of a Complete Response Letter from the FDA for the Iluvien NDA. As we had anticipated, the FDA requested submission of the 36 month safety and efficacy data for Iluvien from the pivotal FAME study (the Iluvien NDA was submitted in June 2010 based on the 24-month data from FAME). The 36-month trial was completed in October 2010, so the data are currently being analyzed and prepared for submission. However, the FDA's CRL also cited observed cGMP deficiencies during its pre-approval inspections of the third-party manufacturers for Iluvien. Alimera states that the manufacturers are in the process of resolving these deficiencies, but resolution of these issues likely will be the gating factor to a timely response to the FDA's CRL. The FDA also requested information from Alimera regarding manufacturing, packaging, and sterilization controls, which the company currently is compiling. Alimera management has requested a meeting with the FDA to clarify the requirements for the CRL response.

In our Iluvien sales and Alimera P&L projections, we had built in a 6-8 month delay in the FDA approval and launch of Iluvien (until late Q3:2011), as we had assumed that the FDA would request the 36-month FAME study data. However, the FDA's citation of cGMP deficiencies at the third party manufacturers adds uncertainty to Alimera's response timeline. Therefore, we have trimmed our 2011 Iluvien sales estimate from \$25MM to just \$5MM, assuming Iluvien can reach the market late next year. We also have trimmed our 2012-14 Iluvien U.S. sales estimates, from \$85MM, \$125MM, and \$170MM, respectively, to \$70MM, \$110MM, and \$160MM, respectively, to reflect the later launch timing. We have not changed our 2015 and 2016 Iluvien U.S. sales estimates of \$210MM and \$250MM, respectively.

Factoring the Iluvien launch timing uncertainty, we and our clinical consultants continue to believe that Iluvien will be a successful treatment for DME, with \$400MM+ WW sales potential in 2016. Based on our DCF and sum-of-the-parts valuation analyses, we believe ALIM shares can outperform the market by 30%+ over the next 12-18 months from today's expected open, and we would use the weakness as an opportunity to build positions in the shares.

Alimera management will host a conference call this morning at 8:30am EST to discuss the FDA's CRL for Iluvien and what the company's planned next steps are. The conference call dial in information is: (877) 369-6586 (U.S. and Canada) or (253) 237-1165 (international) and the webcast will be broadcast at www.alimerasciences.com.

Please see addendum of this report for important disclosures.

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Our thesis on ALIM shares is unchanged: assuming a 15% DME patient share in the U.S. and a 10% patient share in Europe, coupled with Alimera's modest infrastructure requirements, we believe Iluvien can drive rapid profit growth for Alimera in 2012-2016. As visibility rises on Iluvien's launch timing and market potential over 2011, we believe investors will re-value the Iluvien opportunity. Based on our DCF and sum-of-the-parts valuation analyses, we believe ALIM shares can outperform the market by 30%+ over the next 12-18 months.

ALIM - VALUATION PERSPECTIVES

ALIMERA SCIENCES - CURRENT VALUATION PARAMETERS								
ALIMERA Share Price:	\$11.22							
Diluted Shares Outstanding (MM):	31.3							- Includes in-the-money options and employee shares
Equity Market Capitalization (\$MM):	\$351							109% - Post-money valuation
Plus: LT Debt (\$MM)	\$25							8% - \$25MM milestone payable to pSivida upon Iluvien approval
Less Cash: (\$MM)	\$55							- Includes net IPO proceeds of \$66.3MM
Total Enterprise Value (\$MM):	\$321							- Net enterprise value (EV)
Implied Multiples:	2009	2010E	2011E	2012E	2013E	2014E	2015E	2016E Comments
Estimated Revenues (MM)	\$0.0	\$0.0	\$5.0	\$75.0	\$125.0	\$185.0	\$245.0	\$320.0
Implied EV/Revenue			64.3x	4.3x	2.6x	1.7x	1.3x	1.0x
Estimated EBITDA (MM)	(\$19.2)	(\$24.0)	(\$27.3)	\$21.4	\$57.8	\$99.9	\$137.3	\$184.9
Implied EV/EBITDA				15.0x	5.6x	3.2x	2.3x	1.7x
Estimated Net Income (MM)	(\$29.3)	(\$27.7)	(\$27.2)	\$21.7	\$40.9	\$65.7	\$90.3	\$121.7
Implied Equity Value/Earnings (P/E)				14.8x	7.9x	4.9x	3.6x	2.6x

Source: Company reports, Cowen and Company estimates

ALIMERA - SUM OF THE PARTS VALUATION ANALYSIS (\$MM)								
	2009	2010E	2011E	2012E	2013E	2014E	2015E	2016E Comments
Product Sales (\$MM)								
Iluvien - US Sales	\$0.0	\$0.0	\$5.0	\$70.0	\$110.0	\$160.0	\$210.0	\$275.0 - 24-36 month fluocinolone acetonide implant
Est'd Gross Margin			70.0%	84.0%	83.0%	84.0%	84.0%	83.9% - Net of pSivida profit share (20%)
Est'd Operating Margin				28.5%	46.2%	54.0%	56.0%	57.8% - High margin contribution
Est'd EBIT			(\$27.3)	\$20.0	\$50.8	\$86.4	\$117.6	\$158.9
Terminal Multiple	5.0							- NDA to be filed June 2010; priority review
Discount Rate	25%							- Marketed in US, Canada by Alimera
Present Value	\$341							- Phase II for dry AMD
Per Share Valuation	\$10.89							
Royalties	\$0.0	\$0.0	\$0.0	\$5.0	\$15.0	\$25.0	\$35.0	\$45.0 - Assume 25% average royalty on ex-US sales
Terminal Multiple	6.0							- EMEA filing in Q3:2010
Discount Rate	30%							- Will partner in Europe
Present Value	\$77							
Per Share Valuation	\$2.47							
Pipeline/Other	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0 - early-stage programs/other revenues
Terminal Multiple	6.0							
Discount Rate	35%							
Present Value	\$0							
Per Share Valuation	\$0.00							
TOTAL VALUATION (\$MM)	\$418							
Less: Debt	\$25							- \$15MM obligation to pSivida repaid post IPO
Plus: Cash & Investments	\$55							- Includes net IPO proceeds of \$66.3MM
Net Equity Value	\$448							
Per Share Value	\$14.31							

Source: Company reports, Cowen and Company estimates

Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
ALIM	Alimera Sciences

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Outperform (1)	Stock expected to outperform the S&P 500
Neutral (2)	Stock expected to perform in line with the S&P 500
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(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

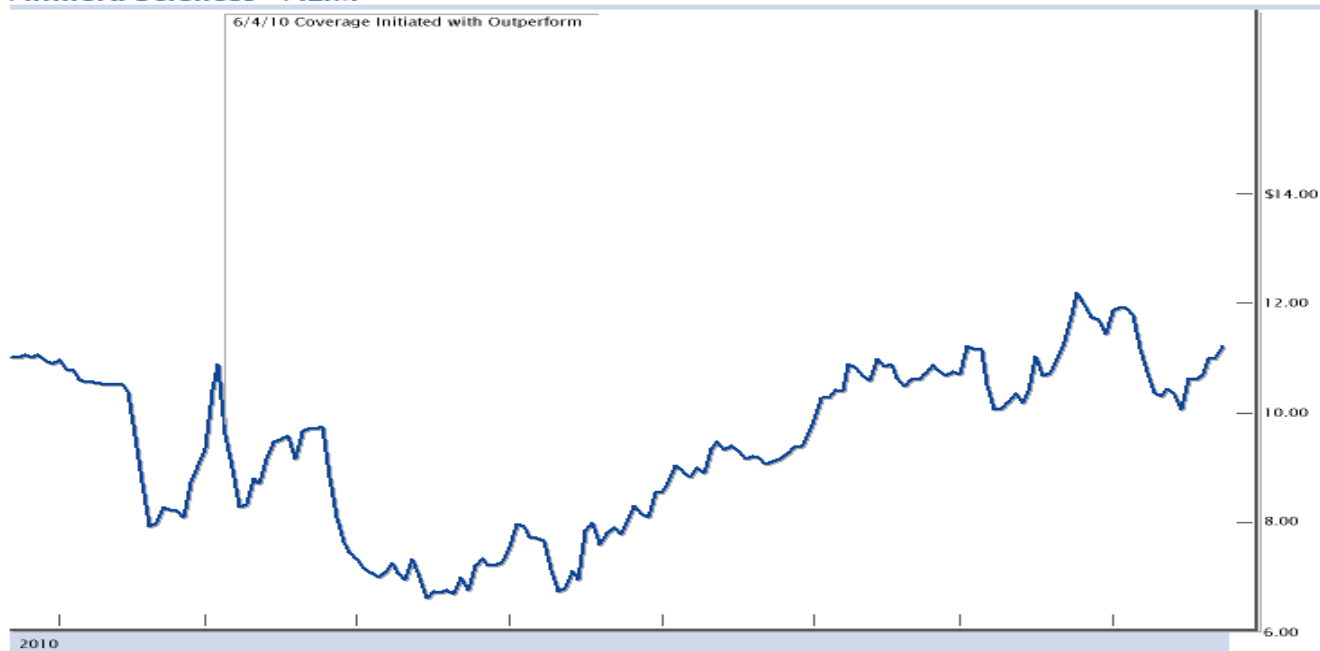
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Cowen and Company Price and Ratings History

Alimera Sciences - ALIM



Pricing data provided by Reuters America. Chart as of 12/23/10 in \$US.