



# Rating (from Outperform) UNDERPERFORM\* [V] Price (27 Feb 15, US\$) 11.17 Target price (US\$) (from 22.00) 13.00¹ 52-week price range 18.95 - 8.00 Market cap. (US\$ m) 198.36 Enterprise value (US\$ m) 159.99

\*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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### Achaogen (AKAO)

**SMALL & MID CAP RESEARCH** 

## **Uncertain Phase III Timeline Likely to Impede Performance in 2015**

We are downgrading AKAO to Underperform from Outperform (and target price to \$13 from \$22) based on our expectation that timelines for the plazomicin Phase III are likely longer than originally projected and news flow in 2015 is likely to be very limited. We have not changed our probability of success, but outperformance may require nearer-term clinical data and a solid timeline to commercial launch.

- Upcoming amendments to the protocol, likely announced in March/April, may help accelerate the current slow pace of enrollment by increasing the number of patients who qualify for the trial, especially in CRE hot spots like Greece. We believe this news will be accompanied by an extension of the Phase III timeline from original guidance. There may also be some risk that the SPA for the Phase III is withdrawn, as amending the SPA could delay protocol changes. Current guidance is completion in H1:17; NDA by YE:17.
- Regulatory environment for new antibiotics has significantly improved and pending legislation could improve it further. Passage of the DISARM Act would remove pricing hurdles for certain hospital antibiotics, and the ADAPT Act would further streamline regulatory approval for certain antibiotics like plazomicin. Both have bipartisan support. AKAO could rally on passage of these bills, but so would the other antibiotic players.
- Consolidation in the space favors M&A as an exit strategy: The acquisitions of DRTX and CBST in 2014 highlight the renewed interest in hospital antibiotics. However, we do not think AKAO will be acquired in 2015, and believe that an acquirer would require greater visibility on the pace of Phase III enrollment and likely timing of results.

#### 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\$)	_	_	_	_
P/E (x)	-8.2	-8.0	-10.5	-9.3
P/E rel. (%)	-45.7	-45.0	-67.3	-66.5
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	-0.79	-0.78	-0.99
P/OCF (x)	_	-14.1	-14.2	-11.3
EV/EBITDA (current)	-13.4	-8.1	-8.1	-5.4
Net debt (US\$ m)	-3	-38	-24	-93
ROIC (%)	-241.36	-74.92	-77.38	-116.73
Number of shares (m)	17.76	IC (current, US\$ n	n)	4.96
BV/share (Next Qtr., ÚS\$)	3.6	EV/IC (x)	,	6.2
Net debt (Next Qtr., US\$ m)	-38.4	Dividend (current,	US\$)	_
Net debt/tot eq (Next Qtr., %)	-59.7	Dividend yield (%)	,	_
Source: Company data, Credit Suisse estimates				

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#### **Upcoming Phase III protocol amendments**

Enrollment in the Phase III trial of plazomicin for treating confirmed CRE infections has proceeded slower than originally anticipated despite careful site selection and protocol design. AKAO is in discussions with FDA on amendments to the protocol that would speed the pace of enrollment, primarily by modifying the inclusion and exclusion criteria to reduce the number of patients who are disqualified but likely have CRE infections.

We believe that AKAO has recently met with FDA and should have minutes from that meeting by the end of March. We suspect that AKAO will provide new guidance at that time, assuming the feedback from FDA is clear.

It is uncertain how quickly protocol changes could be implemented.

- At the clinical site level, there may be a need to gain approvals for any protocol changes, which may delay the implementation of any changes.
- At the FDA level, there could be further delays, because AKAO has an SPA for this trial. Any change in the protocol would require the company to apply for a change to the SPA. We are not clear on exactly how long that could take. It is possible that AKAO will choose to abandon the SPA to expedite the protocol changes. While we do not believe an SPA is essential, abandoning the SPA may be perceived negatively by investors.

We do not expect to have good visibility on how the protocol changes have impacted enrollment until H2:15.

#### Potential legislation that could help AKAO

The ADAPT and DISARM Acts have bipartisan support and possibly one or both could pass this year. It is possible that these bills could be added as an amendment to larger pieces of legislation such as the Medicare Doc Fix bill or as part of the Cures bill.

- ADAPT Act (Antibiotic Development to Advance Patient Treatment Act of 2013, or H.R. 3742) to give FDA greater flexibility to approve drugs for underserved multi-drug resistant bacteria. 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.
- DISARM Act (Developing an Innovative Strategy for Antimicrobial Resistant Microorganism, or HR 4187) to improve the reimbursement environment for new antibiotics that treat significant disease threats. Simplistically, this bill would replace the current DRG reimbursement model, which penalizes hospitals for using expensive drugs with an ASP plus a CMS-determined percentage, which would remove the "penalty" for using more expensive drugs, and provide a framework for companies to charge higher prices, more in line with the high unmet need and smaller target patient populations.

#### Valuation change: \$13 target price

Our new valuation is driven by three changes to our model and DCF valuation: (1) We pushed the launch of plazomicin out one year to 2019 form 2018, (2) we increased our discount rate to 15% to reflect the increased uncertainty around the timing and trial design, and (3) we removed the pipeline from our valuation as AKAO as we do not expect any programs to advance into the clinic in 2015.



**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	Plazomic in
H2:15	Initiate safety trial	Plazomic in
H2:15	First interim - Phase 3	Plazomic in
Q4:15	"Supportive" Phase 2 top-line data release	Plazomic in
2015	Select development candidate	Antipseudomonal
2016	File IND	Antipseudomonal
H2:16	Second interim - Phase 3	Plazomic in
H1:17	Top-line data for Phase 3	Plazomic in
YE:17	File NDA with FDA	Plazomic in

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
Revenues												
Plazomicin US sales											70.0	115.8
Plazomicin EU royalties (20%)											3.3	10.1
Contract revenue	18.5	6.0	5.2	4.5	5.0	20.7	23.2	21.2	40.0	41.3		
Total revenues	18.5	6.0	5.2	4.5	5.0	20.7	23.2	21.2	40.0	41.3	73.3	125.9
Expenses												
COGS											8.3	14.4
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
Total operating expenses	30.5	9.2	8.5	12.9	9.5	40.1	42.7	49.9	70.3	103.5	101.3	121.3
Operating income (loss)	(12.0)	(3.2)	(3.3)	(8.3)	(4.5)	(19.4)	(19.5)	(28.8)	(30.3)	(62.3)	(28.1)	4.6
Total Other Income (Expense)	(1.1)	(0.2)	(0.2)	0.0	(0.1)	(0.5)	0.3	0.4	0.4	0.5	0.5	0.5
Pre Tax Income	(13.1)	(3.5)	(3.6)	(8.3)	(4.6)	(19.9)	(19.2)	(28.4)	(29.9)	(61.8)	(27.6)	5.1
Income tax expense (benefit)												
Net Income	(13.1)	(3.5)	(3.6)	(8.3)	(4.6)	(19.9)	(19.2)	(28.4)	(29.9)	(61.8)	(27.6)	5.1
FDC diluted (conferme)		(\$4.00)	(¢0.20)	(\$0.47)	(¢0.24)	(64, 40)	(\$4.04)	(64.24)	(\$4.2E)	(¢2 F4)	(64.44)	60.40
EPS - diluted (proforma)		(\$1.00)	(\$0.20)	(\$0.47)	(\$0.26)	(\$1.40)	(\$1.06)	(\$1.21)	(\$1.25)	(\$2.56)	(\$1.14)	\$0.19
Shares outstanding - diluted (proforma)		3.46	17.69	17.71	17.87	14.18	18.09	23.49	23.97	24.09	24.21	26.41

Source: Company data, Credit Suisse estimates



#### Companies Mentioned (Price as of 27-Feb-2015)

Achaogen (AKAO.OQ, \$11.17, UNDERPERFORM[V], 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	0 *

<sup>\*</sup> 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.

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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