

Alimera Sciences (ALIM - \$4.63)

Healthcare / Biotechnology

Ticker: ALIM
Rating: Buy
Price Target: \$12.00

Iluvien launch coming into focus

We recently spent time with the senior management of ALIM and we come away incrementally more positive on the name as we watch the continued ramp of Iluvien in the US overshadow the relatively lackluster EU launch to date. Management notes that the key hurdles early in the adoption is high prescribing practices (5-6 injections), which may have temporarily slowed adoption as they await reimbursements to begin rolling in. Counter-detailing by Allergan (AGN) appears to focus on the 3-year Iluvien implant vs the 3-month Ozurdex implant, and the relative merits of being able to discontinue treatment if intra-ocular pressure (IOP) side effects crop up. ALIM counters that treating IOP is straightforward, and moreover if treatment is discontinued due to IOP, what is used to treat the underlying diabetic macular edema (DME) then? Seen in this light, a three year implant doesn't really change the treatment paradigm. We continue to like ALIM here, and we reiterate our Buy rating, \$12 price target based on a sum-of-the-parts analysis, with US Iluvien sales valued at \$10/share, EU Iluvien sales valued at \$1.5/share, and cash and tech valued at \$0.5/share.

Trading Data:

Last Price (07/06/2015)	\$4.63
52-Week High (09/03/2014)	\$6.54
52-Week Low (05/26/2015)	\$3.98
Market Cap. (MM)	\$205.6
Shares Out. (MM)	44.35

- **Reimbursement concerns should ease in 2H15.** Management anticipates that in 2H15 there could be a resurgence of orders from their current highest prescribing practices as their backlog of reimbursement payments start to roll in. The typical reimbursement timeline can be as long as 120 days, and an ophthalmic practice may be leery of extending a \$50K-\$60K account receivable much further.
- **Allergan counter detail misses the point.** By suggesting that 3-month therapy (Ozurdex) is better than 3-year therapy (Iluvien) due to the ability to stop therapy in the face of a rise in IOP after 3 months, it begs the question what then? After anti-VEGF & steroids there are no real options for treating DME.
- **Targeting profitability in 2016, reiterate Buy rating \$12 PT.** We anticipate ALIM turns EPS positive in 1H16 driven by US Iluvien sales approaching \$20M/Q. Our \$12 price target based on a sum-of-the-parts analysis, with US Iluvien sales valued at \$10/share, EU Iluvien sales valued at \$1.5/share, and cash and tech valued at \$0.5/share. Please see next page for additional details on bullets.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY16E	\$0.00	\$0.04	\$0.07	\$0.14	\$0.25	17.9x
FY15E	(\$0.27)A	(\$0.18)	(\$0.18)	(\$0.13)	(\$0.75)	NA
FY14	(\$0.21)	(\$0.16)	(\$0.22)	(\$0.25)	(\$0.84)	NA
FY13	(\$0.27)	(\$0.30)	(\$0.25)	(\$0.24)	(\$1.11)	NA

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Source: Laidlaw & Company estimates

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Reimbursement concerns should ease in 2H15. Management notes that with the out of pocket Iluvien cost per injection of ~\$8,800, and a reimbursement turnaround of ~120 days, a physician’s practice which has done 5-6 procedures can be sitting on a \$50K accounts receivable, which can delay additional procedures until the reimbursements start coming in from payers. ALIM has extended payment terms to allow practices to delay until reimbursements are received, but ALIM believes the early adopting high prescribing practices will likely wait until 2H15 before performing additional injections

Ozurdex counter-detail omits a key question. The main counter-detail by Allergan reps to Iluvien appears to be that Ozurdex has a three month duration vs. Iluvien’s three years, allowing doctors to discontinue treatment if there’s a rise in intra-ocular pressure (IOP). Which begs the question of what then? DME patients on steroid are Lucentis/Eylea refractory, and there aren’t any other treatment options. Are physicians going to stop treating DME in Ozurdex patients with a rise in IOP and allow vision loss/blindness to continue? In clinical trials 95% of IOP patients on Iluvien were controlled without surgery. We believe that when walked through the alternatives (nothing) ophthalmologists will agree that treating IOP in a three year implant is manageable

Iluvien may be performing better in practice than it did in clinical trials. Management believes that with the advent of anti-VEGF therapies as first line treatment for DME may be selecting better candidates for steroid therapy than were in the FAME trials, which had to take all comers.

Figure 1. Iluvien Revenue Projections

Alimera Sciences						
Iluvien US sales model						
(values in 000's)	2015E	2016E	2017E	2018E	2019E	2020E
US diabetic population	21,420	21,848	22,285	22,731	23,186	23,649
% Diabetic Macular Edema (DME)	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
# US DME patients (000)	643	655	669	682	696	709
% unresponsive to anti-VEGF	30%	30%	30%	30%	30%	30%
# US unresponsive to anti-VEGF	193	197	201	205	209	213
% Iluvien of unresponsive US patients	1.5%	4.6%	9.4%	16.5%	20.0%	23.5%
# Iluvien unresponsive US patients (000)	2.8	9.1	18.8	33.8	41.7	50.0
Annual cost of therapy	\$8,250	\$8,250	\$8,588	\$8,694	\$9,128	\$9,767
Iluvien US sales (\$000)	\$23,220	\$75,232	\$162,122	\$293,789	\$380,969	\$488,552
growth Y-Y		224%	115%	81%	30%	28%

Source: Company Reports: Laidlaw & Company estimates

Quarterly Income Statement

Alimera Sciences
Quarterly income statement

(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
Revenues										
Iluvien - US						\$2,438	\$4,771	\$6,759	\$10,099	\$23,220
Iluvian ex-US	\$2,084	\$2,190	\$2,408	\$1,741	\$8,423	1,500	2,685	3,580	4,475	13,202
Total Revenue	\$2,084	\$2,190	\$2,408	\$1,741	\$8,423	\$3,938	\$7,456	\$10,340	\$14,575	\$36,309
Expenses:										
Cost of Revenue (COGS)	564	376	372	130	1,442	283	1,790	2,481	3,498	8,052
Gross Margin	1,520	1,814	2,036	1,611	6,981	3,655	5,667	7,858	11,077	28,257
Research and development	2,626	1,809	3,941	2,987	11,363	3,329	3,500	3,750	4,500	15,079
General & administration	2,927	2,827	3,040	4,236	13,030	4,191	4,250	4,500	4,500	17,441
Sales & marketing	3,411	3,136	3,680	5,308	15,535	7,129	6,000	7,750	8,000	28,879
Total operating expenses	8,964	7,772	10,661	12,531	39,928	14,649	13,750	16,000	17,000	61,399
Income (loss) from Operations	(7,444)	(5,958)	(8,625)	(10,920)	(32,947)	(10,994)	(8,083)	(8,142)	(5,923)	(33,142)
Int inc (expense), other net	(129)	(325)	(408)	(1,228)	(2,090)	(1,122)	(150)	(150)	(150)	(1,572)
Income (loss) before taxes	(20,759)	1,185	(6,964)	(9,198)	(35,736)	(9,724)	(8,233)	(8,292)	(6,073)	(32,322)
Income tax exp (benefit)		69	45	60	174	69	-	-	-	69
Net Income (Loss)	(20,759)	1,116	(7,009)	(9,258)	(35,910)	(9,793)	(8,233)	(8,292)	(6,073)	(32,391)
Pref stock conversion exp				(750)	(750)					
Net Income (Loss) to common				(10,008)	(36,660)					
1x items & non-cash exp	(13,186)	7,468	1,885	2,016	(1,817)	2,208				2,208
Adj NI less non cash & 1x items	(7,573)	(6,352)	(8,894)	(11,274)	(34,093)	(12,001)				(34,599)
EPS as reported	(\$0.58)	\$0.02	(\$0.17)	(\$0.23)	(\$0.91)	(\$0.22)	(\$0.18)	(\$0.18)	(\$0.13)	(\$0.71)
Adj EPS ex-1x & non-cash items	(\$0.21)	(\$0.16)	(\$0.22)	(\$0.25)	(\$0.84)	(\$0.27)				(\$0.75)
Weighted avg. shares (000)	35,853	40,276	41,063	44,296	40,397	44,348	45,348	46,348	47,348	45,848

Source: Company reports and Laidlaw estimates

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Annual Income Statement

Alimera Sciences
Annual income statement

(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	Comments
Revenues						
Iluvien - US	-	23,220	75,232	162,122	293,789	US launch 1Q15
Iluvian ex-US	8,423	13,202	29,671	57,037	77,174	EU roll-out through 2016
Total Revenue	\$8,423	\$36,309	\$104,902	\$219,158	\$370,963	
Expenses:						
Cost of Revenue (COGS)	1,442	8,052	24,128	50,406	85,322	pSivida payments here
Gross Margin	6,981	28,257	80,775	168,752	285,642	
R&D	11,363	15,079	13,500	14,500	16,500	
General & administration	13,030	17,441	18,750	19,250	20,000	
Sales & marketing	15,535	28,879	30,500	36,250	37,750	50 reps for US launch
Total op exp	39,928	61,399	62,750	70,000	74,250	
Inc/(loss) from Ops	(32,947)	(33,142)	18,025	98,752	211,392	
Int income (exp), net	(2,090)	(1,572)	(600)	(600)	(600)	
Other expenses, net	-	-	-	-	-	
Inc/(loss) before taxes	(35,736)	(32,322)	17,425	98,152	210,792	
Income tax exp (benefit)	174	69	-	12,342	50,586	Substantial tax loss carryforwards
Net Income (Loss)	(\$35,910)	(\$32,391)	\$17,425	\$85,810	\$160,206	
1x items & non-cash exp	(1,817)	2,208	0	0	0	
Adj NI less non cash & 1x items	(\$34,093)	(\$34,599)	\$0	\$0	\$0	
Earning per Share	(\$0.91)	(\$0.71)	\$0.25	\$1.25	\$2.25	
Adj EPS ex-1x & non-cash items	(\$0.84)					
Weighted avg. shares (000)	40,397	45,848	48,598	50,598	53,598	
Fully diluted shares (000)	61,800	65,848	68,598	68,598	71,098	
Cash balance	\$76,697	\$44,101	\$72,725	\$171,985	\$346,541	\$50MM Deerfield Series B shares 4Q14

Source: Company reports and Laidlaw estimates

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Major Risks

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Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

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Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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Date	Rating	Closing Price (\$)
04/28/2015	Buy (B)	4.61

Date	Target Price (\$)	Closing Price, (\$)
04/28/2015	12.00	4.61

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Allergan (AGN – Not Rated)

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