

Alimera Sciences (ALIM - \$1.18)

US Iluvien Misses on Seasonality, September Looking Stronger

ALIM recently reported their 3Q16 with a top line miss due mostly to seasonality as July US Iluvien sales of \$6.2M missed our estimated \$7.3M. We had expected weaker Y-Y sales growth than 2Q16 and are encouraged by ALIM's report of a strong uptick of sales in September. ALIM reiterated the challenges associated with penetrating the market with a paradigm changing treatment procedure as well as the lack of quarterly pull through once a patient is on a 3-year product. Nonetheless, the real world data of Iluvien, such as lower incidence of Intraocular pressure (IOP), should help keep growing volume. We are also pleased to see ex-US Iluvien sales more or less hitting our estimates as Germany and Portugal lead the charge and look forward to following the progress of Iluvien in the Middle East as their first patient received treatment in 3Q16. ALIM continues to contemplate expanding the Iluvien label in non-proliferative diabetic retinopathy or retinal vein occlusion after the company becomes cash flow positive. We are reiterating our Buy rating and our \$10 price target.

- **US Iluvien sales miss, seasonality highlighted.** US Iluvien sales of \$6.2M missed our estimate of \$7.3M due to seasonality especially in the month of July, according to ALIM. Although we had anticipated slower sales in the summer because of vacations, we understand that the company is seeing a strong uptick in sales in September, which should help 4Q16.
- **Paradigm shifting treatments require patience.** Educating physicians that are used to using shorter duration steroid therapies is taking longer than we had anticipated. That said we believe that the advantages of real world data (such as IOP incidence 18%-20% vs 38% in clinical trials) and the resolution of reimbursement issues, should lead to continued volume growth.
- **Ex-US Iluvien sales ok, label expansion still an option.** Ex-US Iluvien sales of \$2.1M were roughly in line with our \$2.3M estimate, with Portugal and Germany leading the charge. ALIM reiterated their interest in expanding the Iluvien label but this would be a 2017 event, after reaching cash flow positive.
- **Reiterate Buy rating and \$10 PT.** Our \$10 price target is based on a sum-of-the-parts analysis, with US Iluvien sales valued at \$7.5/share, EU Iluvien sales valued at \$2/share, and cash and technology valued at \$0.50/share.

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(\$0.06)	(\$0.03)	\$0.00	\$0.01	(\$0.08)	NA
FY16E	(\$0.21)A	(\$0.15)A	(\$0.14)A	\$(0.10)	(\$0.57)	NA
FY15	(\$0.26)	(\$0.23)	(\$0.20)	(\$0.22)	(\$0.92)	NA
FY14	(\$0.21)	(\$0.16)	(\$0.22)	(\$0.25)	(\$0.83)	NA

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

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

Trading Data:

Last Price (08/04/2016)	\$1.18
52-Week High (04/21/2016)	\$5.15
52-Week Low (07/22/2016)	\$1.01
Market Cap. (MM)	\$76.4
Shares Out. (MM)	64.77

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Figure 1: Variance analysis

Alimera Sciences					
Variance analysis					
(000's except per share)	3Q15A	3Q16A	3Q16E	Variance	% Y/Y
Iluvien - US	\$5,032	\$6,200	\$7,300	(\$1,100)	23.2%
Iluvien - ex US	1,869	2,098	2,282	(184)	12.3%
Total Revenue	\$6,901	\$8,298	\$9,582	(\$1,284)	20.2%
COGS	381	486	548	(62)	27.6%
Gross Profit	6,520	7,812	9,035	(1,223)	19.8%
R&D Expense	4,078	3,261	3,200	61	-20.0%
G&A Expense	3,031	3,645	3,500	145	20.3%
Sales & Marketing Exp	6,949	7,452	8,250	(798)	7.2%
Operating Inc (loss)	(7,538)	(6,546)	(5,915)	(631)	-13.2%
Int. inc. (expense), net	(1,317)	(1,330)	(1,250)	(80)	1.0%
Pretax Income	(8,855)	(7,876)	(7,165)	(711)	-11.1%
Income Tax exp (benefit)	82	33	0	33	-59.8%
Adj NI ex-1x & noncash	(8,937)	(7,909)	(7,165)	(744)	-11.5%
1x items & non-cash exp	7,394				-100.0%
EPS as reported	(1,543)				-100.0%
Weighted avg. shares (000)	44,436	56,104	64,088	(7,985)	26.3%
Fully diluted shares (000)	75,844	90,622	97,588	(6,966)	19.5%
Adj EPS ex-1x & noncash	(\$0.20)	(\$0.14)	(\$0.11)	(\$0.03)	-29.9%
EPS as reported	(\$0.03)				-100.0%

Source: Company Reports: Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
Iluvien - US	\$734,893	\$7.5
Iluvien - EU	\$203,501	\$2.0
Net cash '17 & tech value	\$41,331	\$0.5
SUM	\$979,725	\$10
Shares out '17E (000)		98,479

Source: Company Reports: Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

Alimera Sciences										
Quarterly income statement										
(\$000 except per share)	2015A				2015A Year	2016E				2016E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
Revenues										
Iluvien - US	\$2,438	\$3,776	\$5,032	\$3,923	\$15,169	\$4,119	\$7,208	\$6,200	\$8,111	\$25,638
Iluvian ex-US	1,500	2,000	1,869	1,900	7,269	1,682	2,349	2,098	2,282	8,411
Total Revenue	\$3,938	\$5,776	\$6,901	\$5,823	\$22,438	\$5,801	\$9,557	\$8,298	\$10,394	\$34,050
Expenses:										
Cost of Revenue (COGS)	280	320	381	336	1,317	328	556	486	552	1,922
Gross Margin	3,658	5,456	6,520	5,487	21,121	5,473	9,001	7,812	9,842	32,128
Research and development	3,329	3,815	4,078	3,618	14,840	3,020	3,205	3,261	3,200	12,686
General & administration	3,619	3,821	3,031	3,719	14,190	3,395	4,039	3,645	3,750	14,829
Sales & marketing	7,129	6,925	6,949	7,087	28,090	7,109	7,510	7,452	7,500	29,571
Total operating expenses	14,077	14,561	14,058	14,424	57,120	13,524	14,754	14,358	14,450	57,086
Income (loss) from Operations	(10,419)	(9,105)	(7,538)	(8,937)	(35,999)	(8,051)	(5,753)	(6,546)	(4,608)	(24,958)
Int inc (expense), other net	(1,122)	(1,151)	(1,317)	(1,103)	(4,693)	(1,335)	(1,177)	(1,330)	(1,250)	(5,092)
Income (loss) before taxes	(11,541)	(10,256)	(8,855)	(10,040)	(40,692)	(9,386)	(6,930)	(7,876)	(5,858)	(30,050)
Income tax exp (benefit)	69	4	82	(25)	130	9	42	33	-	84
Adjusted NI ex-1x & noncash	(11,610)	(10,260)	(8,937)	(10,015)	(40,822)	(9,395)	(6,972)	(7,909)	(5,858)	(30,134)
1x items & non-cash exp	1,817	1,664	7,394	(698)	10,177	(1,750)	114	(1,336)		(2,972)
EPS as reported	(9,793)	(8,596)	(1,543)	(10,713)	(30,645)	(11,145)	(6,858)	(9,245)		(33,106)
Adjusted EPS ex-1x & noncash	(\$0.26)	(\$0.23)	(\$0.20)	(\$0.22)	(\$0.92)	(\$0.21)	(\$0.15)	(\$0.14)	(\$0.09)	(\$0.57)
EPS as reported	(\$0.22)	(\$0.19)	(\$0.03)	(\$0.24)	(\$0.69)	(\$0.25)	(\$0.15)	(\$0.16)		(\$0.63)
Weighted avg. shares (000)	44,348	44,397	44,436	44,617	44,450	45,006	45,088	56,104	64,104	52,575
Fully diluted shares (000)	75,841	76,003	75,844	78,772	76,615	78,522	78,627	90,622	98,354	86,531

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	25,030	42,495	104,953	US launch 1Q15
Iluvian ex-US	8,423	7,269	8,411	17,227	39,181	EU roll-out through 2016
Total Revenue	\$8,423	\$22,438	\$33,441	\$59,723	\$144,133	
Expenses:						
Cost of Revenue (COGS)	610	1,317	1,919	4,446	20,899	pSivida payments here
Gross Margin	7,813	21,121	31,522	55,277	123,234	
R&D	11,363	14,840	12,686	13,000	15,000	
General & administration	12,371	14,190	14,829	13,000	19,500	
Sales & marketing	15,535	28,090	29,571	29,250	30,150	50 reps for US launch
Total op exp	39,269	57,120	57,086	55,250	64,650	
Inc/(loss) from Ops	(31,456)	(35,999)	(25,564)	27	58,584	
Int income (exp), net	(2,090)	(4,693)	(5,092)	(5,000)	(5,000)	
Other expenses, net	(542)	(106)	-	-	-	
Inc/(loss) before taxes	(33,546)	(40,692)	(30,656)	(4,973)	53,584	
Income tax exp (benefit)	174	130	84	-	3,181	Substantial tax loss carryforwards
Adjusted NI ex-1x & noncash	(\$33,720)	(\$40,822)	(\$30,740)	(\$4,973)	\$50,403	
1x items & non-cash exp	(2,940)	10,177	(2,972)	0	0	
EPS as reported	(\$36,660)	(\$30,645)	(\$33,712)	\$0	\$0	
Earning per Share	(\$0.83)	(\$0.92)	(\$0.58)	(\$0.08)	\$0.50	
Adj EPS ex-1x & non-cash items	(\$0.91)	(\$0.69)				
Weighted avg. shares (000)	40,397	44,450	52,575	64,729	65,854	
Fully diluted shares (000)	70,392	76,615	86,531	98,479	99,854	
Cash balance	\$76,697	\$31,075	\$18,149	\$18,226	\$72,279	18M share offering 3Q16
Margin & Expense Analysis						
COGS as % of Revenues	7%	6%	6%	7%	15%	
R&D	135%	66%	38%	22%	10%	
SG&A	184%	125%	88%	49%	21%	
Gross Profit	93%	94%	94%	93%	86%	
Op. margin cont. ops	NA	NA	-76%	0%	41%	
Taxes	-1%	0%	0%	0%	6%	
Net margin	NA	NA	-92%	-8%	35%	
Year-over-year change						
Net revenue	350%	166%	49%	79%	141%	
R&D	35%	31%	-15%	2%	15%	
SG&A	-5%	81%	5%	-1%	3%	
Operating income	NA	NA	NA	NA	NA	
Net income	NA	NA	NA	NA	NA	

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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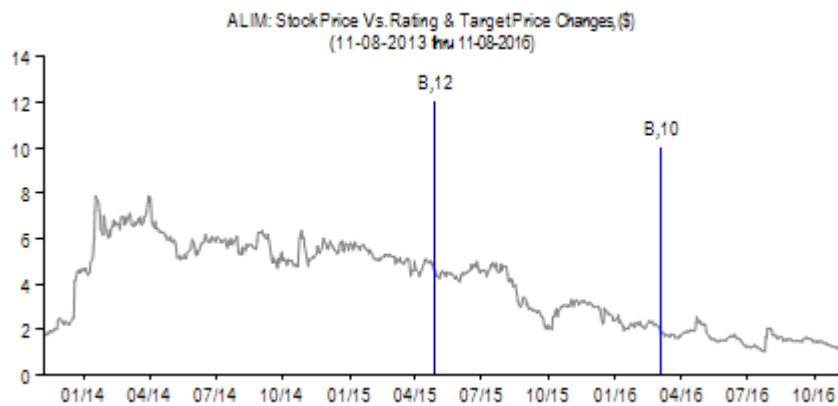
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Rating and Price Target Change History



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

Date	Target Price (\$)	Closing Price, (\$)
04/28/2015	12.00	4.61
03/04/2016	10.00	1.85

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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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