

Alder Biopharmaceuticals (ALDR)

SMALL & MID CAP RESEARCH

Full Focus on ALD403 - Phase IIb Underway

There were three big take aways from ALDR's Q3 call, which all support our positive thesis. Our 2014 and 2015 net loss decreases on lower forecast expenses.

- **ALDR confirmed the initiation of a large Phase IIb trial** in chronic migraine (IV formulation) and plans to start a trial in frequent episodic migraine (subcutaneous formulation) in H1:15. We highlighted the design of the trial and the competitive landscape for anti-CGRP antibodies in our recent note ([LINK](#)).
- **ALDR stated its intention to partner clazakizumab** rather than take a go-alone strategy. This was not clear when the rights were returned from Bristol, and we view the current strategy as positive. A Phase III ready asset, with significant Phase II data and ready material for Phase III should be partnerable, and the most likely timing is after the Phase IIb data in RA in H1:15. We currently include clazakizumab with a 25% probability of success. Clean Phase IIb data and a new partner would take this probability back up to the 70%+ level. Importantly, ALDR is not going to commit significant resources to this program, keeping the focus on ALD403.
- **ALDR stated that it intends to seek a partner for ALD403 (likely ex-US)**, and that these discussions were farther along than discussions for clazakizumab. An ex-US partner could provide significant resources in the form of an upfront payment and Phase IIb development costs.

Rating	OUTPERFORM* [V]
Price (03 Nov 14, US\$)	18.02
Target price (US\$)	19.00 ¹
52-week price range	20.34 - 9.91
Market cap. (US\$ m)	555.08
Enterprise value (US\$ m)	502.55

*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).

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Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US\$)	-0.94	0.36	-1.56	-2.23
Prev. EPS (US\$)	—	0.09	-2.10	—
P/E (x)	-19.1	50.4	-11.5	-8.1
P/E rel. (%)	-111.5	316.3	-80.6	-63.1
Revenue (US\$ m)	18.8	54.5	9.6	10.3
EBITDA (US\$ m)	-19.8	11.7	-57.0	-87.1
OCFPS (US\$)	-1.65	-1.31	-0.34	-2.11
P/OCF (x)	—	-13.8	-53.4	-8.5
EV/EBITDA (current)	-25.1	42.7	-8.7	-5.7
Net debt (US\$ m)	-23	-53	-169	-86
ROIC (%)	37.60	132.87	173.20	266.90
Number of shares (m)	30.80	IC (current, US\$ m)		-55.22
BV/share (Next Qtr., US\$)	1.9	EV/IC (x)		60.9
Net debt (Next Qtr., US\$ m)	-52.5	Dividend (current, US\$)		—
Net debt/tot eq (Next Qtr., %)	-86.4	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

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ALDR initiates large Phase II trial

ALDR recently initiated a 600-patient Phase IIb 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 data expected in H2:15. 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.

ALDR plans to initiate a repeat dosing "roll-over" study in 2015 for patients in this trial who wish to continue on therapy. The dose, interval, and exact design of the trial have not been determined.

Second Phase IIb trial in H1:15

ALDR plans to initiate a second Phase IIb trial in frequent episodic migraine (4-15 days/month) in H1:15. This trial is expected to enroll over 400 patients. It will also be a placebo controlled, dose-ranging trial, testing monthly subcutaneous (subQ) injections.

Competitive data from AMGN coming by year-end 2014

AMGN highlighted its AMG 334 (anti-CGRP receptor) program at its analyst event last week as one of its programs with the greatest potential to impact patient quality of life and described the opportunity as "huge". Results from its Phase II trial in episodic migraine are expected in Q4, and the chronic migraine Phase II trial is ongoing.

The read through for ALDR may be a bit complicated. If AMGN's drug is successful, it will provide more evidence to support the drug class and its multi-billion dollar opportunity. If AMG 334 has some safety issue or the efficacy is not completely impressive, it could reflect on the target (AMG 334 targets the CGRP receptor vs. ALD403 that targets the ligand). Our expectation is that the study will be positive.

Q3:14 results and changes to our estimates

Q3 results were directionally in-line with our expectations. The major variances came from lower than expected revenue recognition associated with the end of the Bristol agreement. The 6.2M shortfall vs. our estimate will be recognized in Q4, and thus we are bringing our revenue expectation for Q4 up accordingly. On the expense side, R&D was lower and will likely stay lower than our prior forecasts as enrollment in the large Phase IIb trial is just now starting. We have lowered R&D for both 2014 and H1:2015.

Our new estimates include:

- Revenue of \$54.5M in 2014 (no change) and \$9.6M in 2015 (no change)
- Expenses of \$43.5M in 2014 (down from prior \$51.8M) and \$67.2M in 2015 (down from \$79.5M)
- Net income of \$11.1M in 2014 (up from \$2.8M) and a net loss of \$57.6M in 2015 (up from a net loss of \$69.9M)

Exhibit 1: ALDR Variance Table

Income Statement	3Q:14 Act.	CS	
		3Q:14 Est	Delta
Revenues	\$ -	\$ -	\$ -
Royalties on Clazakizumab	\$ -	\$ -	
Collaboration and license agreement	\$ 38.8	\$ 45.0	\$ (6.2)
Total Revenues	\$ 38.8	\$ 45.0	\$ (6.2)
Expenses	\$ -	\$ -	\$ -
Research and development	\$ 7.0	\$ 10.0	\$ (3.0)
Sales, general, administrative	\$ 3.2	\$ 3.5	\$ (0.3)
Total Operating Expenses	\$ 10.2	\$ 13.5	\$ (3.3)
Operating income (loss)	\$ 28.6	\$ 31.5	\$ (2.9)
Total Other Income (Expense)	\$ 0.1	\$ 0.0	\$ 0.1
Pre Tax Income	\$ 28.6	\$ 31.5	\$ (2.9)
Income tax	\$ -	\$ -	\$ -
Net Income	\$ 28.6	\$ 31.5	\$ (2.9)
EPS - basic (proforma)	\$0.93	\$1.02	(\$0.09)

Source: Company data, Credit Suisse estimates

Exhibit 2: ALDR News Flow

Product	Catalyst	Expected Date
Clazakizumab	Phase II data in psoriatic arthritis	Nov. 2014
New target	Select new clinical stage candidate	Q4:14
Clazakizumab	Phase IIb dose exploration data in RA	H1:15
ALD403	Start Phase IIb dose ranging study in frequent episodic migraine patients (subQ)	H1:15
ALD403	Phase IIb data	H2:15
New target	First clinical study start (one or more)	H2:15
Clazakizumab	Potential development partner	2015
ALD403	End of Phase II meeting with FDA	YE:15
ALD403	Start Phase III in migraine	2016

Source: Company data, Credit Suisse estimates

Exhibit 3: ALDR Pipeline

Drug	Target	Indication	Stage	Partner
ALD403	CGRP	Migraine	Phase II	Proprietary
Clazakizumab	IL-6	Rheumatoid Arthritis	Phase IIb	Proprietary
		Psoriatic Arthritis	Phase II	Proprietary
4 preclinical programs	TBA	TBA	Preclinical	Proprietary

Source: Company data, Credit Suisse estimates

Exhibit 4: ALDR Model

	2012A	2013A	Q1:14A	Q2:14A	Q3:14A	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	38.8	6.2	54.5	9.6	10.3	10.3	65.7	94.8	12.0
Total Revenues	20.1	18.8	4.8	4.7	38.8	6.2	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	7.0	7.5	30.9	51.0	74.0	90.0	92.0	87.0	77.0
Sales, general, administrative	7.2	7.7	3.2	2.7	3.2	3.5	12.6	16.2	24.0	24.0	26.0	35.0	40.0
Total Operating Expenses	37.9	39.6	10.2	12.1	10.2	11.0	43.5	67.2	98.0	114.0	118.0	122.0	117.0
Operating income (loss)	(17.8)	(20.8)	(5.4)	(7.4)	28.6	(4.8)	11.0	(57.6)	(87.7)	(103.7)	(52.3)	3.9	53.3
Total Other Income (Expense)	0.0	0.1	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.2	0.2	0.2
Pre Tax Income	(17.8)	(20.6)	(5.4)	(7.4)	28.6	(4.8)	11.1	(57.6)	(87.7)	(103.7)	(52.1)	4.1	53.5
Income tax													
Net Income	(17.8)	(20.6)	(5.4)	(7.4)	28.6	(4.8)	11.1	(57.6)	(87.7)	(103.7)	(52.1)	4.1	53.5
EPS - basic (proforma)	(\$3.55)	(\$3.84)	(\$5.38)	(\$0.40)	\$0.93	(\$0.15)	\$0.54	(\$1.56)	(\$2.23)	(\$2.20)	(\$1.08)	\$0.08	\$1.09
EPS - diluted (proforma)	(\$3.55)	(\$3.84)	(\$5.38)	(\$0.40)	\$0.88	(\$0.15)	\$0.36	(\$1.56)	(\$2.23)	(\$2.20)	(\$1.08)	\$0.08	\$1.02
Shares outstanding - basic (proforma)	5.01	21.89	1.00	18.56	30.81	31.20	20.39	36.87	39.38	47.23	48.06	48.54	49.03
Shares outstanding - diluted (proforma)	5.01	21.89	1.00	18.56	32.51	31.20	30.93	36.87	39.38	47.23	51.04	51.67	52.32

Source: Company data, Credit Suisse estimates

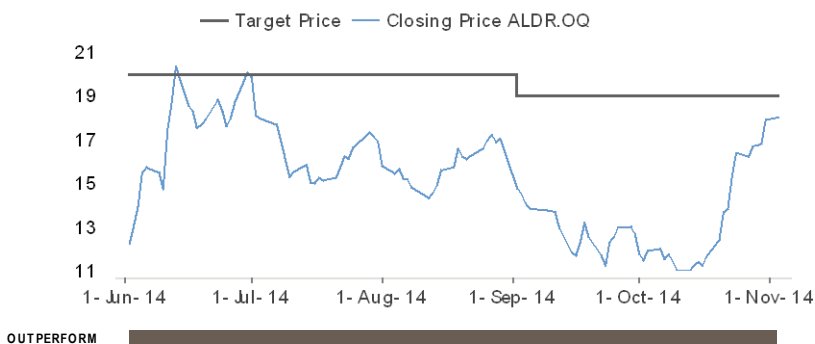
Companies Mentioned (Price as of 03-Nov-2014)**Alder Biopharmaceuticals** (ALDR.OQ, \$18.02, OUTPERFORM[V], TP \$19.0)**Disclosure Appendix****Important Global Disclosures**

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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.

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