

Alimera Sciences (ALIM - \$1.79)

J-Code Sales bump appears to be below expectations in 2016

ALIM 4Q15 EPS came in more or less in line with consensus and our estimates, but the anemic top line growth of Iluvien continued to dog the shares in the quarter and will likely impact 1Q16 as well. ALIM did not provide guidance for 2016 but management did indicate that the conversion of Benefit Investigations (BI) to an actual sale of Iluvien appears to be taking 2-3 months on average. BI's can be seen as a precursor to sales, as it means that physicians are investigating if Iluvien is covered by the patients' insurance. Some doctors that last year delayed initiating a BI until the J-code was enacted in January 2016 appear to be utilizing Ozurdex (3-month steroid) initially before moving the patient over to Iluvien. The key for ALIM in 2016 will be speeding up the BI conversion to sales from 2-3 months, and effectively counter-detailing Iluvien vs. Ozurdex on the concerns of the incidence and treatment of any increases in intra-ocular pressure (IOP) in Iluvien patients. We are lowering our PT to \$10 from \$12 to account for a more moderated ramp of Iluvien due to the 2-3 month BI conversion delay, maintain Buy rating.

- **US sales estimates lowered in light of lackluster 1Q16.** Worldwide Iluvien sales in 4Q15 were below our estimates by ~\$1.2M, driven primarily (in the US) by doctors delaying procedures until the Iluvien specific J-code became active in January. Management specifically did not give guidance on the call, but comments about the 2-3 month conversion from BI's to sales seem to indicate 1Q16 could be below our prior estimates. See table below for our Iluvien sales adjustments.
- **Ozurdex counter-detail focuses on IOP concerns.** The 3-month reversibility of Ozurdex (vs. 3 years for Iluvien) remains the key counter-detail from Allergan for doctors concerned about IOP. ALIM notes that in the ~4K Iluvien injections to date only 2 patients worldwide have required surgery to treat IOP that wasn't controlled by medication, well below the 5% of patients in the FAME studies.
- **Additional fund raise possible 2016.** ALIM ended 2015 with ~\$31M in cash, and we anticipate the company will burn ~\$26M in cash from operations in 2016, which suggests to us that ALIM could return to the capital markets in 2H16, likely following a positive ramp in Iluvien sales in 2016.
- **Reiterate Buy rating, lowering PT from \$12 to \$10.** Our \$10 price target based on a sum-of-the-parts analysis, with US Iluvien sales valued at \$8/share, EU Iluvien sales valued at \$2/share, and cash and technology valued at \$0/share.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(\$0.05)	(\$0.02)	\$0.01	\$0.08	\$0.05	35.8x
FY16E	(\$0.21)	(\$0.19)	(\$0.15)	\$(0.12)	(\$0.65)	NA
FY15	(\$0.27)	(\$0.24)	(\$0.21)	(\$0.24)	(\$0.97)	NA
FY14	(\$0.21)	(\$0.16)	(\$0.22)	(\$0.25)	(\$0.84)	NA

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker:	ALIM
Rating:	Buy
Price Target:	↓ \$10.00

Trading Data:

Last Price (03/04/2016)	\$1.79
52-Week High (03/12/2015)	\$5.29
52-Week Low (03/03/2016)	\$1.67
Market Cap. (MM)	\$80.0
Shares Out. (MM)	44.55

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Figure 1: Variance analysis

Alimera Sciences Variance analysis										
(000's except per share)	4Q14A	4Q15A	4Q15E	Variance	% Y/Y	FY14A	FY15A	FY15E	Variance	% Y/Y
Iluvien - US	\$0	\$3,923	\$4,771	(\$848)	NM	\$0	\$15,169	\$15,964	(\$795)	NM
Iluvien - ex US	1,741	1,900	2,238	(338)	9.1%	8,423	7,269	7,697	(428)	-13.7%
Total Revenue	\$1,741	\$5,823	\$7,009	(\$1,186)	234.5%	\$8,423	\$22,438	\$23,624	(\$1,186)	166.4%
COGS	130	336	370	(34)	158.5%	1,442	1,317	1,663	(346)	-8.7%
Gross Profit	1,611	5,487	6,639	(1,152)	240.6%	6,981	21,121	21,961	(840)	202.5%
R&D Expense	2,987	3,618	4,000	(382)	21.1%	11,363	14,840	15,222	(382)	30.6%
G&A Expense	4,236	4,410	4,000	410	4.1%	13,030	16,092	15,682	410	23.5%
Sales & Marketing Exp	5,308	7,087	7,000	87	33.5%	15,535	28,090	28,003	87	80.8%
Operating Inc (loss)	(10,920)	(9,628)	(8,361)	(1,267)	-11.8%	(32,947)	(38,213)	(36,946)	(1,267)	16.0%
Int. inc. (expense), net	(1,228)	(1,103)	(1,250)	147	-10.2%	(2,090)	(4,693)	(4,840)	147	124.5%
Pretax Income	(9,198)	(10,731)	(9,611)	(1,120)	16.7%	(35,736)	(30,508)	(29,388)	(1,120)	-14.6%
Income Tax exp (benefit)	60	(25)	0	(25)	-141.7%	174	130	155	(25)	-25.3%
Net income (loss)	(9,258)	(10,706)	(9,611)	(1,095)	15.6%	(35,910)	(30,638)	(29,543)	(1,095)	-14.7%
1x items & non-cash exp	2,016	7	2,250	(2,243)	-99.7%	(1,817)	12,437	14,680	(2,243)	-784.5%
Adj NI ex-1x/non cash	(11,274)	(10,713)	(11,861)	1,148	-5.0%	(34,093)	(43,075)	(44,223)	1,148	26.3%
Weighted avg. shares (000)	44,296	44,617	44,486	130	0.7%	40,397	44,450	44,417	34	10.0%
Fully diluted shares (000)	65,776	76,617	76,486	130	16.5%	63,028	76,076	76,044	33	20.7%
EPS as reported	(\$0.23)	(\$0.24)	(\$0.22)	(\$0.02)	6.2%	(\$0.91)	(\$0.69)	(\$0.67)	(\$0.02)	-24.0%
Adj EPS ex-1x & non-cash	(\$0.25)	(\$0.24)	(\$0.27)	\$0.03	-5.7%	(\$0.84)	(\$0.97)	(\$1.00)	\$0.03	14.8%

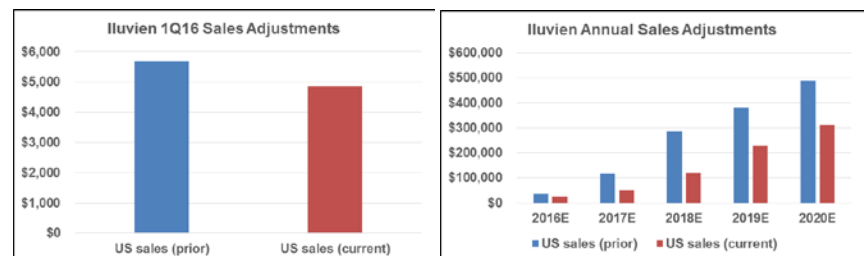
Source: Company Reports: Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts value: ALIM		
Segment	Valuation (000's)	Per share value
Iluvien - US	\$588,049	\$8.0
Iluvien - EU	\$128,182	\$2.0
Net cash '16 & tech value	\$2,884	\$0.0
SUM	\$719,114	\$10
Shares out '16E (000)		76,076

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Sales revisions



Source: Company Reports: Laidlaw & Company estimates

Figure 3: Current Iluvien US Revenue Projections

Alimera Sciences Iluvian US sales model						
(values in 000's)	2015A	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 capture % of anti-VEGF failures	1.0%	1.6%	2.9%	6.8%	12.0%	15.0%
Iluvien capture # of anti-VEGF failures	1.8	3.1	5.9	13.8	25.0	31.9
Annual cost of therapy	\$8,250	\$8,250	\$8,588	\$8,694	\$9,128	\$9,767
Iluvien US sales (\$000)	\$15,115	\$25,753	\$50,750	\$120,542	\$228,581	\$311,842
growth Y-Y		70%	97%	138%	90%	36%

Source: Company Reports: Laidlaw & Company estimates

Quarterly Income Statement

Alimera Sciences Quarterly income statement										
(\$000 except per share)	2014A				2014A Year	2015A				2015A Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QA	
Revenues										
Iluvien - US						\$2,438	\$3,776	\$5,032	\$3,923	\$15,169
Iluvian ex-US	\$2,084	\$2,190	\$2,408	\$1,741	\$8,423	1,500	2,000	1,869	1,900	7,269
Total Revenue	\$2,084	\$2,190	\$2,408	\$1,741	\$8,423	\$3,938	\$5,776	\$6,901	\$5,823	\$22,438
Expenses:										
Cost of Revenue (COGS)	564	376	372	130	1,442	283	376	634	336	1,317
Gross Margin	1,520	1,814	2,036	1,611	6,981	3,655	5,400	6,267	5,487	21,121
Research and development	2,626	1,809	3,941	2,987	11,363	3,329	3,815	4,078	3,618	14,840
General & administration	2,927	2,827	3,040	4,236	13,030	4,191	4,460	3,031	4,410	16,092
Sales & marketing	3,411	3,136	3,680	5,308	15,535	7,129	6,925	6,949	7,087	28,090
Total operating expenses	8,964	7,772	10,661	12,531	39,928	14,649	15,200	14,058	15,115	59,022
Income (loss) from Operations	(7,444)	(5,958)	(8,625)	(10,920)	(32,947)	(10,994)	(9,800)	(7,791)	(9,628)	(38,213)
Int inc (expense), other net	(129)	(325)	(408)	(1,228)	(2,090)	(1,122)	(1,151)	(1,317)	(1,103)	(4,693)
Income (loss) before taxes	(20,759)	1,185	(6,964)	(9,198)	(35,736)	(9,724)	(8,592)	(1,461)	(10,731)	(30,508)
Income tax exp (benefit)		69	45	60	174	69	4	82	(25)	130
NI (Loss) as reported	(20,759)	1,116	(7,009)	(9,258)	(35,910)	(9,793)	(8,596)	(1,543)	(10,706)	(30,638)
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	2,175	8,047	7	12,437
Adj NI less non cash & 1x items	(7,573)	(6,352)	(8,894)	(11,274)	(34,093)	(12,001)	(10,771)	(9,590)	(10,713)	(43,075)
EPS as reported	(\$0.58)	\$0.02	(\$0.17)	(\$0.23)	(\$0.91)	(\$0.22)	(\$0.19)	(\$0.03)	(\$0.24)	(\$0.69)
Adj EPS ex-1x & non-cash items	(\$0.21)	(\$0.16)	(\$0.22)	(\$0.25)	(\$0.84)	(\$0.27)	(\$0.24)	(\$0.21)	(\$0.24)	(\$0.97)
Weighted avg. shares (000)	35,853	40,276	41,063	44,296	40,397	44,348	44,397	44,436	44,617	44,450

Source: Company Reports: Laidlaw & Company estimates

Figure 5: Annual Income Statement

Alimera Sciences						
Annual income statement						
(\$000 except per share)	2014A	2015A	2016E	2017E	2018E	Comments
Revenues						
Iluvien - US	-	15,169	25,753	50,750	120,542	US launch 1Q15
Iluvian ex-US	8,423	7,269	10,271	26,772	62,927	EU roll-out through 2016
Total Revenue	\$8,423	\$22,438	\$36,024	\$77,522	\$183,469	
Expenses:						
Cost of Revenue (COGS)	1,442	1,317	5,975	12,872	33,024	pSivida payments here
Gross Margin	6,981	21,121	30,049	64,650	150,444	
R&D	11,363	14,840	15,000	14,000	15,000	
General & administration	13,030	16,092	16,250	16,500	18,000	
Sales & marketing	15,535	28,090	28,500	29,000	31,000	50 reps for US launch
Total op exp	39,928	59,022	59,750	59,500	64,000	
Inc/(loss) from Ops	(32,947)	(38,213)	(29,701)	5,150	86,444	
Int income (exp), net	(2,090)	(4,693)	(1,000)	(1,200)	(600)	
Other expenses, net	-	-	-	-	-	
Inc/(loss) before taxes	(35,736)	(30,508)	(30,701)	3,950	85,844	
Income tax exp (benefit)	174	130	-	-	4,527	Substantial tax loss carryforwards
Net Income (Loss)	(\$35,910)	(\$30,638)	(\$30,701)	\$3,950	\$81,317	
1x items & non-cash exp	(1,817)	12,437	0	0	0	
Adj NI less non cash & 1x items	(\$34,093)	(\$43,075)	\$0	\$0	\$0	
Earning per Share	(\$0.91)	(\$0.69)	(\$0.65)	\$0.05	\$0.95	
Adj EPS ex-1x & non-cash items	(\$0.84)	(\$0.97)				
Weighted avg. shares (000)	40,397	44,450	47,304	52,142	53,267	
Fully diluted shares (000)	63,028	76,076	79,304	84,142	85,767	
Cash balance	\$76,697	\$31,100	\$11,958	\$19,859	\$103,776	3.25M share offering 2H16

Source: Company Reports: Laidlaw & Company estimates

Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

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.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

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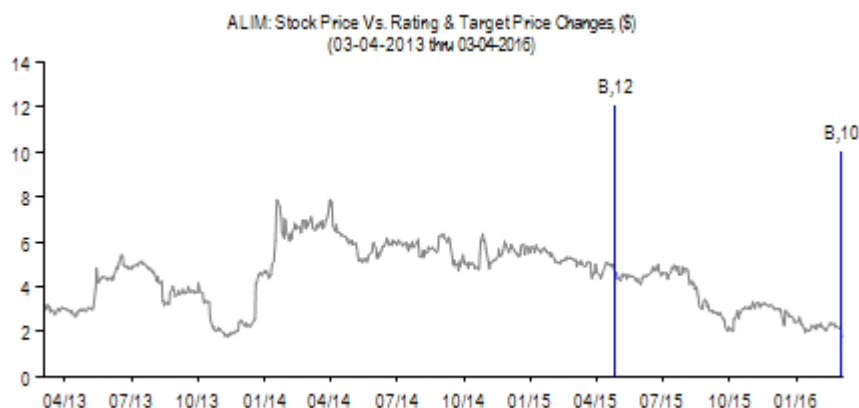
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Rating and Price Target Change History



3 Year Rating Change History

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

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/28/2015	12.00	4.61
03/04/2016	10.00	1.80*

* Previous Close 3/3/2016

Source: Laidlaw & Company

Created by: Blue-Compass.net

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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.	65.71%	25.71%	2.86%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Allergan plc (AGN – Not Rated)

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