Achaogen (AKAO)

SMALL & MID CAP RESEARCH

Q1 Earnings: Expect First Patient Treated in Phase III in Q2

- **Q1 results:** AKAO reported a Q1 net loss of ($3.46M), better than our forecast of ($6.65M) on higher reimbursements from BARDA. We increased our R&D expense for 2014, and this is partially offset by higher BARDA revenue. Our net loss for 2014 is now ($20M) vs. prior ($16M). Our 2014 EPS is now ($1.40) vs prior ($1.00). AKAO ended Q1 with $84.9M in cash, and expects to pay down the remainder of its $5M debt in Q2.
- **Expect first patient in Phase III:** AKAO has already activated several clinical sites in its Phase III trial and plans to roll out more clinical sites throughout 2014 across 14-15 countries. The most important sites could be those in geographies with high CRE rates such as Greece and Brazil. AKAO will pay a $4M milestone to ISIS upon treatment of the first patients, which we expect will occur in Q2:14. AKAO reiterated its timeline for top-line data in H1:17 with interim analyses in 2015 and 2016.
- **Catalysts:** In 2014, we see progress in Phase II and Phase III studies of plazomicin in CRE. In 2015, catalysts include first interim analysis of Phase III (H2:15), data from the Phase II CRE study (Q4:15), and the initiation of a clinical program for a second antibiotic (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	**OUTPERFORM* [V]**
Price (09 May 14, US$)	12.53
Target price (US$)	22.00[1]
52-week price range	18.95 - 12.52
Market cap. (US$ m)	221.54
Enterprise value (US$ m)	153.50

**Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.*
[1]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$)	-1.36	-1.40	-1.26	-1.27
Prev. EPS (US$)	—	-1.00	-0.91	-0.95
P/E (x)	-9.2	-8.9	-9.9	-9.9
P/E rel. (%)	-53.8	-56.2	-69.6	-76.8
Revenue (US$ m)	18.5	23.4	23.2	21.2
EBITDA (US$ m)	-11.5	-19.2	-22.9	-30.0
OCFPS (US$)	-1.43	-0.94	-0.97	-1.05
P/OCF (x)	—	-13.3	-12.9	-12.0
EV/EBITDA (current)	-19.1	-11.4	-9.6	-7.3
Net debt (US$ m)	-3	-68	-50	-118
ROIC (%)	-241.36	499.52	476.86	546.69

Number of shares (m)	17.68	IC (current, US$ m)	4.96
BV/share (Next Qtr., US$)	22.8	EV/IC (x)	63.6
Net debt (Next Qtr., US$ m)	-76.6	Dividend (current, US$)	—
Net debt/tot eq (Next Qtr., %)	-97.1	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

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
2014	Initiate "Supportive" Phase 2	Plazomicin
2014	Select development candidate	Antipseudomonal
H2:15	Initiate safety trial	Plazomicin
H2:15	First interim - Phase 3	Plazomicin
Q4:15	"Supportive" Phase 2 top-line data release	Plazomicin
2015	File IND	Antipseudomonal
2015	File IND	LpxC inhibitor
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.

Investment Positives

- **Plazomicin Is Being Developed to Treat an Urgent Threat:** The CDC identifies CRE as one of the most urgent infectious disease threats and plazomicin is active against these resistant bacteria. The FDA recognizes the need for new agents targeting drug-resistant organisms, and this could help facilitate a faster review of plazomicin.
- **Robust Phase III Study Could Solidify Plazomicin as Leading Agent:** Plazomicin is the only antibiotic being tested for superiority using an overall survival endpoint, and a successful outcome from this study could lead to the drug becoming the preferred agent for CRE and provide the company with significant pricing power.
- **Favorable Regulatory Environment:** Increased concern regarding antibiotic resistant bacteria and the passage of the GAIN Act in 2012, set the stage for a more permissive and cooperative FDA. The GAIN Act gives ten years of exclusivity to new antibiotics and provides regulatory paths to approval that were not previously available. The FDA has indicated a willingness to approve new antibiotics for specific bacteria on smaller trials, and this could directly benefit AKAO.
- **Phase III Largely Funded by BARDA:** The Biomedical Advanced Research and Development Authority (BARDA) has a contract with AKAO to provide funding for the ongoing Phase III trial. BARDA has committed up to $60.4M for the Phase III clinical trial, which is in addition to the $43.4M already received for this program. The BARDA funding provides meaningful leverage to the capital raised from investors for the Phase III trial. AKAO plans to combine approximately $35-$40M from the equity raise with the BARDA funding to complete the Phase III study.
- **Focus on Gram-Negative Drug Development:** In recent years, companies have been more focused on developing Gram-positive antibiotics, and we believe AKAO's focus on Gram-negative antibiotics places it in the area of highest unmet medical

need. We expect that AKAO could take one or two new Gram-negative drug candidates into the clinic in 2015. Both candidates are novel and address the problem of drug-resistant pseudomonas infections.

- **Phase II Results in Urinary Tract Infections:** The Phase II data demonstrated plazomicin's efficacy in a standard model of Gram-negative infections using the same target dose as the Phase III study. It also established a safety profile that is consistent with other drugs in its class.

Investment Risks

- **Superiority Trial Is Riskier than Most:** Antibiotics are usually developed using "non-inferiority" studies, in which a new drug needs to be no worse than existing therapies. Superiority is a more difficult endpoint, and it is possible that plazomicin demonstrates efficacy in the CRE setting, yet fails to demonstrate statistically significant improvements in overall survival.
- **Difficult Trial to Conduct:** CRE is still a relatively rare infection and the patients being targeted are extremely ill. Enrollment could be challenging, and predicting enrollment rate and mortality in the control arm is difficult. Even with the projected enrollment, the timeline to final data is not until H1:17.
- **Competition:** Several Gram-negative drugs are in development that could potentially treat CRE, including drugs from The Medicines Company and Forest/AstraZeneca. The Medicines Company has publicly stated that it intends to pursue a faster strategy for potential approval and carbavance could reach the market before or at the same time as plazomicin.
- **Activity and Safety in Pneumonia and Blood Stream Infections Unknown:** The relative efficacy and safety of plazomicin in CRE pneumonia and blood stream infections is not known. The previous clinical trials were conducted in patients with complicated urinary tract infections.
- **Pricing:** Most companies developing drugs for resistant bacteria hope to price their drugs at a significant premium to currently used antibiotics. Another alternative approach is to base pricing on the value captured by using the therapeutic (i.e., improvement in survival, hospital avoidance, etc.). However, value-based pricing is not established in this market place, and real clinical benefits will need to be shown to support higher prices.
- **Safety:** Plazomicin belongs to the class of antibiotics called aminoglycosides, which are known to cause kidney toxicity and ototoxicity (hearing loss). AKAO is using dose adjustments to enhance safety and efficacy, but toxicity remains a clinical, regulatory, and competitive risk.
- **CRE Is an Emerging Threat:** Currently, the outbreak of CRE is concentrated in certain hotspots. Resistance has spread over time and will likely continue to grow, but forecasting the exact future market size is difficult.

Exhibit 3: AKAO Model

	2013A	Q1:14A	Q2:14E	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	5.8	5.8	5.8	23.4	23.2	21.2	40.0	41.3		
Total revenues	18.5	6.0	5.8	5.8	5.8	23.4	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	10.8	7.1	7.6	32.1	34.6	38.1	41.9	53.5	38.0	49.1
G&A	7.0	2.6	2.7	2.7	2.8	10.8	11.8	11.1	17.0	50.0	55.0	57.8
Total operating expenses	30.5	9.2	13.5	9.8	10.4	42.9	46.4	51.5	72.0	111.1	106.0	126.8
Operating income (loss)	(12.0)	(3.2)	(7.7)	(4.0)	(4.6)	(19.5)	(23.2)	(30.3)	(32.0)	(3.2)	6.4	45.5
Total Other Income (Expense)	(1.1)	(0.2)	(0.1)	(0.1)	(0.1)	(0.5)	0.3	0.4	0.4	0.5	0.5	0.5
Pre Tax Income	(13.1)	(3.5)	(7.8)	(4.1)	(4.6)	(20.0)	(22.9)	(29.9)	(31.6)	(2.7)	6.9	46.0
Income tax expense (benefit)												
Net Income	(13.1)	(3.5)	(7.8)	(4.1)	(4.6)	(20.0)	(22.9)	(29.9)	(31.6)	(2.7)	6.9	46.0
EPS - diluted (proforma)		($1.00)	($0.44)	($0.23)	($0.26)	($1.40)	($1.26)	($1.27)	($1.31)	($0.11)	$0.26	$1.74
Shares outstanding - diluted (proforma)		3.46	17.77	17.86	17.95	14.26	18.17	23.58	24.05	24.17	26.37	26.50

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 09-May-2014)*

Achaogen (AKAO.OQ, $12.53, OUTPERFORM[V], TP $22.0)

Disclosure Appendix

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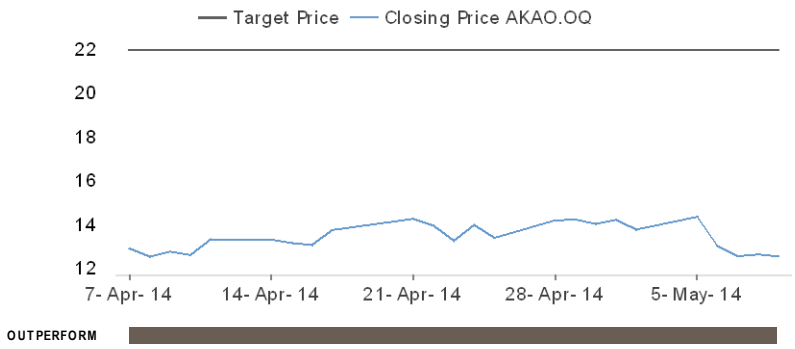
3-Year Price and Rating History for Achaogen (AKAO.OQ)

AKAO.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
07-Apr-14	12.89	22.00	O *

** 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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