



Quick Take

Alimera Sciences — Outperform (1)

ALIM: \$6.80

Quick Take: Q2 Results In-Line, Priority Review Decision Expected In August

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After the market close yesterday, Alimera reported a Q2 net loss of \$6.5MM or \$0.27/share on an operating basis and a reported net loss of \$0.20/share, which included a \$0.07 gain on debt retirement and preferred stock revaluation. The Q2 operating loss was in-line with our estimate. Management projects that SG&A will ramp in H2 with the build out of the salesforce. At the close of the June quarter Alimera had \$60MM in cash and equivalents.

Management noted that it expects to receive a decision from the FDA on the Iluvien priority review status by the end of August. The Iluvien NDA for the DME indication was filed on June 28th. The company also plans to submit a Canadian marketing application for Iluvien later this quarter. The full 36-month data (not included in the NDA submission) from the FAME trial, which includes both a low-dose and a high-dose arm, is on track to be released in Q4. Management is building the sales force in H2 in anticipation of a U.S. approval for Iluvien in late-December, assuming a 6-month priority review.

In early July, Alimera also submitted the Iluvien MAA to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom via a decentralized procedure. MAAs for Iluvien also were submitted in Austria, France, Germany, Italy, Portugal, and Spain. Analogous to the NDA submission, the MAA submissions were based on the low-dose, 24-month data from the ongoing 36-month FAME trial of Iluvien in the treatment of diabetic macular edema (DME).

In our projections, we have assumed a 10-12 month review cycle at FDA, so a 6-month review cycle would be upside. 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 late-2011/early-2012 European approvals for Iluvien. Alimera plans to seek European marketing partner(s) for Iluvien closer to regulatory approval and no further partnering visibility was provided on the call. We project Iluvien sales in Europe and Canada at \$20MM in 2012, \$40MM in 2013, \$80MM in 2014, and \$140MM in 2016; we project that Alimera yields 25% of ex-US Iluvien sales via royalties.

Alimera is obligated to pay pSivida a \$25MM milestone payment upon FDA approval of Iluvien.

Please see addendum of this report for important disclosures.

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2010/11 Spending Guidance Provided

Management stated that it projects R&D spending on Iluvien in DME of approximately \$11.6MM in 2010 and \$1.8MM in 2011 to complete the Phase III program and registration. We project total R&D expenses of \$15.7MM (+4% Y/Y) in 2010. Management also indicated that it expects SG&A to increase in Q3 and Q4 for the sales force build out ahead of the Iluvien U.S. launch. We project SG&A expenses of \$10MM (+138% Y/Y) in 2010.

ALIMERA Q2:10 RESULTS ANALYSIS

	Q1:10	Q2:09	Reported		Our Estimate		
			Q2:10A	% D	Q2:10E	% D	Comments
Product Sales	\$0.0	\$0.0	\$0.0	nm	\$0.0	nm	-
Royalties	0.0	0.0	0.0	nm	0.0	nm	-
R&D Revenues/Other	0.0	0.0	0.0	nm	0.0	nm	-
Total Revenue	\$0.0	\$0.0	\$0.0	nm	\$0.0	nm	In-line: no revs
% Change	nm	nm	nm		nm		
Cost of Goods Sold	\$0.0	\$0.0	\$0.0	nm	\$0.0	nm	In-line: no COGS
Gross Profit	\$0.0	\$0.0	\$0.0	nm	\$0.0	nm	
Gross Margin	nm	nm	nm		nm		
R&D	\$3.1	\$3.8	\$4.1	+9%	\$4.2	+10%	In-line
% Revenues	nm	nm	nm		nm		
SG&A	\$1.2	\$0.9	\$1.6	+64%	\$2.0	+112%	Just below
% Revenues	nm	nm	nm		nm		
Total Operating Expenses	\$4.2	\$4.7	\$5.7	+20%	\$6.2	+31%	Below target
% Revenues	nm	nm	nm		nm		
Operating Income	(\$4.2)	(\$4.7)	(\$5.7)	nm	(\$6.2)	nm	Slightly lower loss than anticipated on lower spending
% Revenues	nm	nm	nm		nm		
Interest Income	\$0.0	\$0.0	\$0.0		\$0.0		
Interest Expense	(\$0.5)	(\$0.5)	(\$0.1)		(\$0.1)		
Preferred Stock Accretion/Dividends	(\$2.4)	(\$1.1)	(\$0.7)		\$0.0		- Preferred stock accretion/dividends
Total Non-Operating Income	(\$2.9)	(\$1.5)	(\$0.9)		(\$0.1)		
Pretax Income	(\$7.1)	(\$6.3)	(\$6.5)		(\$6.3)		
Taxes	\$0.0	\$0.0	\$0.0	nm	\$0.0	nm	-
Tax Rate	0.0%	0.0%	0.0%		0.0%		
Net Income - Operations	(\$7.1)	(\$6.3)	(\$6.5)	nm	(\$6.3)	nm	Loss in-line with expectations
% Change	nm	nm	nm		nm		
Extraordinary Items	\$7.3	(\$1.9)	\$1.7		\$0.0		- Gain on extinguishment of debt, preferred stock revaluation
EPS - Operations*	(\$0.29)	(\$4.20)	(\$0.27)	nm	(\$0.20)	nm	Below our target, due to preferred stock accretion, dividends
% Change	nm	nm	nm		nm		
EPS - Reported	\$0.01	(\$5.46)	(\$0.20)	nm	(\$0.20)	nm	In-line, due to gain on debt extinguishment
Shares (MM) - Diluted	24.5	1.5	24.3	nm	31.1	nm	Below target, based on timing of IPO

Source: Company reports, Cowen and Company estimates

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 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 bioerodable 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%
Triescence (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 Triescence (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
Triescence 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% - New corticosteroids and anti-VEGFs could drive upside
% Change	+20%	+22%	+18%	+21%	+20%	+18%	+14%	+11%	

* Note: Patient share percentages add to more than 100% given broad combination use of treatments
Source: IMS; Cowen and Company estimates

ILUVIEN BEING TESTED IN OTHER INFLAMMATORY EYE DISEASES

ILUVIEN - CLINICAL STUDIES SUMMARY

INDICATION	TRIAL	STATUS	EFFICACY OBJECTIVE	PATIENT ENROLLMENT	DATA REPORTED
DME	Phase III FAME A	In Process	36-Month Visual Acuity	n=481 (completed)	12/09, 12/10
DME	Phase III FAME B	In Process	36-Month Visual Acuity	n=475 (completed)	12/09, 12/10
DME	Phase II PK Study	In Process	36-Month FA Plasma Exposure	n=37 (completed)	9/09, 9/10
Dry AMD	Phase II MAP GA	In Process	24-Month Geographic Atrophy Baseline Change	n=40 (targeted)	2011
Wet AMD	Phase II MAP	In Process	6-Month Visual Acuity	n=30 (targeted)	2011
RVO	Phase II FAVOR	In Process	3-Month Visual Acuity	n=20 (targeted)	2011

Source: Company reports; Cowen and Company

ILUVIEN GAINING VISIBILITY OVER NEXT 3 - 6 MONTHS

ILUVIEN DEVELOPMENT MILESTONES

Event	Projected Timing
NDA submission - low-dose Iluvien ✓	June
Priority review notification (60 days)	August
Projected regulatory filings in Europe, Canada ✓	Q3:2010
FAME Phase III 36-month data readouts - on track	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 SCIENCES - R&D PIPELINE

Therapeutic Class/Product	P-C	I	II	III	NDA	MKT	Comments
DME							
Iluvien				•	Q2:10	Q1:11	Sustained-release fluocinolone acetonide non-bioerodible intravitreal implant for the treatment of DME evaluated in 2 registration Phase III studies – FAME; 36-month Phase III readouts expected in H2:10; targeted NDA filing in Q2:10; targeted MAA filing in Q3:10 based on 24-month data
Age-Related Macular Edema							
Iluvien			•				Geographic atrophy associated with dry AMD (MAP GA Phase II currently enrolling); as an adjunctive therapy to Lucentis in wet AMD (MAP Phase II currently enrolling)
NADPH Oxidase Inhibitor Program	•						Geographic atrophy associated with dry AMD
Retinal Vein Occlusion							
Iluvien			•				Phase II FAVOR study in retinal vein occlusion (RVO) currently enrolling
Other Ocular Diseases							
NADPH Oxidase Inhibitor Program	•						Allergic conjunctivitis, wet AMD, and diabetic retinopathy
Total Drugs In Development	1	0	1	1			2

Source: Company reports; Cowen and Company

ALIMERA - VALUATION PERSPECTIVES

ALIMERA SCIENCES - CURRENT VALUATION PARAMETERS								
ALIMERA Share Price:	\$7.15							
Diluted Shares Outstanding (MM):	34.3							- Includes in-the-money options and employee shares
Equity Market Capitalization (\$MM):	\$245							133% - Post-money valuation
Plus: LT Debt (\$MM)	\$0							0% - \$15MM obligation to pSivida repaid post IPO
Less Cash: (\$MM)	\$60							- Includes net IPO proceeds of \$66.3MM
Total Enterprise Value (\$MM):	\$185							- 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			12.3x	2.8x	1.7x	1.1x	0.8x	0.6x
Estimated EBITDA (MM)	(\$19.2)	(\$25.7)	(\$25.3)	\$8.7	\$35.3	\$78.9	\$112.3	\$159.5
Implied EV/EBITDA				21.3x	5.2x	2.3x	1.6x	1.2x
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)				32.0x	8.0x	3.6x	2.5x	1.8x

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	\$60							- Includes net IPO proceeds of \$66.3MM
Net Equity Value	\$526							
Per Share Value	\$15.34							

Source: Company reports, Cowen and Company estimates

Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
ALIM	Alimera Sciences

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Rating	Definition
Outperform (1)	Stock expected to outperform the S&P 500
Neutral (2)	Stock expected to perform in line with the S&P 500
Underperform (3)	Stock expected to underperform the S&P 500

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

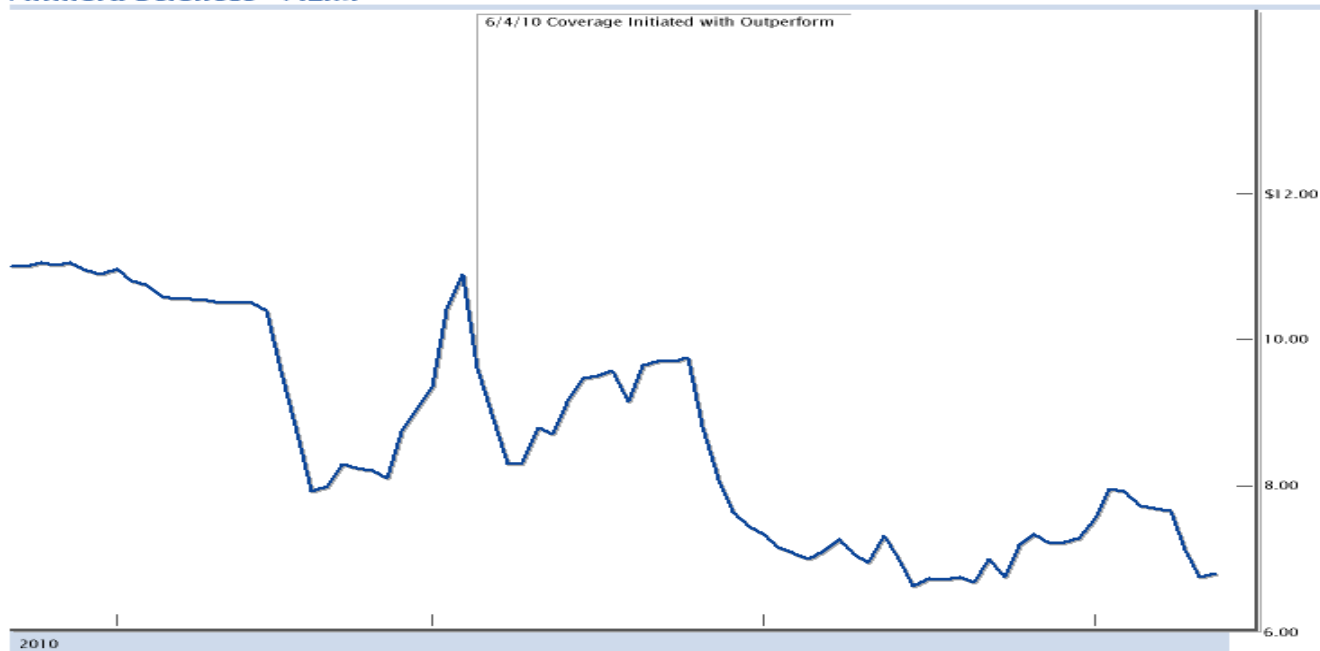
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Rating	Pct of companies under coverage with this rating	Pct for which Investment Banking services have been provided within the past 12 months
Buy (b)	47.8%	3.3%
Hold (c)	48.1%	1.0%
Sell (d)	4.1%	0.0%

(a) As of 06/30/2010. (b) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions (see above). (c) Corresponds to "Neutral" as defined in Cowen and Company, LLC's ratings definitions (see above). (d) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions (see above). Note: "Buy," "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with NASD and NYSE regulations.

Cowen and Company Price and Ratings History

Alimera Sciences - ALIM



Pricing data provided by Reuters America. Chart as of 8/12/10 in \$US.