

Alder Biopharmaceuticals (ALDR)

SMALL & MID CAP RESEARCH

Q4: Focus on New Migraine Trial and Competitive Data

The primary value driver for ALDR remains its Phase II migraine program. While this is likely to be a competitive space (AMGN, TEVA, LLY), the market opportunity for a truly game-changing migraine drug is extremely large. ALDR has presented the most complete data, with efficacy lasting up to 3 months from a single dose.

ALDR initiates large Phase II trial:

ALDR recently initiated a 600-patient Ph2 trial of ALD403 in chronic migraine (15-25 migraine days per month). The trial tests four different single doses of ALD403 (by IV infusion) vs. placebo. The primary endpoint is change in migraine days from baseline to 12 weeks, with an expected completion by year-end 2015. The goal is to establish a minimally effective dose for quarterly administration.

We believe the IV formulation of ALD403 could be competitive if it provides adequate migraine relief for a large portion of patients over the full 12 week period. More frequent administration would likely be better served with a subcutaneous (subQ) injection. ALDR expects data from the Phase I trial of its subQ formulation by year-end and plans to start a monthly subQ Phase II in episodic migraine in 2015.

AMGN plans Phase II data announcement by year-end:

AMGN highlighted its AMG 334 (anti-CGRP receptor) program at its analyst event today as one of its programs with the greatest potential to impact patient quality of life and described the opportunity as "huge". They made the case that targeting the receptor may have advantages over targeting CGRP (AMG 334 is the only antibody targeting the receptor). Results from its Ph2 trial in episodic migraine are expected in Q4, and the chronic migraine Ph2 trial is ongoing.

Rating	OUTPERFORM* [V]
Price (27 Oct 14, US\$)	16.23
Target price (US\$)	19.00 ¹
52-week price range	20.34 - 9.91
Market cap. (US\$ m)	499.94
Enterprise value (US\$ m)	455.72

*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.

¹Target price is for 12 months.

[V] = Stock considered volatile (see Disclosure Appendix).

Research Analysts

Jason Kantor, PhD

415 249 7942

jason.kantor@credit-suisse.com

Jeremiah Shepard, PhD

415 249 7933

jeremiah.shepard@credit-suisse.com

Ravi Mehrotra PhD

212 325 3487

ravi.mehrotra@credit-suisse.com

Koon Ching PhD

212 325 6286

koon.ching@credit-suisse.com

Anuj Shah

212 325 6931

anuj.shah@credit-suisse.com

Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US\$)	-0.94	0.09	-2.10	-2.23
Prev. EPS (US\$)	—	—	—	—
P/E (x)	-17.2	182.6	-7.7	-7.3
P/E rel. (%)	-100.4	NM	-54.1	-56.7
Revenue (US\$ m)	18.8	54.5	9.6	10.3
EBITDA (US\$ m)	-19.8	3.4	-69.3	-87.1
OCFPS (US\$)	-1.65	-1.58	-0.74	-2.12
P/OCF (x)	—	-10.3	-21.9	-7.7
EV/EBITDA (current)	-21.7	126.1	-6.2	-4.9
Net debt (US\$ m)	-23	-44	-149	-65
ROIC (%)	37.60	32.92	210.17	266.90
Number of shares (m)	30.80	IC (current, US\$ m)		-55.22
BV/share (Next Qtr., US\$)	2.2	EV/IC (x)		53.5
Net debt (Next Qtr., US\$ m)	-59.7	Dividend (current, US\$)		—
Net debt/tot eq (Next Qtr., %)	-87.9	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

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The CGRP Competitive Landscape

There are four Phase II programs targeting CGRP signaling. Three target CGRP and one targets the CGRP receptor. All of the programs are in large dose finding Phase II trials in chronic and/or episodic migraine.

- The next major data read out will be AMGN's Phase II in episodic migraine. This 483-patient trial tested 3 doses of AMG 334 vs placebo in patients with 4-14 migraine days per month. The primary endpoint was change in monthly migraine days from baseline to 12 weeks.

Exhibit 1: CGRP Antibodies in Development for Migraine

Company	Drug	MOA	Stage
Amgen	AMG 334	Anti-CGRP receptor	Phase II
Alder	ALD403	Anti-CGRP	Phase II
Eli Lilly	LY2951742	Anti-CGRP	Phase II
Teva (Labrys)	LBR-101 (RN-307)	Anti-CGRP	Phase II

Source: Company data, Credit Suisse estimates

Exhibit 2: ALD403 Clinical Program

	ALD403-CLIN-002	ALD403-Clin-005
Stage	Phase Ib	Phase II
# of patients	163	600
Indication	High frequency episodic migraine	Chronic migraine
Migraine days per month	5-14 migraine days/ month	15-25 migraine days/ month
Treatment arms	ALD403 (1g) vs. placebo	ALD403 (4 doses) vs. placebo
Dosing	IV infusion (1x)	IV infusion
Duration	12 weeks	12 weeks
Primary endpoint	Safety	Change in migraine days from baseline
Secondary endpoints		Safety, PK
Start	Jan-13	Oct-14
Primary completion	Dec-13	Dec-15
Status	Data presented at AAN 2014	Enrolling
Identifier	NCT01772524	NCT02275117

Source: www.clinicaltrials.gov, Credit Suisse estimates

Exhibit 3: AMG 334 Clinical Program

	20120178	20120295	20130255
Stage	Phase II	Phase II	Phase II
# of patients	483	490	Chronic migraine: Long-term safety 490
Indication	High frequency episodic migraine	Chronic migraine	Open label extension of study 20120295
Migraine days per month	4-14 migraine days/ month (past 3 months)	≥15 migraine days/ month	
Treatment arms	AMG 334 (3 doses) vs. placebo	AMG 334 (SC, 2 doses) vs. placebo	Open label AMG 334
Dosing	not disclosed	not disclosed	
Duration	12 weeks	12 weeks	10 months (open label)
Primary endpoint	Change in monthly migraine days from baseline to last 4 weeks of 12 week dosing	Change in monthly migraine days from baseline to last 4 weeks of 12 week dosing	Safety
Secondary endpoints	50% responder analysis	50% responder analysis	50% responder analysis
Start	Aug-13	Feb-14	Jun-14
Primary completion	Aug-14	Feb-16	Sep-16
Status	Completed enrollment Jul 2014	Enrolling	Enrolling
Identifier	NCT01952574	NCT02066415	NCT02174861

Source: www.clinicaltrials.gov, Credit Suisse estimates

Exhibit 4: LY2951742 Clinical Program

	ART-01	15414
Stage	Phase II	Phase IIb
# of patients	190	402
Indication	High frequency episodic migraine	Episodic migraine (# not defined)
Migraine days per month	4-14 migraine days/ month	
Treatment arms	LY2951742 (150mg) vs. placebo	LY2951742 (4 doses) vs placebo
Dosing	subcutaneous every 2 weeks	subcutaneous every 4 weeks
Duration	12 weeks	12 weeks
Primary endpoint	Change from baseline in number of migraines in a 28d period	Change from baseline in number of migraine days in a 28d period
Start	Jun-12	Jul-14
Primary completion	Sep-13	Jun-15
Status	Data reported at AAN 2014	Enrolling
Identifier	NCT01625988	NCT02163993

Source: [www.clinicaltrials.gov](#), Credit Suisse estimates

Exhibit 5: LBR-101 Clinical Program

	LBR-101-022	LBR-101-021
Stage	Phase II	Phase II
# of patients	270	225
Indication	High frequency episodic migraine	Chronic migraine
Migraine days per month	8-14 migraine days/ month	≥15 migraine days/ month
Treatment arms	LBR-101 high and low dose vs. placebo	LBR-101 high and low dose vs. placebo
Dosing	Monthly subcutaneous	Monthly subcutaneous
Duration	12 weeks	12 weeks
Primary endpoint	Mean change in monthly migraine days	Mean change in headache hours
Start	Jan-14	Jan-14
Primary completion	Jan-15	Feb-15
Status	Enrolling	Completed enrollment 10/2/14
Identifier	NCT02025556	NCT02021773

Source: [www.clinicaltrials.gov](#), Credit Suisse estimates

Comments from AMGN's Business Review

AMG 334 is different because it targets the receptor (Is this a good thing?)

AMGN highlighted AMG 334 as one of its most important pipeline programs. As the only drug in the class that directly targets the receptor (the other target the ligand – CGRP), AMGN made a point to emphasize what it thought were the benefits of targeting the receptor.

The primary benefit in their view was that it might be easier to block the receptors than to mop up all the CGRP that is released in a very short period of time into the synapse. AMGN also suggested that the CGRP receptor was very difficult to "drug" and that their expertise contributed to their ability to have a unique drug in the class.

We asked AMGN about potential safety concerns of blocking the receptor chronically, and they pointed to significant preclinical toxicity work that supported their approach.

Receptor vs. Ligand

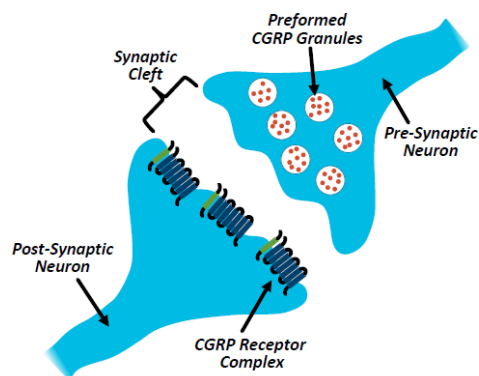
The benefits of targeting the ligand vs. the receptor are likely to persist unless one approach shows a clear efficacy advantage or safety concern. There are good examples of antibodies that target either the ligands (e.g. Humira and Avastin) and the receptors (e.g. Actemra and Herceptin).

- The primary risk of targeting the receptor is that the antibody could cause damage to the target cell through activation of the immune system (ADCC) or it could cross link the receptors and lead to some unwanted signaling.

- Targeting the ligand can be a problem if there are more than one ligand that hits the receptors and you want to block all of them, or if the ligand hits multiple receptors and you only want to block one of them.
- Companies targeting the ligand point out that the knockout for the receptor is lethal while the knockout for the ligand is not. Obviously, this does not specifically mean that targeting the receptor will be less safe, but it does point to potentially non-overlapping roles of the two molecules and the potential for some differences to emerge in these strategies.

For CGRP, we believe the data will be the key determinant of which approach (if any) is better.

Exhibit 6: AMG 334 Targets the CGRP Receptor



- **CGRP is a validated target for migraine**
- **CGRP receptors at interface of neurovascular junction**
- **Receptor antagonism is independent of CGRP release and concentration**
- **Currently in Phase 2b for episodic and chronic migraine**
 - Dosed monthly
 - Data from episodic study expected in Q4 2014

Source: AMGN Business Review, October 2014

Exhibit 7: AMGN's View of the Market Opportunity

AMG 334 Has the Potential to Address the Significant Unmet Need In Migraine Prophylaxis

- ~ 26M Americans suffer from migraine, ~ 8M > 2 days/month^{1,2}
- Options for prophylaxis are limited by poor efficacy and significant side effects
- Migraine affects patients in prime working years
 - Most have reduced ability to function during the attack, one third require bed rest
 - **Disability increases with increased attack frequency**

Source: AMGN Business Review, October 2014

Exhibit 8: ALDR Model

	2012A	2013A	Q1:14A	Q2:14A	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues													
US sales of ALD403												29.7	154.6
Ex-US royalties on ALD403												0.7	0.7
Royalties on Clazakizumab												1.4	3.1
Collaboration and license agreement	20.1	18.8	4.8	4.7	45.0		54.5	9.6	10.3	10.3	65.7	94.8	12.0
Total Revenues	20.1	18.8	4.8	4.7	45.0		54.5	9.6	10.3	10.3	65.7	125.9	170.3
Expenses													
Cost of goods												3.0	15.5
Research and development	30.7	31.9	7.0	9.4	10.0	12.0	38.4	58.5	74.0	90.0	92.0	87.0	77.0
Sales, general, administrative	7.2	7.7	3.2	2.7	3.5	4.0	13.4	21.0	24.0	24.0	26.0	35.0	40.0
Total Operating Expenses	37.9	39.6	10.2	12.1	13.5	16.0	51.8	79.5	98.0	114.0	118.0	122.0	117.0
Operating income (loss)	(17.8)	(20.8)	(5.4)	(7.4)	31.5	(16.0)	2.7	(69.9)	(87.7)	(103.7)	(52.3)	3.9	53.3
Total Other Income (Expense)	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.2
Pre Tax Income	(17.8)	(20.6)	(5.4)	(7.4)	31.5	(16.0)	2.8	(69.9)	(87.7)	(103.7)	(52.1)	4.1	53.5
Income tax													
Net Income	(17.8)	(20.6)	(5.4)	(7.4)	31.5	(16.0)	2.8	(69.9)	(87.7)	(103.7)	(52.1)	4.1	53.5
EPS - basic (proforma)	(\$3.55)	(\$3.84)	(\$5.38)	(\$0.40)	\$1.02	(\$0.51)	\$0.13	(\$2.10)	(\$2.23)	(\$2.20)	(\$1.09)	\$0.08	\$1.09
EPS - diluted (proforma)	(\$3.55)	(\$3.84)	(\$5.38)	(\$0.40)	\$0.95	(\$0.51)	\$0.09	(\$2.10)	(\$2.23)	(\$2.20)	(\$1.09)	\$0.08	\$1.02
Shares outstanding - basic (proforma)	5.01	21.89	1.00	18.56	31.04	31.20	20.45	33.34	39.31	47.16	47.99	48.47	48.95
Shares outstanding - diluted (proforma)	5.01	21.89	1.00	18.56	33.24	31.20	30.93	33.34	39.31	47.16	50.97	51.60	52.24

Source: Company data, Credit Suisse estimates

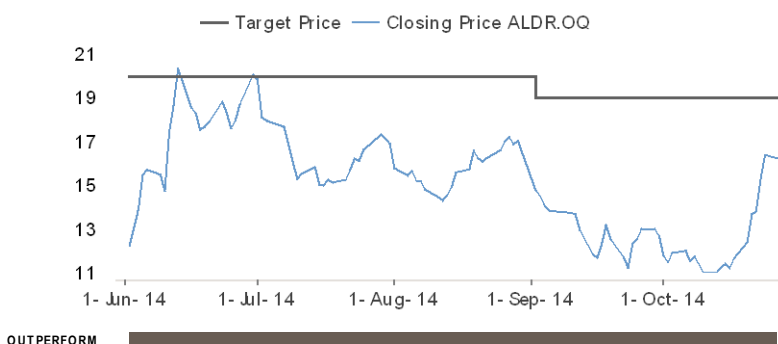
Companies Mentioned (Price as of 27-Oct-2014)**Alder Biopharmaceuticals** (ALDR.OQ, \$16.23, OUTPERFORM[V], TP \$19.0)**Disclosure Appendix****Important Global Disclosures**

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3-Year Price and Rating History for Alder Biopharmaceuticals (ALDR.OQ)

ALDR.OQ	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
02-Jun-14	12.26	20.00	O *
02-Sep-14	14.80	19.00	

* Asterisk signifies initiation or assumption of coverage.



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Price Target: (12 months) for Alder Biopharmaceuticals (ALDR.OQ)

Method: Our \$19 target includes \$16 for ALD-403, \$2 for Clazakizumab, and \$1 for its NOLs. Our \$19 valuation is justified by a fully-taxed, probability weighted, product level DCF for each of the two clinical stage programs plus the value of future NOLs. We assume an ex-US partner for ALD403 and significant dilution from future equity raises prior to profitability. For our DCF analysis, we use a 12% discount rate and 35% tax rate.

Risk: Risks to our \$19 TP include: 1) unexpected negative result for proprietary clinical programs, 2) financing risk from expected future equity raises, 3) significant delay in one or more clinical programs that pushes potential approval timeline(s) out.

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