

Achaogen (AKAO)

SMALL & MID CAP RESEARCH

First Patient Enrolled in Phase III; Enrollment Rate Will be Key Metric to Follow

AKAO marked a significant milestone with the first patient enrolled in its Phase III trial of plazomicin for the treatment of serious infections caused by the deadly drug-resistant bacteria known as CRE. This follows a prior delay announced on its Q2 call in August. AKAO expects to have all sites fully activated in Q1:15 and anticipates interim analyses in H2:15 and H2:16, with top-line data in H1:17. Changes to our quarterly estimates reflect the expected recognition of the \$4M milestone payment to ISIS in Q3 (previously modeled in Q4).

- **Enrollment trajectory will be key to watch:** The plazomicin Phase III trial is one of the most ambitious trials in the antibiotic space. It aims to enroll some of the sickest patients who are infected with a relatively rare but deadly bacteria (CRE). The primary endpoint is superiority in overall survival, which is atypical in the antibiotic space, but potentially a huge differentiator and a reason for future premium pricing. AKAO has carefully selected sites in regions known to have higher rates of CRE and where diagnostic labs are well run to conduct the trial.
- **Catalysts:** For the remainder of 2014, we expect updates on the expansion of the Ph III to additional clinical sites, potential updates on enrollment, and guidance on the planned Phase II trial, which could offer another (potentially shorter) path to registration. In 2015, AKAO expects an interim analysis of Phase III (H2:15), and potentially data from the Phase II CRE study in Q4:15 (timing may change depending on trial design and when it starts).
- **Valuation:** Our \$22 target price is based on a 65% probability of success for plazomicin, approximately \$473M in peak sales, and an ex-U.S. partner.

Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US\$)	-1.36	-1.30	-1.11	-1.21
Prev. EPS (US\$)	—	—	—	—
P/E (x)	-6.5	-6.8	-7.9	-7.3
P/E rel. (%)	-36.3	-41.1	-53.5	-54.9
Revenue (US\$ m)	18.5	22.8	23.2	21.2
EBITDA (US\$ m)	-11.5	-17.6	-20.1	-28.4
OCFPS (US\$)	-1.43	-0.91	-0.85	-1.00
P/OCF (x)	—	-9.6	-10.4	-8.8
EV/EBITDA (current)	-7.4	-4.8	-4.2	-3.0
Net debt (US\$ m)	-3	-62	-46	-115
ROIC (%)	-241.36	-506.70	-666.83	-1,043.50
Number of shares (m)	17.71	IC (current, US\$ m)		4.96
BV/share (Next Qtr., US\$)	3.9	EV/IC (x)		44.8
Net debt (Next Qtr., US\$ m)	-67.0	Dividend (current, US\$)		—
Net debt/tot eq (Next Qtr., %)	-97.1	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

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Exhibit 1: AKAO Pipeline

Drug	Indication	Stage	Partner
Plazomicin	Carbapenam-resistant enterobacteriaceae	Phase III	Proprietary
LpxC inhibitor	Pseudomonas	Preclinical (IND 2015)	Proprietary
Antibacterial Ab	Pseudomonas	Preclinical (IND 2015)	Proprietary

Source: Company data, Credit Suisse estimates.

Exhibit 2: AKAO News Flow

Timing	Expected News Flow	Program
YE:14/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	Q1:14A	Q2:14A	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues												
Plazomicin US sales										63.5	105.0	154.4
Plazomicin EU royalties (20%)										3.1	7.3	18.0
Contract revenue	18.5	6.0	5.2	5.8	5.8	22.8	23.2	21.2	40.0	41.3		
Total revenues	18.5	6.0	5.2	5.8	5.8	22.8	23.2	21.2	40.0	107.9	112.4	172.4
Expenses												
COGS										7.6	13.0	20.0
R&D	23.5	6.6	6.2	10.8	7.3	30.9	33.3	36.6	40.2	53.5	38.0	49.1
G&A	7.0	2.6	2.3	2.4	2.4	9.8	10.4	11.1	17.0	50.0	55.0	57.8
Total operating expenses	30.5	9.2	8.5	13.2	9.7	40.7	43.6	49.9	70.3	111.1	106.0	126.8
Operating income (loss)	(12.0)	(3.2)	(3.3)	(7.4)	(3.9)	(17.9)	(20.4)	(28.8)	(30.3)	(3.2)	6.4	45.5
Total Other Income (Expense)	(1.1)	(0.2)	(0.2)	(0.1)	(0.1)	(0.6)	0.3	0.4	0.4	0.5	0.5	0.5
Pre Tax Income	(13.1)	(3.5)	(3.6)	(7.5)	(4.0)	(18.5)	(20.1)	(28.4)	(29.9)	(2.7)	6.9	46.0
Income tax expense (benefit)												
Net Income	(13.1)	(3.5)	(3.6)	(7.5)	(4.0)	(18.5)	(20.1)	(28.4)	(29.9)	(2.7)	6.9	46.0
EPS - diluted (proforma)		(\$1.00)	(\$0.20)	(\$0.42)	(\$0.22)	(\$1.30)	(\$1.11)	(\$1.21)	(\$1.25)	(\$0.11)	\$0.26	\$1.74
Shares outstanding - diluted (proforma)		3.46	17.69	17.78	17.87	14.20	18.09	23.49	23.97	24.09	26.28	26.41

Source: Company data, Credit Suisse estimates

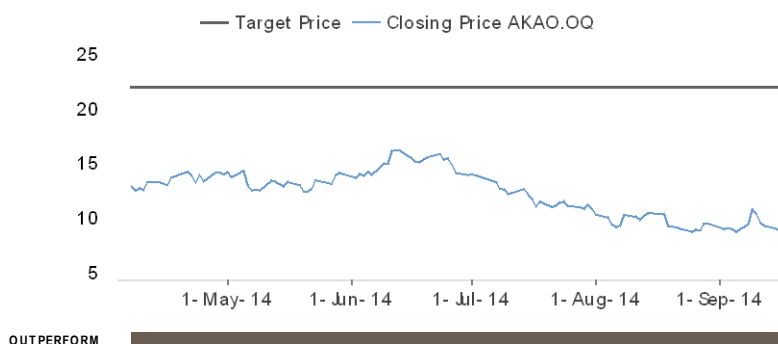
Companies Mentioned (Price as of 16-Sep-2014)**Achaogen** (AKAO.OQ, \$8.82, OUTPERFORM[V], TP \$22.0)**Disclosure Appendix****Important Global Disclosures**

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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 *

* Asterisk signifies initiation or assumption of coverage.



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

Method: Our \$22 target is based on a 65% probability of success for plazomicin, approximately \$473M 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. Our valuation includes a very small nominal value for the preclinical assets

Risk: Risks to our \$22 target are (1) unexpected safety signal in the "supportive" Phase 2 or pivotal Phase 3 study, (2) slower than expected spread of CRE in the developed world, and (3) competitive product for CRE reaches the market ahead of or at the same time as plazomicin.

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