

Alimera Sciences (ALIM - \$1.47)

Healthcare / Biotechnology

US Real-World Data Shows Clear Lowering in Treatment Burden

We recently spent time with ALIM management following their presentation of real-world data on Iluvien at the Ophthalmology Innovation Summit (OIS) held in conjunction with the Annual Scientific Meeting of the American Society of Retinal Specialists (ASRS) and come away incrementally more positive as Iluvien showed statistically significant reduction ($p < 0.01$) in treatment frequency. The U.S. Retrospective Chart Review in Patients Receiving Iluvien (USER) study reported 160 eyes in 130 patients (~23% of patients received Iluvien in both eyes). It demonstrated that visual acuity remained relatively constant while treatment burden was significantly reduced as treatment frequency went from once every 2.9 months to once every 14.3 months following treatment with Iluvien. Additionally, we were especially encouraged by the change in visual acuity data once stratified between $>20/200$ ($n=12$), $20/200$ to $<20/100$ ($n=20$), $20/100$ to $<20/50$ ($n=61$) and $20/40$ & better ($n=67$) as not only was treatment frequency significantly reduced in all groups, there seemed to be improvement in visual acuity in the two worst patient populations ($>20/200$ and $20/200$ to $<20/100$). We also saw as a significant positive in the lack of IOP changes with data up to 24 months post-Iluvien treatment. On the back of a strong 2Q17, which saw US Iluvien sales grow 84% vs 1Q17 as well as positive adjusted EBITDA for the first time, we believe this recent presentation should help increase end user demand and enable ALIM to hit their target of cash flow positive from operations by YE17. With more conference presentations to come in September at the Retina Society and November at the American Academy of Ophthalmology, we believe familiarity to ALIM's paradigm changing product should grow and we reiterate our Buy rating and \$5 price target.

- **USER study data impressive, treatment burden reduction should help drive topline.** Regardless of visual acuity severity, US data now demonstrates the importance of reducing treatment frequency as it represents a significant burden to the DME population and those responsible for caring for them.
- **Paradigm changing treatments take time, US real-world data should speed up process.** As US and ex-US shows clear benefits, we believe Iluvien sales should lead to continued topline growth at ALIM.
- **Maintain our Buy rating and our \$5 PT.** Our \$5 price target is based on a sum-of-the-parts analysis, with US Iluvien sales at \$3/share, EU Iluvien sales at \$1.5/share, and cash and technology at \$0.50/share.

Ticker: **ALIM**
Rating: **Buy**
Price Target: **\$5.00**

Trading Data:

Last Price (08/03/2017)	\$1.47
52-Week High (08/17/2016)	\$1.77
52-Week Low (11/03/2016)	\$1.03
Market Cap. (MM)	\$94.4
Shares Out. (MM)	64.9

Earnings Estimates: (per share)

	1Q	2Q	3Q	4Q	FY	P/E
FY17E	(\$0.10)A	(\$0.03)A	(\$0.04)	\$0.01	(\$0.16)	NA
FY16	(\$0.21)	(\$0.15)	(\$0.14)	(\$0.09)	(\$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

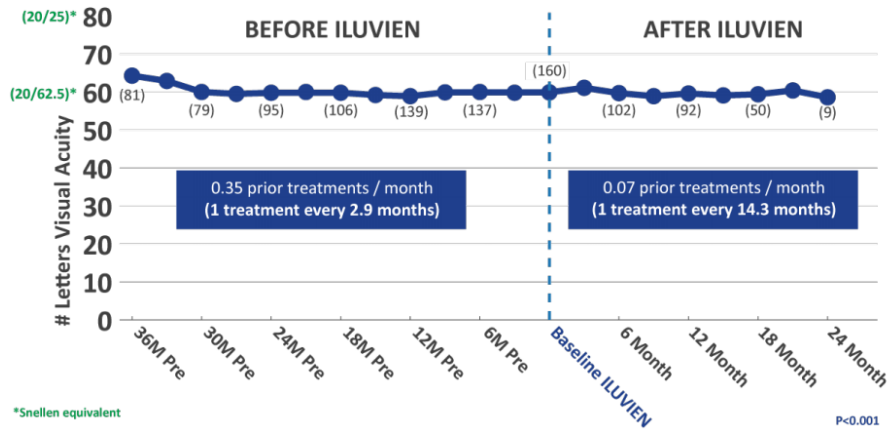
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Source: Laidlaw & Company estimates

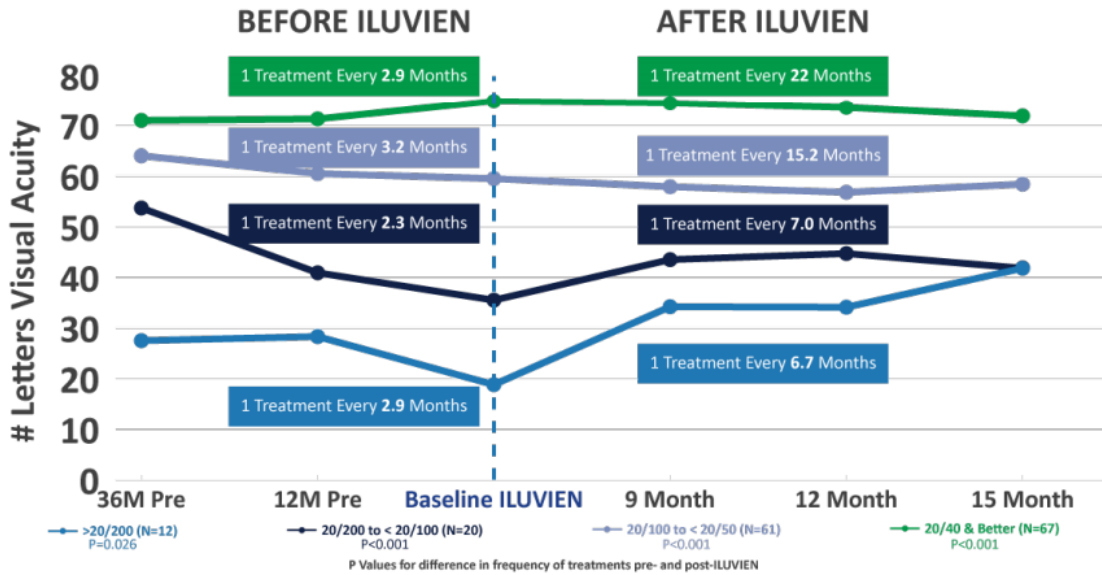
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Figure 1: Change in Visual Acuity of Entire Population – Clear reduction in treatment burden



Source: Alimera Presentation

Figure 2: Change in Visual Acuity – Reduction in treatment burden and improvement in visual acuity in worse case patients



Source: Alimera Presentation

Figure 3: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
Iluvien - US	\$278,199	\$3.0
Iluvien - EU	\$132,203	\$1.5
Net cash '18 & tech value	\$49,818	\$0.5
SUM	\$460,221	\$5
Shares out '18E (000)		100,363

Source: Company Reports: Laidlaw & Company estimates

Figure 4: Quarterly Income Statement

Alimera Sciences										
Quarterly income statement										
(\$000 except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
Revenues										
Iluvien - US	\$4,119	\$7,208	\$6,200	\$8,300	\$25,827	\$4,400	\$8,100	\$7,961	\$9,815	\$30,277
Iluvian ex-US	1,682	2,349	2,098	2,377	8,506	2,200	2,300	3,026	4,656	12,182
Total Revenue	\$5,801	\$9,557	\$8,298	\$10,677	\$34,333	\$6,618	\$10,368	\$10,988	\$14,471	\$42,445
Expenses:										
Cost of Revenue (COGS)	328	556	486	924	2,344	587	769	275	362	1,992
Gross Margin	5,473	9,001	7,812	9,753	31,989	6,031	9,599	10,713	14,110	40,453
Research and development	3,020	3,205	3,261	2,889	12,375	2,110	2,238	2,350	2,350	9,048
General & administration	3,395	4,039	3,645	4,184	15,263	3,264	3,012	3,250	3,250	12,776
Sales & marketing	7,109	7,510	7,452	7,360	29,431	5,502	5,060	6,500	6,500	23,562
Total operating expenses	13,524	14,754	14,358	14,433	57,069	10,876	10,310	12,100	12,100	45,386
Income (loss) from Operations	(8,051)	(5,753)	(6,546)	(4,680)	(25,030)	(4,845)	(711)	(1,387)	2,010	(4,933)
Int inc (expense), other net	(1,335)	(1,177)	(1,330)	(1,336)	(5,178)	(1,337)	(1,384)	(1,250)	(1,250)	(5,221)
Income (loss) before taxes	(9,386)	(6,930)	(7,876)	(6,016)	(30,208)	(6,182)	(2,095)	(2,637)	760	(10,154)
Income tax exp (benefit)	9	42	33	(88)	(172)	26	44	-	-	70
Adjusted NI ex-1x & noncash	(9,395)	(6,972)	(7,909)	(5,928)	(30,204)	(6,208)	(2,139)	(2,637)	760	(10,224)
1x items & non-cash exp	(1,750)	114	(1,336)	178	(2,970)	(527)	(618)			
EPS as reported	(11,145)	(6,858)	(9,245)	(5,750)	(33,174)	(6,735)	(2,757)			
Adjusted EPS ex-1x & noncash	(\$0.21)	(\$0.15)	(\$0.14)	(\$0.09)	(\$0.57)	(\$0.10)	(\$0.03)	(\$0.04)	\$0.01	(\$0.16)
EPS as reported	(\$0.25)	(\$0.15)	(\$0.16)	(\$0.09)	(\$0.63)	(\$0.10)	(\$0.04)			
Weighted avg. shares (000)	45,006	45,088	56,104	64,840	52,802	64,863	65,485	65,735	65,985	65,517
Fully diluted shares (000)	78,522	78,627	90,622	99,090	86,715	98,613	99,235	99,485	99,735	99,267

Source: Company Reports: Laidlaw & Company estimates

Figure 5: Annual Income Statement

Alimera Sciences							
Annual income statement							
(\$000 except per share)	2015A	2016A	2017E	2018E	2019E	2020E	Comments
Revenues							
Iluvien - US	15,169	25,827	30,277	36,724	54,043	96,178	US launch 1Q15
Iluvian ex-US	7,269	8,506	12,182	26,120	33,909	45,705	EU roll-out through 2016
Total Revenue	\$22,438	\$34,333	\$42,445	\$62,844	\$87,952	\$141,882	
Expenses:							
Cost of Revenue (COGS)	1,317	2,344	1,992	1,571	5,444	9,060	pSivida payments here
Gross Margin	21,121	31,989	40,453	61,273	82,507	132,822	
R&D	14,840	12,375	9,048	10,500	14,000	20,000	
General & administration	14,190	15,263	12,776	19,500	26,500	29,500	
Sales & marketing	28,090	29,431	23,562	30,150	42,000	60,000	50 reps for US launch
Total op exp	57,120	57,069	45,386	60,150	82,500	109,500	
Inc/(loss) from Ops	(35,999)	(25,030)	(4,933)	1,123	7	23,322	
Int income (exp), net	(4,693)	(5,178)	(5,221)	(5,000)	(5,000)	(5,000)	
Other expenses, net	(106)	(40)	-	-	-	-	
Inc/(loss) before taxes	(40,692)	(30,208)	(10,154)	(3,877)	(4,993)	18,322	
Income tax exp (benefit)	130	(172)	70	27	(427)	5,497	Substantial tax loss carryforwards
Adjusted NI ex-1x & noncash	(\$40,822)	(\$30,204)	(\$10,224)	(\$3,904)	(\$4,565)	\$12,826	
1x items & non-cash exp	10,177	(2,970)	0	0	0	0	
EPS as reported	(\$30,645)	(\$33,174)	\$0	\$0	\$0	\$0	
Adj EPS ex-1x & non-cash items	(\$0.92)	(\$0.57)	(\$0.16)	(\$0.06)	(\$0.07)	\$0.12	
EPS as reported	(\$0.69)	(\$0.63)					
Weighted avg. shares (000)	44,450	52,802	65,517	66,735	68,185	70,035	
Fully diluted shares (000)	76,615	86,715	99,267	100,735	102,185	104,035	

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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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/28/2...	Buy (B)	4.61

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/28/2...	12.00	4.61
03/04/2...	10.00	1.85
05/10/2...	5.00	1.58

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.	63.04%	30.43%	2.17%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.35%	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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