

# Achaogen (AKAO)

## SMALL & MID CAP RESEARCH

### Q3 Earnings In-Line; Near-Term Regulatory and Legislative Events Could Boost AKAO

AKAO dosed the first patient in its Phase III trial of plazomicin (CARE) in Q3:14, and expects to have all sites fully activated in Q1:15. The enrollment has been slower than AKAO anticipated, but is in the process of discussing with the FDA about methods to augment the enrollment rate. Ongoing discussions with US and EU regulators are focused on potential routes to earlier registration for plazomicin with a smaller Phase II study. Our 2014 EPS decreases to (\$1.40) from (\$1.30) with lower H2:14 contract revenue.

- **Discussions with regulators about possible filing based on smaller trials:** AKAO is working with the FDA and EMA to clarify the requirements for a smaller efficacy study that might support early approval. Management believes it will be able to provide an update on these discussions in Q1:15. FDA is planning an AdCom meeting on December 4th, and we believe this discussion may provide insight into the Agency's position on this topic.
- **New legislation that could benefit AKAO:** There are two notable pieces of legislation that could help AKAO: (1) ADAPT Act – to give FDA greater flexibility to approve drugs for underserved multi-drug resistant bacteria, and (2) DISARM Act – to improve the reimbursement environment for new antibiotics that treat significant disease threats. We believe the ADAPT Act has the potential to shorten the development timeline for Plazomicin, and we believe this bipartisan bill has the potential to be passed in 2015.
- **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	-1.40	-1.06	-1.21
Prev. EPS (US\$)	—	-1.30	-1.11	—
P/E (x)	-7.3	-7.0	-9.3	-8.2
P/E rel. (%)	-42.5	-44.2	-65.0	-63.8
Revenue (US\$ m)	18.5	20.7	23.2	21.2
EBITDA (US\$ m)	-11.5	-19.1	-19.1	-28.4
OCFPS (US\$)	-1.43	-1.02	-0.80	-1.00
P/OCF (x)	—	-9.7	-12.4	-9.9
EV/EBITDA (current)	-9.0	-5.4	-5.4	-3.6
Net debt (US\$ m)	-3	-61	-46	-115
ROIC (%)	-241.36	-549.66	-636.01	-1,043.50
Number of shares (m)	17.76	IC (current, US\$ m)		4.96
BV/share (Next Qtr., US\$)	3.8	EV/IC (x)		53.6
Net debt (Next Qtr., US\$ m)	-66.1	Dividend (current, US\$)		—
Net debt/tot eq (Next Qtr., %)	-97.0	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
Dec 4, 2014	FDA ADAC to discuss supportive Ph2 studies for early approval	Plazomicin
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	Q3:14A	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Revenues</b>												
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	4.5	5.0	20.7	23.2	21.2	40.0	41.3		
<b>Total revenues</b>	18.5	6.0	5.2	4.5	5.0	20.7	23.2	21.2	40.0	107.9	112.4	172.4
<b>Expenses</b>												
COGS										7.6	13.0	20.0
R&D	23.5	6.6	6.2	10.7	7.3	30.8	33.3	36.6	40.2	53.5	38.0	49.1
G&A	7.0	2.6	2.3	2.2	2.2	9.4	9.4	11.1	17.0	50.0	55.0	57.8
<b>Total operating expenses</b>	30.5	9.2	8.5	12.9	9.5	40.1	42.7	49.9	70.3	111.1	106.0	126.8
<b>Operating income (loss)</b>	(12.0)	(3.2)	(3.3)	(8.3)	(4.5)	(19.4)	(19.5)	(28.8)	(30.3)	(3.2)	6.4	45.5
<b>Total Other Income (Expense)</b>	(1.1)	(0.2)	(0.2)	0.0	(0.1)	(0.5)	0.3	0.4	0.4	0.5	0.5	0.5
<b>Pre Tax Income</b>	(13.1)	(3.5)	(3.6)	(8.3)	(4.6)	(19.9)	(19.2)	(28.4)	(29.9)	(2.7)	6.9	46.0
<b>Income tax expense (benefit)</b>												
<b>Net Income</b>	(13.1)	(3.5)	(3.6)	(8.3)	(4.6)	(19.9)	(19.2)	(28.4)	(29.9)	(2.7)	6.9	46.0
<b>EPS - diluted (proforma)</b>		(\$1.00)	(\$0.20)	(\$0.47)	(\$0.26)	(\$1.40)	(\$1.06)	(\$1.21)	(\$1.25)	(\$0.11)	\$0.26	\$1.74
<b>Shares outstanding - diluted (proforma)</b>		3.46	17.69	17.71	17.87	14.18	18.09	23.49	23.97	24.09	26.28	26.41

Source: Company data, Credit Suisse estimates

**Companies Mentioned** (Price as of 10-Nov-2014)**Achaogen** (AKAO.OQ, \$9.88, 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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