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EQUITY RESEARCH
Company Report

March 9, 2017

Alimera Sciences (ALIM - $1.31)

Healthcare / Biotechnology

Iluvien Gaining Significant Momentum in 2017

Ticker:	**ALIM**
Rating:	**Buy**
Price Target:	**$10.00**

We recently held a KOL call with a leading retinal specialist on ALIM's three-year extended-release corticosteroid Iluvien for diabetic macular edema (DME) and the overall market. Over the past year in particular our KOL has seen building interest in Iluvien amongst the ophthalmic community, with the "buzz" at an all-time high for the therapy. When Iluvien launched in the US (4/21/15), retina specialists were concerned about the potential for elevated intraocular pressure (IOP) from using a 3-year steroid. Since then ALIM's education of the medical community about the much lower "real world" incidence of IOP (18%-20%) than seen in the 2009 FAME trial (38%) has made many ophthalmologists revisit their initial skepticism. Our KOL has found that in properly chosen patients (i.e: no rise in IOP with a previous steroid challenge) he has had zero patients with a rise in IOP requiring surgery, which speaks to the safety of Iluvien, in our opinion. Our KOL also sees future reimbursement changes that should be favorable for Iluvien as reimbursement models will be leaning towards cost-efficiency as opposed to quantity of injections, which would favor a 3-year implant. With our KOL seeing an "exponential" growth of users in his region, we continue to see ALIM as undervalued here and we reiterate our Buy rating and our $10 PT.

- **Long term corticosteroids becoming more accepted.** Over the past 2 years our KOL sees ALIM and AGN as having done a great job educating the ophthalmic community about the reality of IOP management (straightforward) and the importance of corticosteroid therapy for DME (highly effective). Our KOL typically starts Iluvien patients on AGN's Ozurdex initially to see if there are any IOP issues, and he sees both companies significantly raising awareness in the space.
- **Reimbursement landscape is promising.** As the Iluvien J-Code has its first year under its belt, our KOL believes the reimbursement payment model will change in the next 2-3 years, giving an advantage to more cost-efficient options such a 3-year implant like Iluvien over a multiple injection therapy.
- **Iluvien "buzz" at all-time high.** With a significant podium presence at relevant conferences, encouraging real-world data (lower IOP than in trials) our KOL sees a rapidly increasing awareness & use of Iluvien amongst ophthalmologists.
- **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 net cash and tech valued at $0.50/share.
- See page 2 (below) for additional comments from the KOL call.

Trading Data:

Last Price (03/08/2017)	$1.31
52–Week High (04/21/2016)	$5.15
52–Week Low (07/22/2016)	$1.01
Market Cap. (MM)	$84.3
Shares Out. (MM)	64.9

Earnings Estimates: (per share)

(Sep)	1Q	2Q	3Q	4Q	FY	P/E
FY17E	($0.06)	($0.03)	$0.00	$0.01	($0.08)	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

Source: Laidlaw & Company estimates

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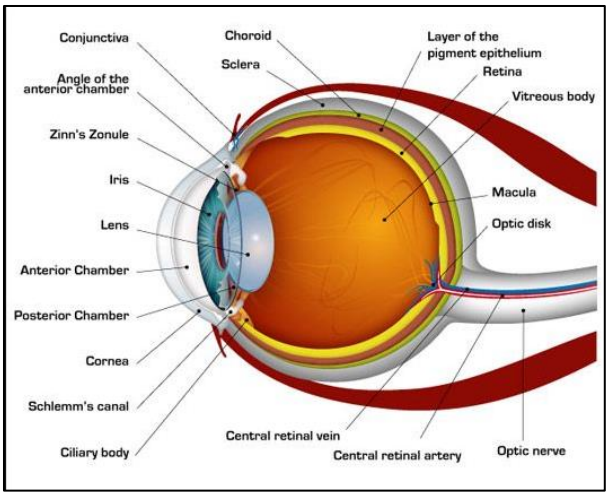
- **Competition and innovation in the field, many acquisition targets.** Our KOL mentioned Clearside Biomedical (CLSD) and their microneedle delivery to the suprachoroidal space while both Iluvien and Ozurdex use a longer needle (~1.5 in.) into the vitreous cavity. Clearside was able to demonstrate substantial reduction in treatment burden for steroid therapy in combination with Eylea in retinal vein occlusion (RVO) in a Phase 2 study. They also showed positive Phase 2 data in uveitis. Our KOL believes the potential for acquisition is significant as this microneedle technology could be appealing for many different drugs. For instance, Spark Therapeutics (ONCE) has arrangements with Clearside to deliver their gene therapy with the microneedle technology. Additionally, Clearside has recently started a Phase 1 trial in DME. He also mentioned Ocular Therapeutix (OCUL) who signed a $300M milestone agreement with Regeneron (REGN) for sustained delivery Eylea, which could be beneficial and complimentary to Iluvien, and Aerie Pharma (AERI) which is developing Rho-associated protein kinase (ROCK) inhibitors for the treatment of IOP & glaucoma.

Figure 1: Diagram of the human eye



Source: National Keratoconus Foundation

- **Iluvien's label expansion seems promising.** A recent paper presented by Dr. Charles Wykoff at the 2016 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO) showed that Iluvien could help decrease progression of diabetic retinopathy, which was surprising as physicians thought only anti-VEGF (Avastin, Eyelea, Lucentis) could do this since it had never been demonstrated with Ozurdex. This seems very interesting and could increase usage of Iluvien for patients with both DME and diabetic retinopathy (~30% nationally present with both diseases).
- **Concerns about "losing" patients for 3 years post an Iluvien injection are misguided.** Initially a barrier to adopting Iluvien was the concern that once a patient is injected with the 3-year steroid a doctor effectively "loses" that patient for 3 years until they need another Iluvien. This eats into the very real economics to a doctor of seeing a patient every 3 months to re-inject an Ozurdex. Our KOL notes that this simply isn't the case, doctors still need see their patients for follow-ups on a regular basis, and to ensure that the treatment is effective and not causing a dangerous rise in IOP, among other things. In fact patients may even need anti-VEGF injections on top of their steroid as many doctors are becoming more accustomed to "combination" therapy to treat their complicated eye patients.
- **AGN counter details against Iluvien don't happen at his practice.** Surprisingly our KOL noted that the 800 pound gorilla on the block – AGN – doesn't actively counter-detail against Iluvien. Something that we've heard is common elsewhere. Our KOL notes that since many of his patients' step therapy to get to Iluvien includes a course of Ozurdex first, and (at least his) reps realize that Iluvien could be driving increased Ozurdex usage in clinical practice.
- **Solid reimbursement support from ALIM.** Our KOL highlighted the good support his practice receives from ALIM on the reimbursement front, which can be a huge barrier to adoption in a Buy & Bill roll-out like Iluvien. In his practice he has never had an Iluvien reimbursement denied.

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Figure 2: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
Illuvien - US	$723,408	$7.5
Illuvien - EU	$195,506	$2.0
Net cash '17 & tech value	$62,668	$0.5
SUM	**$981,583**	**$10**
Shares out '17E (000)		99,215

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Alimera Sciences
Quarterly income statement

	2016A				2016A	2017E				2017E
($000 except per share)	1QA	2QA	3QA	4QA	Year	1QE	2QE	3QE	4QE	Year
Revenues										
Iluvien - US	$4,119	$7,208	$6,200	$8,300	$25,827	$8,687	$9,815	$10,906	$13,087	$42,495
Iluvian ex-US	1,682	2,349	2,098	2,377	8,506	2,794	3,958	4,656	5,820	17,227
Total Revenue	**$5,801**	**$9,557**	**$8,298**	**$10,677**	**$34,333**	**$11,481**	**$13,773**	**$15,562**	**$18,907**	**$59,723**
Expenses:										
Cost of Revenue (COGS)	328	556	486	924	2,344	557	569	578	2,742	4,446
Gross Margin	**5,473**	**9,001**	**7,812**	**9,753**	**31,989**	**10,923**	**13,204**	**14,984**	**16,166**	**55,277**
Research and development	3,020	3,205	3,261	2,889	12,375	3,250	3,250	3,250	3,250	13,000
General & administration	3,395	4,039	3,645	4,184	15,263	3,250	3,250	3,250	3,250	13,000
Sales & marketing	7,109	7,510	7,452	7,360	29,431	7,000	7,250	7,500	7,500	29,250
Total operating expenses	13,524	14,754	14,358	14,433	57,069	13,500	13,750	14,000	14,000	55,250
Income (loss) from Operations	**(8,051)**	**(5,753)**	**(6,546)**	**(4,680)**	**(25,030)**	**(2,577)**	**(546)**	**984**	**2,166**	**27**
Int inc (expense), other net	(1,335)	(1,177)	(1,330)	(1,336)	(5,178)	(1,250)	(1,250)	(1,250)	(1,250)	(5,000)
Income (loss) before taxes	**(9,386)**	**(6,930)**	**(7,876)**	**(6,016)**	**(30,208)**	**(3,827)**	**(1,796)**	**(266)**	**916**	**(4,973)**
Income tax exp (benefit)	9	42	33	(88)	(172)	-	-	-	-	0
Adjusted NI ex-1x & noncash	**(9,395)**	**(6,972)**	**(7,909)**	**(5,928)**	**(30,204)**	**(3,827)**	**(1,796)**	**(266)**	**916**	**(4,973)**
1x items & non-cash exp	(1,750)	114	(1,336)	178	(2,970)					
EPS as reported	**(11,145)**	**(6,858)**	**(9,245)**	**(5,750)**	**(33,174)**					
Adjusted EPS ex-1x & noncash	**($0.21)**	**($0.15)**	**($0.14)**	**($0.09)**	**($0.57)**	**($0.06)**	**($0.03)**	**($0.00)**	**$0.01**	**($0.08)**
EPS as reported	**($0.25)**	**($0.15)**	**($0.16)**	**($0.09)**	**($0.63)**					
Weighted avg. shares (000)	45,006	45,088	56,104	64,840	52,802	65,090	65,340	65,590	65,840	65,465
Fully diluted shares (000)	78,522	78,627	90,622	99,090	86,715	98,840	99,090	99,340	99,590	99,215

Source: Company Reports: Laidlaw & Company estimates

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Figure 4: 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	42,495	104,953	187,507	254,625	US launch 1Q15
Iluvian ex-US	7,269	8,506	17,227	39,181	65,154	98,821	EU roll-out through 2016
Total Revenue	**$22,438**	**$34,333**	**$59,723**	**$144,133**	**$252,661**	**$353,446**	
Expenses:							
Cost of Revenue (COGS)	1,317	2,344	4,446	20,899	36,636	51,250	pSivida payments here
Gross Margin	**21,121**	**31,989**	**55,277**	**123,234**	**216,025**	**302,196**	
R&D	14,840	12,375	13,000	15,000	19,750	24,000	
General & administration	14,190	15,263	13,000	19,500	26,500	29,500	
Sales & marketing	28,090	29,431	29,250	30,150	42,000	60,000	50 reps for US launch
Total op exp	57,120	57,069	55,250	64,650	88,250	113,500	
Inc/(loss) from Ops	**(35,999)**	**(25,030)**	**27**	**58,584**	**127,775**	**188,696**	
Int income (exp), net	(4,693)	(5,178)	(5,000)	(5,000)	(5,000)	(5,000)	
Other expenses, net	(106)	(40)	-	-	-	-	
Inc/(loss) before taxes	**(40,692)**	**(30,208)**	**(4,973)**	**53,584**	**122,775**	**183,696**	
Income tax exp (benefit)	130	(172)	-	3,181	26,334	55,109	Substantial tax loss carryforwards
Adjusted NI ex-1x & noncash	**($40,822)**	**($30,204)**	**($4,973)**	**$50,403**	**$96,441**	**$128,587**	
1x items & non-cash exp	10,177	(2,970)	0	0	0	0	
EPS as reported	**($30,645)**	**($33,174)**	**$0**	**$0**	**$0**	**$0**	
Earning per Share	**($0.92)**	**($0.57)**	**($0.08)**	**$0.50**	**$0.95**	**$1.24**	
Adj EPS ex-1x & non-cash items	**($0.69)**	**($0.63)**					
Weighted avg. shares (000)	44,450	52,802	65,465	66,590	68,040	69,890	
Fully diluted shares (000)	76,615	86,715	99,215	100,590	102,040	103,890	
Cash balance	$31,075	$30,979	$37,668	$94,376	$194,457	$330,987	18M share offering 3Q16

Source: Company Reports: Laidlaw & Company estimates

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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.

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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Additional information available upon request.

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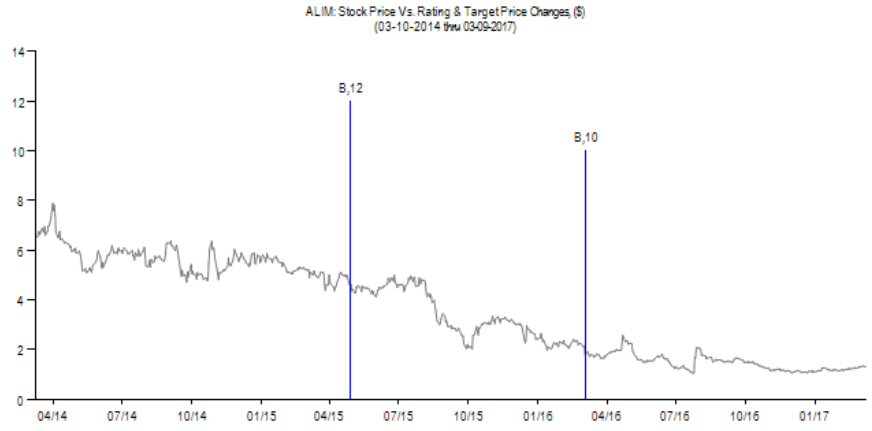
RATINGS INFORMATION

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

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Allergan (AGN – Not Rated)
Clearside Biomedical (CLSD – Not Rated)
Spark Therapeutics (ONCE – Not Rated)
Ocular Therapeutix (OCUL – Not Rated)
Regeneron (REGN – Not Rated)
Aerie Pharmaceuticals (AERI – Not Rated)

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