

# Achaogen (AKAO)

## SMALL & MID CAP RESEARCH

## Q2 Earnings: AKAO Announces Delay in Phase III Start and Other Near-term Events

AKAO announced that it has experienced delays in initiating enrollment for its Phase III plazomicin trial. The first patient is expected to be enrolled in H2:14, and all the sites are expected to be fully activated in Q1:15 (vs the prior goal of YE:14). AKAO reiterated its expectation for interim analyses in H2:15 and H2:16, and top-line data in H1:17. Model adjustments post the Q2:14 release cause our 2014 EPS forecast to increase to (\$1.30) from prior (\$1.40).

- **Delays in getting sites up and running:** AKAO cited two issues: (1) validation of drug level monitoring assays at central labs, which has now been remedied, and (2) contract issues with other clinical sites. AKAO believes it can make up the delay and keep the trial on its original schedule.
- **Other program delays:** In the 10Q, AKAO now expects to start IND enabling studies for one or two of its anti-pseudomonas programs in 2015 and file an IND(s) in 2016 (this is a slip from 2014 and 2015, respectively). AKAO remains very excited with its progress in both the LpxC and antibody programs targeting pseudomonas. We continue to expect the AKAO to initiate the "supportive" Phase II efficacy study of plazomicin in 2014, though without a clearly defined protocol disclosed yet, we now believe it may start in early 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.

Rating	<b>OUTPERFORM* [V]</b>
Price (11 Aug 14, US\$)	10.14
Target price (US\$)	22.00 <sup>1</sup>
52-week price range	18.95 - 9.22
Market cap. (US\$ m)	179.28
Enterprise value (US\$ m)	115.43

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

<sup>1</sup>Target 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\$)	-1.36	-1.30	-1.11	-1.21
Prev. EPS (US\$)	—	-1.40	-1.26	-1.27
P/E (x)	-7.5	-7.8	-9.1	-8.4
P/E rel. (%)	-41.0	-46.3	-60.5	-61.9
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	-0.79	-0.95	-1.00
P/OCF (x)	—	-12.8	-10.7	-10.1
EV/EBITDA (current)	-9.4	-6.1	-5.3	-3.8
Net debt (US\$ m)	-3	-64	-46	-115
ROIC (%)	-241.36	-976.49	-666.83	-1,043.50
Number of shares (m)	17.68	IC (current, US\$ m)		4.96
BV/share (Next Qtr., US\$)	4.1	EV/IC (x)		29.8
Net debt (Next Qtr., US\$ m)	-69.3	Dividend (current, US\$)		—
Net debt/tot eq (Next Qtr., %)	-94.9	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

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- **Q2:14 financials:** AKAO reported a Q2 net loss of (\$3.6M), which is below from consensus of (\$4.5M) and our forecast of (\$7.8M). The primary difference from our estimate was the delay in the first patient treated, which triggers a \$4M milestone payment to ISIS. AKAO ended Q2 with \$74.5M in cash, having made a \$5.7M payment for the remainder of its debt obligation with Oxford Finance and Silicon Valley Bank. We have moved the \$4M payment due to ISIS for treating its first patient to Q4:14 from Q2:14 to account for the delay in the Phase III study initiation, though it may come in Q3.
- **Catalysts:** For H2:14, we expect first patient dosed in the Phase III and potentially initiation of Phase II studies of plazomicin in CRE. 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 initiates).

**Exhibit 1: Q2:14 Variance Table**

Income Statement	2Q:14 Act.	<u>CS</u>		<u>Consensus</u>	
		2Q:14 Est	Delta	2Q:14 Est	Delta
Plazomicin US sales	0.0	0.0	0.0		
Plazomicin EU royalties (20%)	0.0	0.0	0.0		
Contract revenue	5.2	5.8	-0.6		
<b>Total revenues</b>	<b>5.2</b>	<b>5.8</b>	<b>-0.6</b>	<b>6.3</b>	<b>-1.1</b>
Expenses	0.0	0.0	0.0		
COGS	0.0	0.0	0.0		
R&D	6.2	10.8	-4.6		
<b>G&amp;A</b>	<b>2.3</b>	<b>2.7</b>	<b>-0.3</b>		
<b>Total operating expenses</b>	<b>8.5</b>	<b>13.5</b>	<b>-4.9</b>	<b>11.1</b>	<b>-2.5</b>
Operating income (loss)	(3.3)	(7.7)	4.3		
Total Other Income (Expense)	(0.2)	(0.1)	-0.1		
Pre Tax Income	(3.6)	(7.8)	4.2		
Income tax expense (benefit)	0.0	0.0	0.0		
<b>Net Income</b>	<b>(3.56)</b>	<b>(7.77)</b>	<b>4.22</b>	<b>(4.5)</b>	<b>1.0</b>
EPS - diluted (proforma)	(0.20)	(0.44)	0.24	(0.3)	0.0
Shares outstanding - diluted (proforma)	17.7	17.8	-0.1		

Source: Company data, Credit Suisse estimates

**Exhibit 2: 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 3: 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 4: AKAO Model**

	2013A	Q1:14A	Q2:14A	Q3:14E	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	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
<b>Expenses</b>												
COGS										7.6	13.0	20.0
R&D	23.5	6.6	6.2	6.8	11.3	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	9.2	13.7	40.7	43.6	49.9	70.3	111.1	106.0	126.8
Operating income (loss)	(12.0)	(3.2)	(3.3)	(3.4)	(7.9)	(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)	(3.5)	(8.0)	(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)	(3.5)	(8.0)	(18.5)	(20.1)	(28.4)	(29.9)	(2.7)	6.9	46.0
EPS - diluted (proforma)		(\$1.00)	(\$0.20)	(\$0.19)	(\$0.45)	(\$1.30)	(\$1.11)	(\$1.20)	(\$1.24)	(\$0.11)	\$0.26	\$1.74
Shares outstanding - diluted (proforma)		3.46	17.69	17.86	17.95	14.24	18.17	23.58	24.05	24.17	26.37	26.50

Source: Company data, Credit Suisse estimates

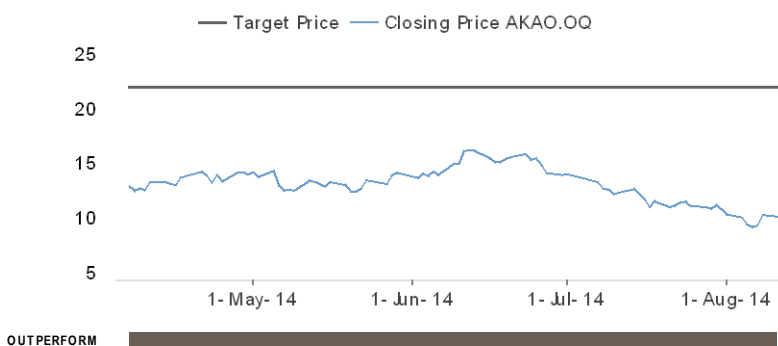
**Companies Mentioned** (Price as of 11-Aug-2014)**Achaogen** (AKAO.OQ, \$10.14, OUTPERFORM[V], TP \$22.0)**Disclosure Appendix****Important Global Disclosures**

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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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**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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