

Quick Take

Alimera Sciences — Outperform (1)

ALIM: \$8.60

Quick Take: Iluvien NDA Submission On Plan, Priority Designation Next Step

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Iluvien NDA Submitted As Expected, Seeking 6-Month Priority Review

Alimera announced this morning, that it has submitted the Iluvien NDA for the DME indication to the FDA, requesting a 6-month priority review designation. The NDA submission was expected this week and is based on 24-month data from the FAME study plus a 36-month pharmacokinetic study measuring systemic exposure of fluocinolone acetonide from the Iluvien implant in 37 patients. The PK study has demonstrated no detectable systemic exposure of FA through 24 months, so Alimera plans to request a waiver of carcinogenicity study requirements.

The FDA has 60 days from yesterday's submission to accept the Iluvien NDA submission and to make its decision on the priority review designation. For conservatism, we have assumed a 10-12 month review cycle at FDA, so a 6-month review cycle would be upside. Alimera plans to file similar data packages with the EMEA (European Union) and Canadian regulatory authorities in Q3. If approved, Iluvien will be the first FDA-approved pharmaceutical treatment for DME, although other agents (intravitreal triamcinolone and anti-VEGF injections) currently are used off-label for the DME indication.

We Project \$400MM+ WW Iluvien Sales In 2016...

Our clinical consultants project that Iluvien may be used in approximately 15% of patients currently treated for DME in the U.S., primarily in patients refractory to, or inappropriate for, laser photocoagulation. That patient share translates to a \$300-400MM U.S. sales opportunity, and a \$200-300MM sales opportunity in Europe. We estimate WW Iluvien sales of \$15MM in H2:2011 (U.S. only), \$80MM in 2012, \$140MM in 2013, and \$405MM in 2016.

WE PROJECT THAT ILUVIEN CAPTURES 13-15% PATIENT SHARE IN U.S. DME TREATMENT MARKET

ESTIMATED U.S. DME MARKET BUILDUP (\$MM)*									
	2009	2010E	2011E	2012E	2013E	2014E	2015E	2016E	CGR
# Diagnosed diabetes patients US (MM)	18.3	19.0	19.8	20.6	21.4	22.3	23.2	24.1	+4%
# DME patients US - annual incidence (MM)	0.3	0.4	0.4	0.4	0.4	0.4	0.4	0.4	+4%
% Treated	50%	50%	50%	50%	50%	50%	50%	50%	- Patients treated with drug therapy
# DME patients treated (MM)	0.17	0.18	0.18	0.19	0.20	0.21	0.22	0.22	+4%
% Treated with Laser Photocoagulation	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	- ~50% of all treated DME patients receive laser therapy
# DME patients treated with LPT (MM)	0.09	0.09	0.09	0.10	0.10	0.10	0.11	0.11	- laser therapy remains the only approved treatment for DME
Cost per patient/per year (\$)	\$4,120	\$4,244	\$4,371	\$4,502	\$4,637	\$4,776	\$4,919	\$5,067	- patients receiving laser therapy are at risk for night vision loss
Laser Photocoagulation Sales (\$MM)	\$350	\$375	\$402	\$430	\$461	\$494	\$529	\$567	+7%
Iluvien (ALIM) Patient Share			1.2%	4.4%	6.8%	9.6%	12.0%	13.5%	- sustained-release corticosteroid fluocinolone acetonide
# DME patients treated with Iluvien (MM)			0.00	0.01	0.01	0.02	0.03	0.03	- 36-month intravitreal implant for DME
Cost per patient/per year (\$)			\$7,000	\$7,175	\$7,354	\$7,538	\$7,727	\$7,920	
Iluvien Sales (\$MM)			\$15	\$60	\$100	\$150	\$200	\$240	
Ozurdex (AGN) Patient Share	1.2%	3.8%	6.2%	7.7%	8.9%	10.0%	10.1%	10.2%	- 3-5 month bioerodible dexamethasone intravitreal implant
# DME patients treated with Ozurdex (MM)	0.00	0.01	0.01	0.01	0.02	0.02	0.02	0.02	- approved for macular edema following RVO in mid-'09
Cost per patient/per year (\$)	\$5,000	\$5,150	\$5,305	\$5,464	\$5,628	\$5,796	\$5,970	\$6,149	
Ozurdex Sales (\$MM)	\$10	\$35	\$60	\$80	\$100	\$120	\$130	\$140	+46%
Lucentis (Roche) Patient Share	1.2%	1.7%	2.0%	2.4%	3.6%	4.6%	5.1%	5.5%	- monoclonal antibody (mAb) ranibizumab
# DME patients treated with Lucentis (MM)	0.00	0.00	0.00	0.00	0.01	0.01	0.01	0.01	- currently in Phase III for DME
Cost per patient/per year (\$)	\$14,280	\$14,566	\$14,857	\$15,154	\$15,457	\$15,766	\$16,082	\$16,403	- off-label use for DME
Lucentis Sales (\$MM)	\$30	\$45	\$55	\$70	\$110	\$150	\$175	\$200	+31%
Avastin (Roche) Patient Share	1.2%	1.4%	1.6%	1.8%	1.9%	2.0%	2.3%	2.6%	- monoclonal antibody (mAb) bevacizumab
# DME patients treated with Avastin (MM)	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.01	- currently in Phase II for DME
Cost per patient/per year (\$)	\$9,690	\$9,884	\$10,081	\$10,283	\$10,489	\$10,699	\$10,913	\$11,131	- off-label use for DME
Avastin Sales (\$MM)	\$20	\$25	\$30	\$35	\$40	\$45	\$55	\$65	+18%
Trivaris (AGN) Patient Share	2.0%	7.4%	8.7%	11.5%	13.9%	16.1%	17.9%	19.5%	- Injectable corticosteroid triamcinolone acetonide for uveitis
# DME patients treated with Trivaris (MM)	0.00	0.01	0.02	0.02	0.03	0.03	0.04	0.04	- used in the treatment of uveitis and other ocular disorders
Cost per patient/per year (\$)	\$1,500	\$1,530	\$1,561	\$1,592	\$1,624	\$1,656	\$1,689	\$1,723	- expected off-label use for DME
Trivaris Sales (\$MM)	\$5	\$20	\$25	\$35	\$45	\$55	\$65	\$75	+47%
Triesence (ACL) Patient Share	1.4%	7.4%	10.5%	13.1%	15.5%	17.5%	19.3%	20.8%	- Injectable corticosteroid triamcinolone acetonide for uveitis
# DME patients treated with Triesence (MM)	0.00	0.01	0.02	0.03	0.03	0.04	0.04	0.05	- used in the treatment of uveitis and other ocular disorders
Cost per patient/per year (\$)	\$1,499	\$1,529	\$1,560	\$1,591	\$1,623	\$1,655	\$1,689	\$1,722	- preservative free synthetic corticosteroid
Triesence Sales (\$MM)	\$4	\$20	\$30	\$40	\$50	\$60	\$70	\$80	+56%
Triamcinolone Generic Patient Share	43.0%	32.0%	25.0%	15.0%	10.0%	8.0%	7.0%	6.0%	- synthetic corticosteroid triamcinolone
# DME patients treated with Kenalog (MM)	0.07	0.05	0.05	0.05	0.05	0.05	0.04	0.04	- off-label use for DME
Cost per patient/per year (\$)	\$206	\$212	\$219	\$225	\$232	\$239	\$246	\$253	
Kenalog Sales (\$MM)	\$15	\$11	\$11	\$12	\$12	\$11	\$11	\$9	-7%
Other Treatments Patient Share	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	- other synthetic corticosteroids and versions of triamcinolone
# DME patients treated with Other (MM)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
Cost per patient/per year (\$)	\$515	\$530	\$546	\$563	\$580	\$597	\$615	\$633	
Other Sales (\$MM)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	
Total Estimated DME Market (\$MM)	\$434	\$531	\$628	\$762	\$918	\$1,085	\$1,235	\$1,376	+18%
% Change	+20%	+22%	+18%	+21%	+20%	+18%	+14%	+11%	- New corticosteroids and anti-VEGFs could drive upside

* Note: Patient share percentages add to more than 100% given broad combination use of treatments

Source: IMS; Cowen and Company estimates

...Driving Strong P&L Leverage

Alimera's management team brings terrific commercial experience in the ophthalmology field: the senior executives were together at Novartis Ophthalmics where they successfully commercialized seven prescription ophthalmology drugs and five OTC agents. Management plans to price Iluvien at a premium to Allergan's Ozurdex (3-5 month bioerodible dexamethasone implant for treatment of RVO), which carries a \$5,000+ annual price tag. At an assumed annual price of approximately \$7,000 per year, we estimate that Iluvien will yield a gross margin of 88-90% by 2012-13, and 82-84% net of the 20% net profit payout to pSivida. Alimera plans to promote Iluvien to the approximately 1,600 retinal specialists in the U.S. and Canada via a 40-50 rep specialty sales force. We estimate the direct sales force and promotional costs at approximately \$15MM, so Iluvien DME achieves operating breakeven at \$20MM of net sales, excluding R&D spending on the AMD and RVO indications. And a modest pipeline, dominated by follow-on indications for Iluvien (wet and dry AMD, RVO), will keep R&D investment relatively low. We currently project that Alimera will reach profitability on \$35-40MM of Iluvien sales in H2:2012, and leverage \$100MM of Iluvien sales to a 30%+ operating margin and \$20-25MM of net income (fully-taxed) in 2013. We currently peg operating earnings at \$105MM

(\$2.50 per share) in 2016, on projected Iluvien sales of \$265MM and total revenues of \$300MM.

Alimera is obligated to pay pSivida a \$25MM milestone payment upon FDA approval of Iluvien. We project that the current proforma cash balance (\$53MM) will be insufficient to fund that payment plus operating cash burn through profitability in H2:2012, so a financing likely will be required in 2011.

ALIM Shares

Iluvien's efficacy profile in DME appears to be slightly superior to that of competitive agents, including triamcinolone injections and Roche's Lucentis. However, Iluvien has the advantage of delivering a very low corticosteroid dose directly to the back of the eye over 24- to 36-months, improving efficacy and compliance, and potentially reducing long-term side effects associated with other DME therapies. That advantage is partially offset by a high cataract formation rate (80%) and elevated intra-ocular pressure (IOP) side effects. 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 FDA approval and launch timing over the next 6-9 months, 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 30-40% over the next 12 months.

ILUVIEN DEVELOPMENT MILESTONES

Event	Projected Timing
NDA submission - low-dose Iluvien ✓	Jun-10
Priority review notification (60 days)	Aug-10
Projected regulatory filings in Europe, Canada	Q3:2010
FAME Phase III 36-month data readouts	Q4:2010
Projected build out of Iluvien salesforce	Q4:2010
Possible FDA approval of low-dose Iluvien (assumes 6-month review)	Dec-10
Possible U.S. market launch (assumes 6-month review)	Q1:2011
Iluvien Phase II results in AMD (dry, wet) and RVO	2011
Projected EMEA approval	H1:2012
Projected E.U. market launches (via partner)	H1:2012

Source: Company reports; Cowen and Company

ALIMERA - VALUATION PERSPECTIVES

ALIMERA SCIENCES - CURRENT VALUATION PARAMETERS

ALIMERA Share Price:	\$8.56	
Diluted Shares Outstanding (MM):	34.3	- Includes in-the-money options and employee shares
Equity Market Capitalization (\$MM):	\$293	122% - Post-money valuation
Plus: LT Debt (\$MM)	\$0	0% - \$15MM obligation to pSivida repaid post IPO
Less Cash: (\$MM)	\$53	- Includes net IPO proceeds of \$66.3MM
Total Enterprise Value (\$MM):	\$240	- Net enterprise value (EV)

	2009	2010E	2011E	2012E	2013E	2014E	2015E	2016E	Comments
Implied Multiples:									
Estimated Revenues (MM)	\$0.0	\$0.0	\$15.0	\$65.0	\$110.0	\$170.0	\$225.0	\$300.0	
Implied EV/Revenue			16.0x	3.7x	2.2x	1.4x	1.1x	0.8x	
Estimated EBITDA (MM)	(\$19.2)	(\$25.7)	(\$25.3)	\$8.7	\$35.3	\$78.9	\$112.3	\$159.5	
Implied EV/EBITDA				27.6x	6.8x	3.0x	2.1x	1.5x	
Estimated Net Income (MM)	(\$29.3)	(\$28.5)	(\$25.0)	\$5.8	\$23.2	\$51.8	\$73.7	\$104.8	
Implied Equity Value/Earnings (P/E)				41.6x	10.4x	4.6x	3.3x	2.3x	

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	\$15.0	\$60.0	\$100.0	\$150.0	\$200.0	\$265.0	- 24-36 month fluocinolone acetonide implant
Est'd Gross Margin			85.0%	84.0%	83.0%	84.0%	84.0%	83.9%	- Net of Psivida profit share (20%)
Est'd Operating Margin				13.4%	32.1%	46.4%	49.9%	53.2%	- High margin contribution
Est'd EBIT			(\$25.3)	\$8.0	\$32.1	\$69.6	\$99.8	\$140.9	
Terminal Multiple	8.0								- NDA to be filed June 2010; priority review
Discount Rate	25%								- Marketed in US, Canada by Alimera
Present Value	\$364								- Phase II for dry AMD
Per Share Valuation	\$10.61								
Royalties	\$0.0	\$0.0	\$0.0	\$5.0	\$10.0	\$20.0	\$25.0	\$35.0	- Assume 25% average royalty on ex-US sales
Terminal Multiple	10.0								- EMEA filing in Q3:2010
Discount Rate	25%								- Will partner in Europe
Present Value	\$102								
Per Share Valuation	\$2.97								
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)	\$466								
Less: Debt	\$0								- \$15MM obligation to pSivida repaid post IPO
Plus: Cash & Investments	\$53								- Includes net IPO proceeds of \$66.3MM
Net Equity Value	\$519								
Per Share Value	\$15.13								

Source: Company reports, Cowen and Company estimates

Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
ALIM	Alimera Sciences

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(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

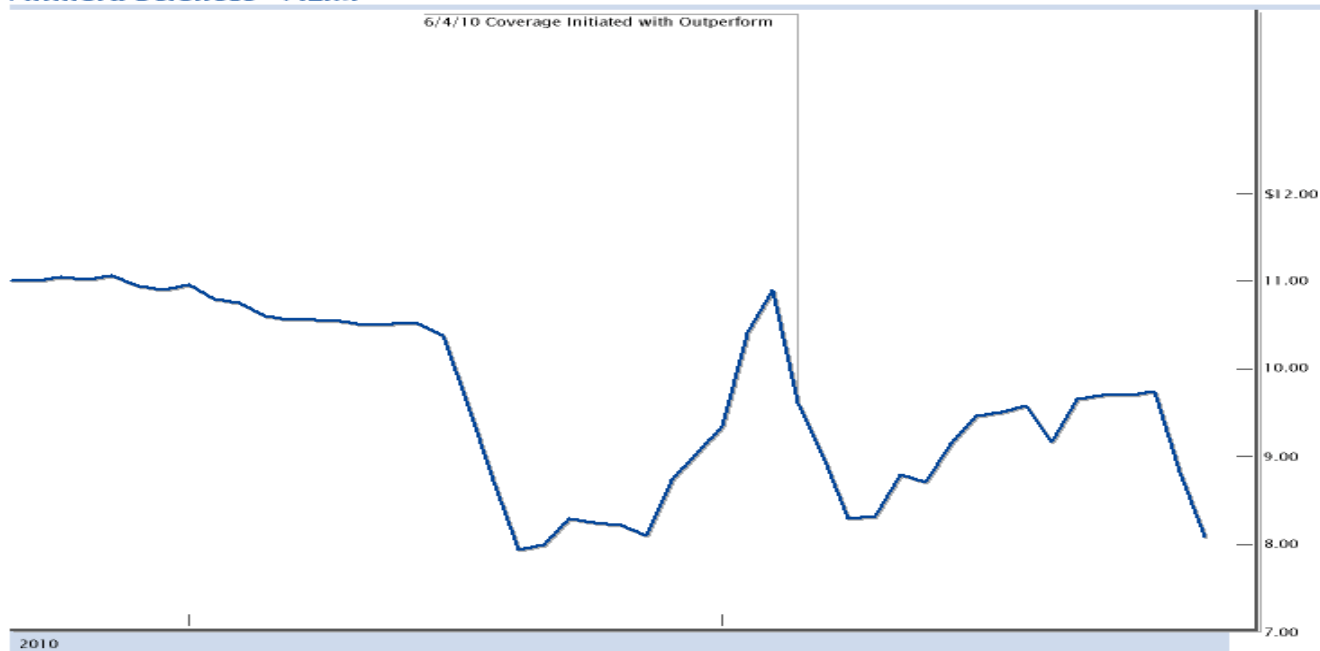
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Alimera Sciences - ALIM



Pricing data provided by Reuters America. Chart as of 6/28/10 in \$US.