

Alimera Sciences (ALIM)

CATALYST ALERT

Priority Review Granted, Year End Approval Expected

Rating **OUTPERFORM* [V]**
Price (30 Aug 10, US\$) 8.10
Target price (US\$) 16.00¹
52-week price range 11.06 - 6.62
Market cap. (US\$ m) 269.61
Enterprise value (US\$ m) 244.35

*Stock ratings are relative to the relevant country benchmark.

¹Target price is for 12 months.

[V] = Stock considered volatile (see Disclosure Appendix).

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- **What Happened:** Alimera announced after the market close on August 30 that it has been granted Priority Review status by the FDA for Iluvien, the company's implantable drug delivery system for treatment of diabetic macular edema (DME).
- **Our Take:** As we have written previously, we expected Iluvien to receive Priority Review, due to the degree of unmet need in DME and the successful precedents in retinal diseases that have received Priority Review. The stock price may rise modestly on the news but it has already appreciated 19% since August 12, likely in large part due to anticipation of this news.
- **Next Stop, FDA approval by year-end?:** We expect that Alimera will receive the FDA's approval decision on approximately December. The company has not disclosed the PDUFA date, but FDA accepted the NDA filing on June 30 and Priority Review decisions are typically rendered about 60 days after NDA acceptance. We assume a 75% probability of Iluvien approval in our model.
- **Investment Case:** We maintain our Outperform rating on Alimera for three main reasons: (1) DME is a large, underserved market; (2) Iluvien has a differentiated product profile with demonstrated clinical advantages; and (3) Alimera's leverageable commercial model can potentially achieve high margins and rapid profitability.
- **Modest EPS revisions upon 10Q review:** Unrelated to the Priority Review news, our EPS estimates are modestly revised, primarily due to changes in share forecasts after review of Alimera's 2Q 10Q filing.

Share price performance



On 08/27/10 the S&P 500 index closed at 1064.59

Quarterly EPS	Q1	Q2	Q3	Q4
2009A	—	—	—	—
2010E	-4.37	-0.27	-0.26	-0.38
2011E	0.00	0.03	0.15	0.18

Financial and valuation metrics

Year	12/09A	12/10E	12/11E	12/12E
EPS (CS adj.) (US\$)	-19.30	-1.53	0.37	1.60
Prev. EPS (US\$)	—	-1.51	0.36	1.56
P/E (x)	NM	NM	22.3	5.1
P/E rel. (%)	NM	NM	207.7	53.6
Revenue (US\$ m)	—	—	96.5	197.7
EBITDA (US\$ m)	-18.1	-29.8	22.5	90.6
OCFPS (US\$)	-11.56	-2.07	-0.08	2.24
P/OCF (x)	—	-3.9	-107.3	3.6
EV/EBITDA (current)	-15.4	-8.2	11.0	1.9
Net debt (US\$ m)	10	-25	-23	-98
ROIC (%)	—	—	—	—
Number of shares (m)	33.00	IC (12/09A, US\$ m)	—	—
BV/share (current, US\$)	1.8	EV/IC (x)	—	—
Net debt (current, US\$ m)	-45.6	Dividend (12/09A, US\$)	—	—
Net debt/tot. cap. (12/09A, %)	—	Dividend yield (%)	—	—

Source: Company data, Credit Suisse estimates.

DISCLOSURE APPENDIX CONTAINS IMPORTANT DISCLOSURES, ANALYST CERTIFICATIONS, INFORMATION ON TRADE ALERTS, ANALYST MODEL PORTFOLIOS AND THE STATUS OF NON-U.S. ANALYSTS. U.S. Disclosure: Credit Suisse 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.

Exhibit 1: Alimera Summary of U.S. Revenue Model*in thousands, unless otherwise stated*

	FY 2007	FY 2008	FY 2009	FY 2010E	FY 2011E	FY 2012E	FY 2013E	FY 2014E	FY 2015E
<u>Treatable Population</u>									
Diagnosed diabetic population	17,900,000	18,347,500	18,806,188	19,276,342	19,758,251	20,252,207	20,758,512	21,277,475	21,809,412
Growth rate									
Annual incidence of DME (CSME)	232,700	238,518	244,480	250,592	256,857	263,279	269,861	276,607	283,522
% of diagnosed diabetics	1.30%	1.30%	1.30%	1.30%	1.30%	1.30%	1.30%	1.30%	1.30%
Effectively treated by laser	(69,810)	(71,555)	(73,344)	(75,178)	(77,057)	(78,984)	(80,958)	(82,982)	(85,057)
percentage	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%
New patients available	162,890	166,962	171,136	175,415	179,800	184,295	188,902	193,625	198,466
Treatable population, year end <i>(assumed = trailing 3 yrs incidence)</i>			500,989	513,513	526,351	539,510	552,998	566,823	580,993
<u>Iluvien</u>									
Market share					2.0%	5.0%	8.0%	12.0%	15.0%
Total patients					10,527	26,975	44,240	68,019	87,149
Total units sold					14,276	28,977	38,574	64,048	80,327
Price per unit (net)					\$6,750	\$6,750	\$6,750	\$6,750	\$6,750
Net US sales					\$96,366	\$195,596	\$260,374	\$432,321	\$542,210
<u>Assumed retreatment rates</u>									
Bilateral disease (second eye)					40%	40%	40%	40%	40%
Second treatment					50%	50%	50%	50%	50%
Third treatment					25%	25%	25%	25%	25%

Source: Company data, Credit Suisse estimates

Exhibit 2: Alimera Income Statement Forecast

n thousands, unless otherwise stated

	FY 2007	FY 2008	FY 2009	1Q10A	2Q10A	3Q10E	4Q10E	FY 2010E	FY 2011E	FY 2012E	FY 2013E	FY 2014E	FY 2015E
Iluvien - US									\$96,366	\$195,596	\$260,374	\$432,321	\$542,210
Iluvien - ROW royalty (based on below sales)									\$100	\$2,074	\$7,824	\$10,415	\$17,293
Total net sales									\$96,466	\$197,669	\$268,197	\$442,736	\$559,503
Iluvien - ROW sales										\$10,368	\$39,119	\$52,075	\$86,464
% of prior year's US sales										11%	20%	20%	20%
COGS									3,569	7,244	9,643	16,012	20,082
Profit Sharing									9,502	27,707	40,358	72,323	92,836
Gross margin									83,395	162,718	218,196	354,401	446,585
R&D Expense	8,363	13,964	15,057	3,065	4,140	4,200	4,200	15,605	13,679	17,530	20,536	22,339	24,323
Marketing Expense	969	1,259	752	247	379	2,000	5,000	7,626	27,000	26,800	26,780	23,958	26,354
Sales Force Expense	0	0	0	0	0	975	2,025	3,000	12,600	13,230	13,892	14,586	15,315
Logistics	0	0	0	0	0	0	0	0	5,788	11,860	16,092	26,564	33,570
G&A	3,184	3,758	3,407	904	1,174	974	695	3,748	4,497	5,397	6,368	7,387	8,569
Total SG&A	4,153	5,017	4,159	1,151	1,553	3,949	7,720	14,374	49,885	57,287	63,131	72,495	83,808
Total expenses	12,516	18,981	19,216	4,216	5,693	8,149	11,920	29,979	63,564	74,817	83,667	94,835	108,132
Operating Income/EBIT	(12,516)	(18,981)	(19,216)	(4,216)	(5,693)	(8,149)	(11,920)	(\$29,979)	\$19,830	\$87,901	\$134,529	\$259,567	\$338,453
Interest Income	1,079	585	37	\$2	\$14	\$15	\$15	46	36	205	489	910	1,550
Interest Expense	(2)	(1,514)	(1,897)	(474)	(144)	0	0	(618)	0	0	0	0	0
Pretax Income/(Loss)	(\$11,439)	(\$19,910)	(\$21,076)	(\$4,688)	(\$5,823)	(\$8,134)	(\$11,905)	(\$30,551)	\$19,867	\$88,106	\$135,018	\$260,477	\$340,004
Tax Expense/(benefit), fully taxed				0	0	0	0	0	7,669	34,009	52,117	100,544	131,242
Net income from continuing operations	(\$11,439)	(\$19,910)	(\$21,076)	(\$4,688)	(\$5,823)	(\$8,134)	(\$11,905)	(\$30,551)	\$12,198	\$54,097	\$82,901	\$159,933	\$208,762
Benefit Conv Feature of Pfd Stock			(355)										
Preferred stock accretion	(248)	(718)	(623)	(359)	(107)			(466)					
Preferred stock dividends	(4,685)	(6,573)	(7,225)	(2,025)	(613)	0	0	(2,638)	0	0	0	0	0
Net income to common	(\$16,372)	(\$27,201)	(\$29,279)	(\$7,072)	(\$6,543)	(\$8,134)	(\$11,905)	(\$33,655)	\$12,198	\$54,097	\$82,901	\$159,933	\$208,762
Wtd Avg Shares (diluted)	1,500	1,510	1,517	1,619	24,293	31,143	31,148	22,051	33,328	33,712	34,307	34,870	35,534
Earnings per Share (diluted)	(\$10.92)	(\$18.01)	(\$19.30)	(\$4.37)	(\$0.27)	(\$0.26)	(\$0.38)	(\$1.53)	\$0.37	\$1.60	\$2.42	\$4.59	\$5.87

Margins & Growth

Margin Analysis

Margin Analysis													
ROW royalty, % of sales										20.0%	20.0%	20.0%	20.0%
Gross margin, excl profit share									96.3%	96.3%	96.4%	96.4%	96.4%
Gross margin									86.5%	82.3%	81.4%	80.0%	79.8%
Rsch & Devel. % sales									14.2%	8.9%	7.7%	5.0%	4.3%
Marketing % sales									28.0%	13.6%	10.0%	5.4%	4.7%
Sales force % sales									13.1%	6.7%	5.2%	3.3%	2.7%
Logistics % sales									6.0%	6.0%	6.0%	6.0%	6.0%
G&A % sales									4.7%	2.7%	2.4%	1.7%	1.5%
Total SG&A % sales									51.7%	29.0%	23.5%	16.4%	15.0%
EBIT margin									20.6%	44.5%	50.2%	58.6%	60.5%
Effective tax rate									38.6%	38.6%	38.6%	38.6%	38.6%
Net margin									12.6%	27.4%	30.9%	36.1%	37.3%

Growth Analysis

Net sales										104.9%	35.7%	65.1%	26.4%
Gross margin										95.1%	34.1%	62.4%	26.0%
Research & Development									(12.3%)	28.1%	10.0%	10.0%	10.0%
Marketing		29.9%	(40.3%)						254.1%	(0.7%)	(0.1%)	(10.5%)	10.0%
Sales force									320.0%	5.0%	5.0%	5.0%	5.0%
Logistics										104.9%	35.7%	65.1%	26.4%
G&A		18.0%	(9.3%)					10.0%	20.0%	20.0%	18.0%	16.0%	16.0%
Total SG&A		20.8%	(17.1%)						247.1%	14.8%	10.2%	14.8%	15.6%
EBIT									(166.1%)	343.3%	53.0%	92.9%	30.4%
Net income									(136.2%)	343.5%	53.2%	92.9%	30.5%
Earnings per Share										338.4%	50.6%	89.8%	28.1%

Source: Company data, Credit Suisse estimates

Exhibit 3: Alimera Balance Sheet Forecast*n thousands, unless otherwise stated*

	FY 2008	FY 2009	1Q10A	2Q10A	3Q10E	4Q10E	FY 2010E	FY 2011E	FY 2012E	FY 2013E	FY 2014E	FY 2015E
ASSETS												
Current Assets												
Cash & cash equivalents	\$17,875	\$4,858	\$14,178	\$45,635	\$44,848	\$25,259	\$25,259	\$22,550	\$97,855	\$181,981	\$310,094	\$502,941
Investments				14,544	14,544	0	0	0	0	0	0	0
Accounts receivable								30,699	56,978	67,049	110,684	139,876
Inventory					0	663	663	1,564	2,411	4,003	5,020	4,292
Prepaid Expenses	1,593	634	751	1,112	680	697	697	767	844	928	1,021	1,123
Prelaunch Costs Receivable - pSivida								1,183	0	0	0	0
Other current assets		815	1,093									
Total current assets	\$19,468	\$6,307	\$16,022	\$61,291	\$60,072	\$26,620	\$26,620	\$56,763	\$158,087	\$253,962	\$426,819	\$648,232
Long-term Assets												
Property and Equipment, net	796	254	229	237	216	198	198	156	122	102	87	77
Deferred tax assets				0	0	0	0	45,370	11,361	0	0	0
Other assets						25,000	25,000	22,500	20,000	17,500	15,000	12,500
TOTAL ASSETS	\$20,264	\$6,561	\$16,251	\$61,528	\$60,288	\$51,818	\$51,818	\$124,789	\$189,570	\$271,564	\$441,906	\$660,809
LIABILITIES AND EQUITY												
Current Liabilities												
Accounts Payable & Accrued Interest	\$1,575	\$1,758	\$2,841	\$1,457	\$7,174	\$9,895	\$9,895	\$12,951	\$15,590	\$17,444	\$20,062	\$23,204
Accrued Expenses	2,308	3,314	2,258	2,498	3,000	3,645	3,645	5,833	9,332	4,371	4,836	5,808
Outsourced Services Payable	1,024	1,157	1,440	1,240	1,240	1,240	1,240	1,240	1,240	1,240	1,240	1,240
Note Payable		4,500	6,000	0	0	0	0	0	0	0	0	0
Capital Lease Obligations	10	6	5	10	10	0	0	0	0	0	0	0
Total Current Liabilities	\$4,917	\$10,735	\$12,544	\$5,205	\$11,424	\$14,781	\$14,781	\$20,024	\$26,162	\$23,055	\$26,138	\$30,252
Long-term Liabilities												
Note Payable, less Current Portion	15,000	10,500	9,000	0	0	0	0	0	0	0	0	0
Capital Lease Obligations	6											
Profit Share Payable to pSivida								3,185	7,645	10,090	18,081	23,209
Fair Value of Pfd Stk Conv Feature	12,656	36,701	36,907	0	0	0	0	0	0	0	0	0
Other Long-term Liabilities	555	708	524	25	700	779	779	857	942	697	33	932
Total Long-term Liabilities	28,217	47,909	46,431	25	700	779	779	4,042	8,587	10,787	18,114	24,141
Preferred Stock												
Series A Redeemable Preferred Stock	34,199	36,467	37,026									
Series B Redeemable Preferred Stock	37,963	40,617	41,271									
Series C Redeemable Preferred Stock	30,855	33,452	34,092									
Series C-1 Redeemable Preferred Stock		2,853	11,382									
Total Preferred Stock	103,017	113,389	123,771									
Shareholders' Equity												
Common Stock	51	54	56	351	351	351	351	351	351	351	351	351
Add'l Paid-in Capital	3,474	4,836	5,090	232,412	232,412	232,412	232,412	232,412	232,412	232,412	232,412	232,412
Series C-1 Preferred Warrants		1,472	0	0	0	0	0	0	0	0	0	0
Common Stock Warrants	58	57	57	54	54	54	54	54	54	54	54	54
Retained Earnings/(deficit)	(119,470)	(171,891)	(171,698)	(176,519)	(184,653)	(196,559)	(196,559)	(132,094)	(77,997)	4,904	164,837	373,599
Total shareholders' equity	(115,887)	(165,472)	(166,495)	56,298	48,164	36,258	36,258	100,723	154,820	237,721	397,654	606,416
TOTAL LIABILITIES & EQUITY	\$20,264	\$6,561	\$16,251	\$61,528	\$60,288	\$51,818	\$51,818	\$124,789	\$189,570	\$271,564	\$441,906	\$660,809

Source: Company data, Credit Suisse estimates

Exhibit 4: Alimera Cash Flow Statement Forecast*n thousands, unless otherwise stated*

	FY 2008	FY 2009	2010	2010	2010	2010	FY 2010E	FY 2011E	FY 2012E	FY 2013E	FY 2014E	FY 2015E
			1Q10	2Q10E	3Q10	4Q10						
STATEMENT OF CASH FLOWS												
Net income/(loss)	(\$61,464)	(\$44,218)	\$2,577	(\$4,101)	(\$8,134)	(\$11,905)	(\$21,564)	\$64,465	\$54,097	\$82,901	\$159,933	\$208,762
Income from Discontinued Operations			(4,000)				(4,000)					
Depreciation & Amortization	241	1,098	\$48	\$47	\$49	\$50	194	212	224	230	235	240
Change in Fair Value of Pfd Stk Conv Feature	10,454	23,142	(3,265)	(379)			(3,644)					
Stock Compensation Expense	750	551	108	271			379					
Noncash R&D Expense/Investment loss	17,809	300		5			5					
Noncash gain on extinguishment of debt				(1,343)			(1,343)					
Change in Current Assets:												
Decr/(Incr) in Accounts Receivable			0	0	0	0	0	(30,699)	(26,279)	(10,072)	(43,635)	(29,192)
Decr/(Incr) in Inventory			0	0	0	(663)	(663)	(900)	(847)	(1,592)	(1,017)	729
Decr/(Incr) in Prepaid Expenses	(1,213)	591	(118)	(481)	432	(17)	(184)	(70)	(77)	(84)	(93)	(102)
Decr/(Incr) in Prelaunch Costs Recvbl			0	0	0	0	0	(1,183)	1,183	0	0	0
Decr/(Incr) in Other Curr. Assets			0	0	0	0	0	0	0	0	0	0
Change in Current Liabilities:												
Incr/(decr) in Accounts Payable	615	183	962	(1,025)	5,717	2,721	8,375	3,056	2,639	1,854	2,618	3,142
Incr/(decr) in Accr. Exps. & Other Curr. Liab.	85	705	(767)	675	502	635	1,045	2,187	3,500	(4,961)	465	972
Change in Other Assets & Liabilities:												
Decr/(Incr) in defd tax assets			0	0	0	0	0	(45,370)	34,009	11,361	0	0
Decr/(Incr) in other long-term assets	24		0	0	0	(25,000)	(25,000)	2,500	2,500	2,500	2,500	2,500
Incr/(Decr) in other long-term liab.	540	153	(184)	186	675	79	756	78	86	(245)	(664)	898
Incr/(decr) in profit split payable			0	0	0	0	0	3,185	4,460	2,444	7,991	5,128
Cash from Discontinued Operations	43	(43)										
Cash from Operating Activities	(\$32,116)	(\$17,538)	(\$4,639)	(\$6,145)	(\$759)	(\$34,101)	(\$45,644)	(\$2,539)	\$75,494	\$84,337	\$128,332	\$193,078
Sale/(Purchase) of Investments				(\$14,550)	\$0	\$14,544	(\$6)	\$0	\$0	\$0	\$0	\$0
Purchase of PP&E	(640)	(65)	(\$23)	(24)	(28)	(32)	(107)	(170)	(190)	(210)	(220)	(230)
Net cash used in investing activs of cont ops			(23)	(14,574)	(28)	14,512	(113)	(170)	(190)	(210)	(220)	(230)
Net cash provided by investing activs of discount ops			4,000				4,000					
Cash from Investing Activities	(640)	(65)	\$3,977	(\$14,574)	(\$28)	\$14,512	\$3,887	(\$170)	(\$190)	(\$210)	(\$220)	(\$230)
Increase/(Decr.) in Note Payable			0	(15,000)	0	0	(15,000)	0	0	0	0	0
Proceeds from Series C Stock Offering	29,938						0					
Proceeds from Series C-1 Stock Offering		4,897					0					
Proceeds from Exercise of Stock Options		7		20			20					
Repurchase of Common Stock	(150)						0					
Proceeds from Common Stock Offering				68,395			68,395					
Proceeds from Exercise of C-1 Warrants	6	31	9,998	(1)			9,997					
Proceeds from Exercise of Common Warrants			148	310			458					
Deferred Offering Costs		(339)	(163)	(1,545)			(1,708)					
Payments on Capital Lease Obligations	(10)	(10)	(1)	(3)			(4)					
Cash from Financing Activities	\$29,784	\$4,586	\$9,982	\$52,176	\$0	\$0	\$62,158	\$0	\$0	\$0	\$0	\$0
Net Increase/(Decrease) in Cash	(\$2,972)	(\$13,017)	\$9,320	\$31,457	(\$787)	(\$19,589)	\$20,401	(\$2,709)	\$75,304	\$84,127	\$128,112	\$192,848
Cash at beginning of year	20,847	17,875	\$4,858	\$14,178	\$45,635	\$44,848	\$4,858	25,259	22,550	97,855	181,981	310,094
Cash at end of year	\$17,875	\$4,858	\$14,178	\$45,635	\$44,848	\$25,259	\$25,259	\$22,550	\$97,855	\$181,981	\$310,094	\$502,941

Source: Company data, Credit Suisse estimates

Companies Mentioned (Price as of 30 Aug 10)

Alimera Sciences (ALIM, \$8.10, OUTPERFORM [V], TP \$16.00)

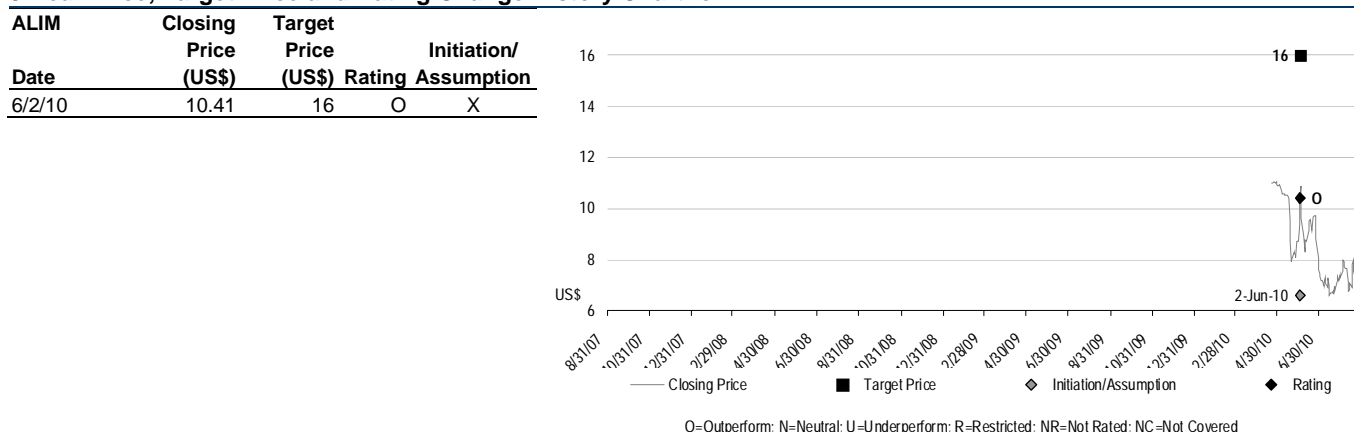
Disclosure Appendix

Important Global Disclosures

I, Michael Faerm, certify that (1) the views expressed in this report accurately reflect my personal views about all of the subject companies and securities and (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

See the Companies Mentioned section for full company names.

3-Year Price, Target Price and Rating Change History Chart for ALIM



The analyst(s) responsible for preparing this research report received compensation that is based upon various factors including Credit Suisse's total revenues, a portion of which are generated by Credit Suisse's investment banking activities.

Analysts' stock ratings are defined as follows:

Outperform (O): The stock's total return is expected to outperform the relevant benchmark* by at least 10-15% (or more, depending on perceived risk) over the next 12 months.

Neutral (N): The stock's total return is expected to be in line with the relevant benchmark* (range of $\pm 10\text{-}15\%$) over the next 12 months.

Underperform (U): The stock's total return is expected to underperform the relevant benchmark* by 10-15% or more over the next 12 months.

*Relevant benchmark by region: As of 29th May 2009, Australia, New Zealand, U.S. and Canadian ratings are based on (1) a stock's absolute total return potential to its current share price and (2) the relative attractiveness of a stock's total return potential within an analyst's coverage universe**, with Outperforms representing the most attractive, Neutrals the less attractive, and Underperforms the least attractive investment opportunities. Some U.S. and Canadian ratings may fall outside the absolute total return ranges defined above, depending on market conditions and industry factors. For Latin American, Japanese, and non-Japan Asia stocks, ratings are based on a stock's total return relative to the average total return of the relevant country or regional benchmark; for European stocks, ratings are based on a stock's total return relative to the analyst's coverage universe**. For Australian and New Zealand stocks a 22% and a 12% threshold replace the 10-15% level in the Outperform and Underperform stock rating definitions, respectively, subject to analysts' perceived risk. The 22% and 12% thresholds replace the +10-15% and -10-15% levels in the Neutral stock rating definition, respectively, subject to analysts' perceived risk.

**An analyst's coverage universe consists of all companies covered by the analyst within the relevant sector.

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Analysts' coverage universe weightings are distinct from analysts' stock ratings and are based on the expected performance of an analyst's coverage universe* versus the relevant broad market benchmark**:

Overweight: Industry expected to outperform the relevant broad market benchmark over the next 12 months.

Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.

Underweight: Industry expected to underperform the relevant broad market benchmark over the next 12 months.

*An analyst's coverage universe consists of all companies covered by the analyst within the relevant sector.

**The broad market benchmark is based on the expected return of the local market index (e.g., the S&P 500 in the U.S.) over the next 12 months.

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Price Target: (12 months) for (ALIM)

Method: Our \$16 target price for ALIM is based on a discounted cash flow analysis (DCF). We have estimated ALIM's future cash flows by forecasting the company's income statement, balance sheet and cash flows through 2020 (the year of patent expiration), and by assuming a fading of cash flows to zero by 2030, with no terminal value. We have used this methodology because we believe that the vast majority of ALIM's value is attributable to a single product, Iluvien, with a finite commercial life. We have applied a 75% probability of success adjustment to our cash flow estimates to account for the risks to approval and launch of the Iluvien. We have used a 12% discount rate for our DCF, applied to the probability-adjusted cash flows. Our ALIM revenue forecast is based on our estimates for the addressable patient population in diabetic macular edema, and our assumption that Iluvien will achieve a peak penetration rate of 15%.

Risks: Risks to our \$16 target price include: (1) single product risk (ALIM's value is virtually entirely attributable to Iluvien, and the company's near to medium term revenues, profits and value depend on the FDA's approval and Alimera's successful commercialization of Iluvien in diabetic macular edema. There is little visibility on additional indications for Iluvien or on the new product pipeline; (2) regulatory risk to timely Iluvien approval, due to missed statistical significance on the MART data set, the possibility that the FDA may wait for 3 year FAME data before issuing an approval decision, and the possibility that FDA may not grant priority review; (3) commercial risk, due to the presence of several established treatments for DME and competing companies that are better-capitalized and have a longer-standing presence in the ophthalmology community than ALIM; (4) liquidity and financing risk, due to the potential need for ALIM to raise additional funds, particularly if Iluvien approval is delayed beyond the expected December 2010; and (5) reimbursement risk, as securing reimbursement from payors is crucial to Iluvien's success and the fact that Iluvien will compete against some relatively inexpensive products.

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