

Achaogen (AKAO)

SMALL & MID CAP RESEARCH

Q4 Earnings Uneventful; Waiting for Clinical Trial Update in Early Q2

AKAO reported Q4 results in-line with our estimates, and expects to provide an update to its clinical/regulatory strategy in early Q2. We anticipate that AKAO will announce amendments to the Phase III CARE trial and potentially new trials to support regulatory approval. The Phase III enrollment has been slower than AKAO originally forecasted, and an amendment to the protocol may help accelerate enrollment. Current guidance is for completion of CARE in 2017. We are increasing our 2015 EPS to (\$0.81) from (\$1.06) following the Q4:14 earnings update.

- **AKAO seeking alternative strategies for Plazomicin.** Disclosures in the 10K suggest that the potential clinical/regulatory update in early Q2 could have important ramifications on the timeline, need for funding, and ultimate label of plazomicin. AKAO is discussing both protocol amendments for the Phase III CARE trial and the design of additional trials that could "support and possibly facilitate regulatory filings." While the details of the proposed changes have not been disclosed, AKAO highlights the potential for these plans to require AKAO to "seek additional funds sooner than planned". We would view an acceleration of the clinical/regulatory timeline as a positive.

Rating	UNDERPERFORM*
Price (16 Mar 15, US\$)	10.05
Target price (US\$)	13.00 ¹
52-week price range	18.95 - 8.00
Market cap. (US\$ m)	178.47
Enterprise value (US\$ m)	173.70

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

¹Target price is for 12 months.

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Financial and valuation metrics

Year	12/14A	12/15E	12/16E	12/17E
EPS (CS adj.) (US\$)	-1.42	-0.81	-0.92	-0.93
Prev. EPS (US\$)	—	-1.06	-1.21	-1.25
P/E (x)	-7.1	-12.5	-10.9	-10.8
P/E rel. (%)	-39.2	-70.4	-69.9	-77.8
Revenue (US\$ m)	20.0	23.2	21.2	40.0
EBITDA (US\$ m)	-19.4	-14.5	-21.6	-22.3
OCFPS (US\$)	-1.01	-0.57	-0.72	0.94
P/OCF (x)	-13.0	-17.7	-14.0	10.7
EV/EBITDA (current)	-8.4	-11.2	-7.5	-7.3
Net debt (US\$ m)	-16	-5	-80	-102
ROIC (%)	-40.38	-30.39	-45.12	-264.08
Number of shares (m)	17.76	IC (current, US\$ m)		49.00
BV/share (Next Qtr., US\$)	3.5	EV/IC (x)		3.4
Net debt (Next Qtr., US\$ m)	-13.1	Dividend (current, US\$)		—
Net debt/tot eq (Next Qtr., %)	-21.1	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

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Comments from the 10-K regarding Plazomicin plans

We believe that AKAO has already met with FDA to discuss its plans but is waiting for the meeting minutes or other communications before disclosing its plans publically. However, the 10-K contains multiple comments regarding possible changes, and we include some of these quotes here:

- "Enrollment in our Phase 3 CARE trial of plazomicin has been slower than anticipated and if this continues, we may decide to change our clinical development plan for plazomicin, in which case, we will need to seek additional funds sooner than planned."
- "We have been exploring strategies to improve patient recruitment and remain in discussions with the FDA regarding potential modifications to the study design as well as additional clinical trials that could support and, possibly, facilitate regulatory filings for plazomicin. We currently expect to provide an update on our development plans for plazomicin by early in the second quarter of 2015."
- "We have initiated discussions with the FDA and the EMA regarding additional clinical trials that could support regulatory filings for plazomicin. We currently expect to be in a position to provide an update on the development of plazomicin by early in the second quarter of 2015."
- "We may choose to revise the enrollment protocol, commence a new trial in a different patient population, or take other actions that may result in a substantial change in the clinical development program of plazomicin."
- "Further, if we choose to revise our current trial protocol or complete an alternative pivotal trial for plazomicin, we may not be able to claim certain of the market and label benefits that a successful superiority trial could provide."

Exhibit 1: AKAO Pipeline

Drug	Indication	Stage	Partner
Plazomicin	Carbapenam-resistant enterobacteriaceae	Phase III	Proprietary
LpxC inhibitor	Pseudomonas	Preclinical	Proprietary
Antibacterial Ab	Pseudomonas	Preclinical	Proprietary

Source: Company data, Credit Suisse estimates.

Exhibit 2: AKAO News Flow

Timing	Expected News Flow	Program
Early 2015	Initiate "Supportive" Phase 2	Plazomicin
H2:15	Initiate safety trial	Plazomicin
H2:15	First interim - Phase 3	Plazomicin
Q4:15	"Supportive" Phase 2 top-line data release	Plazomicin
2015	Select development candidate	Antipseudomonal
2016	File IND	Antipseudomonal
H2:16	Second interim - Phase 3	Plazomicin
H1:17	Top-line data for Phase 3	Plazomicin
YE:17	File NDA with FDA	Plazomicin

Source: Company data, Credit Suisse estimates.

Exhibit 3: AKAO Model

	2013A	2014A	Q1:15E	Q2:15E	Q3:15E	Q4:15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues												
Plazomicin US sales											70.0	115.8
Plazomicin EU royalties (20%)											3.3	10.1
Contract revenue	18.5	20.0	5.8	5.8	5.8	5.8	23.2	21.2	40.0	41.3		
Total revenues	18.5	20.0	5.8	5.8	5.8	5.8	23.2	21.2	40.0	41.3	73.3	125.9
Expenses												
COGS											8.3	14.4
R&D	23.5	30.1	6.4	6.7	7.0	7.4	27.4	30.2	33.2	53.5	38.0	49.1
G&A	7.0	9.6	2.6	2.6	2.7	2.7	10.6	11.1	17.0	50.0	55.0	57.8
Total operating expenses	30.5	39.8	8.9	9.3	9.7	10.1	38.1	43.2	62.7	103.5	101.3	121.3
Operating income (loss)	(12.0)	(19.8)	(3.1)	(3.5)	(3.9)	(4.3)	(14.9)	(22.0)	(22.7)	(62.3)	(28.1)	4.6
Total Other Income (Expense)	(1.1)	(0.4)	(0.0)	0.1	0.1	0.1	0.3	0.4	0.4	0.5	0.5	0.5
Pre Tax Income	(13.1)	(20.2)	(3.2)	(3.4)	(3.8)	(4.2)	(14.6)	(21.6)	(22.3)	(61.8)	(27.6)	5.1
Income tax expense (benefit)												
Net Income	(13.1)	(20.2)	(3.2)	(3.4)	(3.8)	(4.2)	(14.6)	(21.6)	(22.3)	(61.8)	(27.6)	5.1
EPS - diluted (proforma)		(\$1.42)	(\$0.18)	(\$0.19)	(\$0.21)	(\$0.23)	(\$0.81)	(\$0.92)	(\$0.93)	(\$2.56)	(\$1.14)	\$0.19
Shares outstanding - diluted (proforma)		14.21	17.96	18.05	18.14	18.23	18.09	23.49	23.97	24.09	24.21	26.41

Source: Company data, Credit Suisse estimates

Companies Mentioned (Price as of 16-Mar-2015)

Achaogen (AKAO.OQ, \$10.05, UNDERPERFORM, TP \$13.0)

Disclosure Appendix

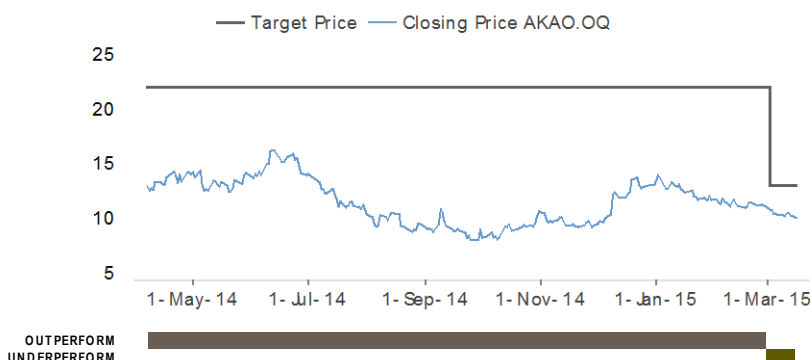
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3-Year Price and Rating History for Achaogen (AKAO.OQ)

AKAO.OQ	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
07-Apr-14	12.89	22.00	O *
02-Mar-15	10.82	13.00	U

* Asterisk signifies initiation or assumption of coverage.



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Price Target: (12 months) for Achaogen (AKAO.OQ)

Method: Our \$13 target is based on a 65% probability of success for plazomicin, approximately \$458M in peak sales, and an ex-US partner. Our estimates could prove conservative on price, penetration, market size, and the economics of the ex-US deal.

Risk: Risks to our \$13 target are (1) sooner than expected efficacy data in the "supportive" Phase 2 or pivotal Phase 3 study, (2) rapid increase in the spread of CRE in the developed world, and (3) competitive product for CRE fails to reach the market ahead of or at the same time as plazomicin.

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