

Biotechnology

Achaogen

Equity Research

December 8, 2014

Price: \$10.03 (12/5/2014) **Price Target: \$23.00**

OUTPERFORM (1)

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Key Data

NASDAQ: AKAO Symbol 52-Week Range: \$19.69 - 7.72 Market Cap (MM): \$178.1 Net Debt (MM): \$(4.1) Cash/Share: \$27.33 Dil. Shares Out (MM): 178 Enterprise Value (MM): \$106.1 ROIC NA ROE (LTM): NA BV/Share: \$3.85 Dividend: NA Yield: NM

FY (Dec)	2013A	2014E	2015E
Earnings Per Sha	are		-
Q1	-	\$(1.00)A	\$(0.19)
Q2	-	\$(0.20)A	\$(0.27)
Q3	-	\$(0.47)A	\$(0.32)
Q4	\$(0.58)	\$(0.47)	\$0.00
Year	\$(3.08)	\$(1.67)	\$(0.78)
P/E	NM	NM	NM
Consensus EPS	-	\$(1.25)	\$(1.10)
Consensus source: T	homson Reuter	re	

Revenue (MM)

Year	\$18.5	\$22.6	\$28.0
EV/S	5.7x	4.7x	3.8x

Company Update

Road Show Key Takeaways: 2015 To Be A Year of Execution

The Cowen Insight

We think AKAO will stay on track for topline Ph3 data in 1H17 from its pivotal trial of plazomicin in CRE. We think there are ways to expand inclusion criteria to keep enrollment on track, if needed, that would not compromise trial powering and conduct. We also think AKAO is in a position to benefit from potential legislation to promote antibiotic drug development and commercial feasibility.

We Expect AKAO's Ph3 Pivotal Superiority Trial of Plazomicin in CRE to Stay On Track to Yield Topline Data in 1H17 - Update Coming in 1Q15

We had AKAO management on the road for investor meetings in NYC and Boston last week. Management reiterated they are on track for topline data in 1H17 from the ongoing pivotal trial of plazomicin in CRE infection. AKAO anticipates running interim analysis for safety and futility in 2H15 and 2H16. We believe AKAO's main focus for 2015 will be executing on enrollment for this trial, as we expect a regulatory and clinical update on other clinical activity in 1Q15 after AKAO has had additional communications with the FDA.

Should Enrollment Become Even More Challenging, We Believe AKAO Has Options For Enrollment Expansion That May Not Compromise Trial Conduct

Should enrollment in the plazomicin pivotal trial slow, we believe there a number of enrollment expansion options AKAO has to keep data on track. Importantly, any expansion of inclusion criteria must only allow patients that are expected to have the same 35% 28-day mortality expected of the current patients on comparator therapy. AKAO could expand the number of clinical sites, include patients with hospital acquired pneumonia not on ventilators, or allow patients with colistin-resistant infections (with a respective protocol amendment). We expect the company to be mindful of its existing SPA for the trial while making any potential changes.

2015 Could Bring Key Legislation That Would Facilitate the Development and Commercialization of New Antibiotics: ADAPT and DISARM Acts

We believe there is a good chance that additional legislation facilitating the development and commercialization of novel antibiotics that specifically target dangerous resistant pathogens could be passed in 2015. Two specific pieces of legislation that will likely be put before Congress in 2015 will be the ADAPT act (which would allow FDA greater flexibility in approving novel antibiotics for resistant pathogens in narrower populations, as well as increased CDC resistance surveillance and breakpoint review) and the DISARM act (which could decouple antibiotic reimbursement for CMS from DRG code bundles). We think if these pieces of legislation are passed, it would represent significant benefit both from clinical development as well as commercial perspective for companies like Achaogen.



Our Investment Thesis

Plazomycin is Achaogen's Phase 3 novel modified aminoglycoside antibiotic that we think has significant clinical promise for treatment of resistant gram negative strains including CRE (carbapenem resistant enterobacteriaceae). The drug has shown impressive activity in a number of serious infection types caused by different resistant gram-negative pathogens. Data suggests even better activity than standard of care, which we think may lead to better clinical outcomes such as improved survival, shorter ICU time and shorter hospital stays.

Base Case Assumptions

- Plazomicin receives FDA approval for CRE based on positive data from the Phase 3 clinical trial and is launched in the U.S. in 2H18
- Plazomicin receives EMA approval for CRE based on positive data from the Phase 3 clinical trial and is launched in the U.S. in 2H19
- Achaogen is able to secure good premium pricing for plazomicin in the CRE market

Upside Scenario

- Achaogen is acquired at or before positive data from its Phase III clinical trial
- Plazomicin is approved based on smaller supplementary trial even before current Ph3 pivotal completes
- Plazomicin achieves faster than expected market penetration

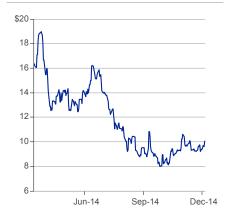
Forthcoming Catalysts

- Initiation of the supportive efficacy trial in 1H15
- First and second interim analyses in the pivotal Phase III clinical trial in 1H16 and 1H17, respectively
- Initiation of the safety study after the first interim analysis

Downside Scenario

- Plazomicin fails to meet the superiority primary endpoint in the pivotal study in spite of strong in vitro and preclinical data
- Achaogen is unable to price plazomicin at a premium or receives strong pushback from payers

Price Performance



Source: Bloomberg

Company Description

Achaogen is developing novel antibiotics for the treatment of multi-drug resistant (MDR) Gram-negative bacterial infections. The lead product candidate plazomicin, a next-generation aminoglycoside antibiotic, is in a pivotal Phase 3 clinical trial for bloodstream infections and nosocomial pneumonia caused by carbapenem-resistant Enterobacteriaceae (CRE). Achaogen has received an SPA from the FDA, as well as a grant of approximately \$60MM from BARDA, for the pivotal study. The study was initiated in 1Q14 and top-line data are expected in 2017. Achaogen has completed a Phase II clinical trial of plazomicin in cUTI and the drug candidate demonstrated non-inferiority to active comparator levofloxacin. *In vitro* and preclinical studies suggest that plazomicin will be efficacious in treating CRE infections and if the pivotal study succeeds, plazomicin will the be first antibiotic specifically developed for CRE pathogens. Achaogen also has preclinical programs for *Pseudomonas aeruginosa*.

Analyst Top Picks

	Ticker	Price (12/5/2014)	Price Target	Rating
Raptor Pharmaceutical Corp.	RPTP	\$9.05	\$24.50	Outperform
Intercept Pharmaceuticals	ICPT	\$143.64	\$420.00	Outperform

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We expect topline Phase 3 plazomicin in 1H17: 2015 to be a key year for execution on enrollment.

Plazomycin is Achaogen's Phase 3 novel modified aminoglycoside antibiotic that we think has significant clinical promise for treatment of resistant gram negative strains. The drug is currently in a Phase 3 trial which enrolled its first patient at the end of 3Q14. AKAO believes that with expected enrollment rates, topline data should be available in the first half of 2016. There will be interim looks for both safety and efficacy/futility in 2H15 and 2H16.

AKAO has not disclosed what the alpha penalty for these interims are. Overall, we think Achaogen's Phase 3 CRE pneumonia/blood stream infection trial is well designed to show improved survival over standard of care and has a good chance of success. The trial is designed to show superiority over the comparator arm which uses standard of care colistin-based combination regimens (which can also include meropenem, tigecycline, amikacin and gentamicin). The trial is 70% powered to detect a 12% absolute difference in survival (28 day mortality) between the two treatment arms with an assumption of 35% 28-day mortality in the comparator arm. Achaogen noted the trial is also 80% powered to detect a 9% mortality difference.

We believe AKAO has flexibility around enrollment criteria should it need to boost enrollment rate.

Enrollment in AKAO's Phase 3 is limited to those patients who have confirmed/suspected CRE infections (a minority of infections) and then further limited to those CRE infections that are in the bloodstream or in ventilator-acquired pneumonia. Patients must also enroll no later than 72 hours after infection onset, and, as colistin in the backbone of comparator arm therapy, patients with colistin-resistant pathogens are not eligible.

AKAO has already experienced some delays in trial enrollment due to these strict criteria, but believes there are potential expansion options in enrollment criteria that would not greatly impact the core assumption of 35% 28-day mortality of the comparator group.

For instance, AKAO could choose to open more clinical trial sites. Further, they believe that they could allow patients with simpler hospital-acquired CRE pneumonia (HAP) rather than only ventilator acquired CRE pneumonia (VAP). AKAO believes that the 28-day mortality between HAP and VAP are similar, although allowing for this expansion may compromise the powering of the 2nd endpoint measuring time on ventilator. Finally, AKAO could change treatment protocol that would allow patients with colistin-resistant infections into the trial, which would require a comparator treatment option that could not include colistin.

ADAPT and DISARM Acts: 2015 could be a key year for antibiotics incentive legislation

There has been significant public health focus on the rising prevalence of infections caused by resistant strains. These infections are associated with significantly worse clinical outcomes and even higher mortality. For example, CRE was included in FDA's list of qualified infectious disease pathogens that is part of the GAIN act, a piece of legislation instituted to provide incentive for antibiotic drug development.

There are 2 key important pieces of legislation that we think my pass in 2015 that will incentivize antibiotic drug development . The first is the ADAPT (Antibiotic

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<u>Development to Advance Patient Treatment Act</u>) Act. This piece of legislation currently has 3 parts.

- It would allow FDA to create an accelerated path to approval for new antibiotics that treat pathogens associated with serious public health issues for more limited or specific patient populations or infection types. It could permit approval of new antibiotics on more efficient clinical trials (smaller patient numbers, novel trial designs) that could greatly expedite clinical development.
- It would also strengthen antibiotic resistance monitoring by the CDC and facilitate public availability and reporting of results. This could greatly assist in the commercialization of novel antibiotics that are most appropriate for resistant pathogens (such as plazomicin).
- 3. The legislation would also formally update susceptibility test interpretive criteria for pathogens. In other words, it would update the potency "breakpoints" after which a pathogen would be deemed resistant to a certain antibiotic. This is key as there is significant disagreement as to where breakpoints for commonly used antibiotics like vancomycin lie.

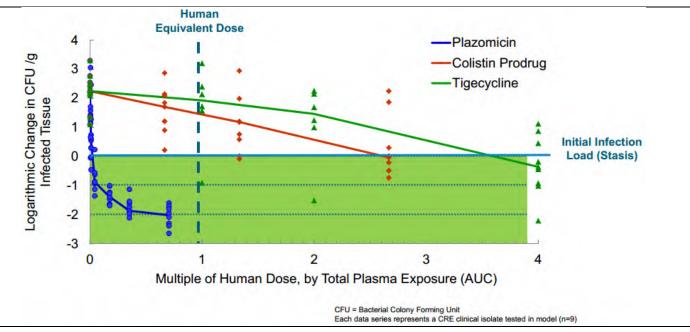
The other important piece of legislation that could pass in 2015 is the DISARM (Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms) act which could decouple in-patient novel antibiotics CMS reimbursement from overall DRG reimbursement. Currently, all antibiotics used in treatment (regardless of if they are generic or branded, or if the patients' infection is susceptible or resistant to standard of care) are included in the CMS reimbursement bundle, which is diagnosis dependent. Separate reimbursement for antibiotics would make hospitals less cost sensitive to new, normally higher priced antibiotics. This could also greatly assist in the commercialization of novel antibiotics like plazomicin as it could move premium antibiotics from a cost-center to a profit center in the eyes of hospital administrators.

Preclinical data suggests good chance of Ph3 success based on increased potency of plazomicin.

We think in-vitro and pre-clinical data suggests that plazomicin has significant efficacy again resistant gram-negative strains, with potency better than current antibiotic options. One particularly compelling piece of preclinical data suggests that colistin and tigecycline are not potent enough against CRE to be even bacteriostatic until concentrations well above safe human doses (Fig 1). In contrast, plazomicin showed strong comparative potency, and was highly bactericidal at equivalent doses where tigecycline and colistin did not even reach bacteriostatic activity.

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Figure 1 – Plazomicin Has Demonstrated Superior Activity Against CRE in Mouse Infection Model



Source: Achaogen

Figure 2 - Achaogen pNPV Table

Assumptions / Results						
Total NPV	23.2					
Number of Shares (m)	17.7					
Pharma PE	14.0x					
Discount rate	30%					
Current year	2014.75					

					Peak Sales			Probability weighted	Discount	
Drug name	Indication	Status	Launch	Success	(US\$m)	Royalty	Profitability	Peak Profit (US\$m)	Factor	NPV (US\$)
US Plazomicin	CRE	Phase 3	2018	60%	391	100%	80%	187.74	6.70	22.15
EU top 5 Plazomicin	CRE	Phase 3	2019	60%	204	20%	100%	24.44	19.14	1.01
TOTAL										23.16

Source: Cowen and Company

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Figure 3 - Achaogen P&L Statement

	2012A	2013A	Q1:14A	Q2:14A	Q3:14A	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Plazomicin Sales Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	98.7	181.5	245.2	286.3	330.8	379.2	415.1
Plazomicin Royalty Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.8	17.6	24.7	30.3	40.4	47.8	55.8
Contract Revenue	17.9	18.5	6.0	5.2	4.5	6.9	22.6	28.0	23.0	17.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenues	17.9	\$18.5	\$6.0	\$5.2	\$4.5	\$6.9	\$22.6	\$28.0	\$23.0	\$17.5	\$3.0	\$106.5	\$199.1	\$269.9	\$316.6	\$371.3	\$427.0	\$470.8
COGS	-	-	-	-	-	-	-	-	-	-	0.5	13.8	23.6	29.4	31.5	33.1	37.9	41.5
Research and Development	26.6	23.5	6.6	6.2	10.7	11.5	35.0	34.0	34.5	30.0	28.0	28.0	28.0	30.0	32.0	35.0	35.0	35.0
General and Administrative	7.3	7.0	2.6	2.3	2.2	3.4	10.5	7.5	8.0	8.5	9.5	11.0	12.5	14.0	15.0	16.0	17.0	18.0
Sales	-	-	-	-	-	-	-	-	-	-	4.5	8.0	8.4	8.8	9.3	9.7	10.2	10.7
Total Operating Expenses	33.9	30.5	9.2	8.5	12.9	14.9	45.5	41.5	42.5	38.5	42.5	60.8	72.5	82.2	87.7	93.8	100.1	105.2
Income (Loss) from Operations	(\$16.0)	(\$12.0)	(\$3.2)	(\$3.3)	(\$8.3)	(\$8.0)	(\$22.9)	(\$13.5)	(\$19.5)	(\$21.0)	(\$39.4)	\$45.7	\$126.7	\$187.7	\$228.8	\$277.5	\$326.9	\$365.6
Interest Expense and Other, net	(2.4)	(1.3)	(0.2)	(0.2)	0.0	(0.4)	(0.8)	(0.5)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest Income and Other, net	0.1	0.2	0.0	0.0	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	(\$18.4)	(\$13.1)	(\$3.5)	(\$3.6)	(\$8.3)	(\$8.4)	(\$23.7)	(\$14.0)	(\$19.5)	(\$21.0)	(\$39.4)	\$45.7	\$126.7	\$187.7	\$228.8	\$277.5	\$326.9	\$365.6
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	8%	13%	18%	23%	27%	35%
Income Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.1	24.4	41.2	63.8	88.3	128.0
Net Income (Loss) Attributable to Common Shareholders	(18.4)	(13.1)	(3.5)	(3.6)	(8.3)	(8.4)	(23.7)	(14.0)	(19.5)	(21.0)	(39.4)	45.7	116.5	163.3	187.6	213.6	238.6	237.6
GAAP EPS, Basic and Diluted	(\$4.80)	(\$3.08)	(\$1.00)	(\$0.20)	(\$0.47)	(\$0.47)	(\$1.67)	(\$0.78)	(\$1.04)	(\$0.82)	(\$1.49)	\$1.38	\$3.43	\$4.66	\$5.21	\$5.77	\$6.28	\$6.09
Weighted Average Shares Outstanding - Basic and Diluted	3.8	4.3	3.5	17.7	17.7	17.9	14.2	18.0	18.8	25.5	26.5	33.0	34.0	35.0	36.0	37.0	38.0	39.0

Source: Cowen and Company.

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Figure 4 - Achaogen World Wide Market Model

		2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
WW Empiric CRE Infection Cases (000s)	1%	884.51	893.36	902.29	911.32	920.43	929.63	938.93	948.32	957.80	967.38	977.05	986.82	996.69
WW Confirmed CRE Infection Cases (000s)	1%	114.47	115.61	116.77	117.93	119.11	120.31	121.51	122.72	123.95	125.19	126.44	127.71	128.98
WW Suspected CRE Infection Cases (000s)		770.05	777.75	785.52	793.38	801.31	809.33	817.42	825.59	833.85	842.19	850.61	859.12	867.71
WW Confirmed CRE Infection Cases (000s)	1%	114.47	115.61	116.77	117.93	119.11	120.31	121.51	122.72	123.95	125.19	126.44	127.71	128.98
WW Bloodstream & Pneumonia Confirmed CRE	1%	31.22	31.53	31.85	32.16	32.49	32.81	33.14	33.47	33.80	34.14	34.48	34.83	35.18
WW Bloodstream Confirmed CRE	60%	18.73	18.92	19.11	19.30	19.49	19.69	19.88	20.08	20.28	20.49	20.69	20.90	21.11
WW Pneumonia Confirmed CRE	40%	12.49	12.61	12.74	12.87	12.99	13.12	13.26	13.39	13.52	13.66	13.79	13.93	14.07
WW Abdominal & UTI Confirmed CRE		83.25	84.08	84.92	85.77	86.63	87.49	88.37	89.25	90.15	91.05	91.96	92.88	93.81
WW Abdominal Confirmed Infections CRE	85%	70.76	71.47	72.18	72.91	73.63	74.37	75.11	75.87	76.62	77.39	78.16	78.95	79.74
WW UTI Confirmed Infections CRE	15%	12.49	12.61	12.74	12.87	12.99	13.12	13.26	13.39	13.52	13.66	13.79	13.93	14.07
WW Suspected CRE Infection Cases (000s)		770.05	777.75	785.52	793.38	801.31	809.33	817.42	825.59	833.85	842.19	850.61	859.12	867.71
WW Bloodstream & Pneumonia Suspected CRE	1%	208.12	210.20	212.30	214.43	216.57	218.74	220.92	223.13	225.37	227.62	229.89	232.19	234.52
WW Bloodstream Suspected CRE	60%	124.87	126.12	127.38	128.66	129.94	131.24	132.55	133.88	135.22	136.57	137.94	139.32	140.71
WW Pneumonia Suspected CRE	40%	83.25	84.08	84.92	85.77	86.63	87.49	88.37	89.25	90.15	91.05	91.96	92.88	93.81
WW Abdominal & UTI Suspected CRE		561.93	567.55	573.22	578.95	584.74	590.59	596.50	602.46	608.49	614.57	620.72	626.92	633.19
WW Abdominal Suspected Infections CRE	85%	477.64	482.41	487.24	492.11	497.03	502.00	507.02	512.09	517.21	522.38	527.61	532.88	538.21
WW UTI Suspected Infections CRE	15%	84.29	85.13	85.98	86.84	87.71	88.59	89.47	90.37	91.27	92.19	93.11	94.04	94.98

Source: Cowen and Company.

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Figure 5 - Achaogen US Market Model

			1H18E	2H18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	
US Bloodstream Confirm ed CRE on label (000s)		60%	5.62	5.62	11.24	11.35	11.46	11.58	11.69	11.81	11.93	12.05	12.17	12.29	12.41	12.54	12.66
Plazomicin Bloodstream Confirmed CRE Penetration				8%	4%	20%	35%	50%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Plazomicin Bloodstream Confirmed CRE Patients				0.45	0.45	2.27	4.01	5.79	7.02	7.09	7.16	7.23	7.30	7.37	7.45	7.52	7.60
US Pneumonia Confirmed CRE on label (000s)		60%	3.75	3.75	7.49	7.57	7.64	7.72	7.80	7.87	7.95	8.03	8.11	8.19	8.28	8.36	8.44
Plazomicin Pneumonia Confirmed CRE Penetration				5%	3%	12%	19%	25%	35%	40%	40%	40%	40%	40%	40%	40%	40%
Plazomicin Pneumonia Confirmed CRE Patients				0.19	0.19	0.91	1.45	1.93	2.73	3.15	3.18	3.21	3.25	3.28	3.31	3.34	3.38
US Abdominal Infections Confirmed CRE off label (000s)		60%	21.23	21.23	42.46	42.88	43.31	43.74	44.18	44.62	45.07	45.52	45.97	46.43	46.90	47.37	47.84
Plazomicin Abdominal Confirmed CRE Penetration				4%	2%	10%	15%	20%	24%	27 %	30%	30%	30%	<i>30</i> %	30%	<i>30</i> %	30%
Plazomicin Abdominal Confirmed CRE Patients				0.85	0.85	4.29	6.50	8.75	10.60	12.05	13.52	13.66	13.79	13.93	14.07	14.21	14.35
US UTI Confirmed CRE off label (000s)		60%	3.75	3.75	7.49	7.57	7.64	7.72	7.80	7.87	7.95	8.03	8.11	8.19	8.28	8.36	8.44
Plazomicin UTI Confirmed CRE Penetration				1%	1%	2%	4%	6%	7%	8%	9%	10%	10%	10%	10%	10%	10%
Plazomicin UTI Confirmed CRE Patients				0.04	0.04	0.15	0.31	0.46	0.55	0.63	0.72	0.80	0.81	0.82	0.83	0.84	0.84
TOTAL US CRE Confirmed Plazomicin Patients (000s)				1.52	1.52	7.62	12.27	16.93	20.89	22.91	24.58	24.90	25.15	25.40	25.66	25.91	26.17
Treatment duration in days	*			10	10	10	10	10	10	10	10	10	10	10	10	10	10
Cost per treatment course	\$	1,250 p	er day	1250	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500	\$12,500
TOTAL US PLAZOMICIN CONFIRMED REVENUE (m il)					\$ 19.04	\$ 95.22	\$153.34	\$211.64	\$261.19	\$286.44	\$307.20	\$311.27	\$314.38	\$317.53	\$320.70	\$323.91	\$327.15
			1H18E	2H18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
US Bloodstream Suspected CRE on label (000s)		60%	37.46	37.46	74.92	75.67	76.43	77.19	77.97	78.75	79.53	80.33	81.13	81.94	82.76	83.59	84.43
Plazomicin Bloodstream Suspected CRE Penetration				2%	1%	4%	8%	11%	13%	16%	18%	20%	20%	20%	20%	20%	20%
Plazomicin Bloodstream Suspected CRE Patients				0.75	0.75	3.03	6.11	8.49	10.14	12.60	14.32	16.07	16.23	16.39	16.55	16.72	16.89
US Pneumonia Suspected CRE on label (000s)		60%		0.00	49.95	50.45	50.95	51.46	51.98	52.50	53.02	53.55	54.09	54.63	55.17	55.73	56.28
Plazomicin Pneumonia Suspected CRE Penetration				0.5%	0.3%	2%	4%	6%	7%	8%	9%	10%	10%	10%	10%	10%	10%
Plazomicin Pneumonia Suspected CRE Patients				0.00	0.12	1.01	2.04	3.09	3.64	4.20	4.77	5.36	5.41	5.46	5.52	5.57	5.63
US Abdominal Suspected CRE off label (000s)		60%		42.46	286.58	289.45	292.34	295.27	298.22	301.20	304.21	307.26	310.33	313.43	316.57	319.73	322.93
Plazomicin Abdominal Suspected CRE Penetration				0.5%	0.3%	2%	4%	6%	7%	8%	9%	10%	10%	10%	10%	10%	10%
Plazomicin Abdominal Suspected CRE Patients				0.21	0.72	5.79	11.69	17.72	20.88	24.10	27.38	30.73	31.03	31.34	31.66	31.97	32.29
US UTI Suspected CRE off label (000s)		60%		7.49	50.57	51.08	51.59	52.11	52.63	53.15	53.68	54.22	54.76	55.31	55.86	56.42	56.99
Plazomicin UTI Suspected CRE Penetration				0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Plazomicin UTI Suspected CRE Patients				0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TOTAL US CRE Suspected Plazomicin Patients (000s)				0.96	1.59	9.82	19.85	29.30	34.65	40.90	46.47	52.15	52.67	53.19	53.73	54.26	54.81
Treatment duration in days	*			10	3	3	3	3	3	3	3	3	3	3	3	3	3
Cost per day	\$	1,250			\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750	\$ 3,750
TOTAL US PLAZOMICIN SUSPECTED REVENUE (m ii)					\$ 5.96	\$ 36.84	\$ 74.42	\$109.86	\$129.93	\$153.36	\$174.25	\$195.55	\$197.50	\$199.48	\$201.47	\$203.49	\$205.52
TOTAL US PLAZOMICIN REVENUE (m il)					<u>\$ 25.01</u>	\$132.06	\$227.76	\$321.50	\$391.12	\$439.79	\$481.45	\$506.82	\$511.89	\$517.01	\$522.18	\$527.40	\$532.67

Source: Cowen and Company.

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Figure 6 - Achaogen EU Market Model

			2018E	1H19E	2H19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EU Bloodstream Confirmed CRE on label (000s)		40%	7.49	3.78	3.78	7.57	7.64	7.72		7.87	7.95	8.03	8.11	8.19	8.28	8.36	8.44
Plazomicin Bloodstream Confirmed CRE Penetration					8%	4%	20%	30%	40%	<i>50%</i>	50%	<i>50</i> %	<i>50</i> %	<i>50%</i>	<i>50%</i>	<i>50</i> %	<i>50%</i>
Plazomicin Bloodstream Confirmed CRE Patients					0.30	0.30	1.53	2.32	3.12	3.94	3.98	4.02	4.06	4.10	4.14	4.18	4.22
EU Pneumonia Confirmed CRE on label (000s)		40%	4.99	2.52	2.52	5.04	5.10	5.15	5.20	5.25	5.30	5.36	5.41	5.46	5.52	5.57	5.63
Plazomicin Pneumonia Confirmed CRE Penetration					5%	3%	12%	19%	25 %	<i>30%</i>	35%	35%	35%	35%	35%	<i>35</i> %	40%
Plazomicin Pneumonia Confirmed CRE Patients					0.13	0.13	0.61	0.98	1.30	1.57	1.86	1.87	1.89	1.91	1.93	1.95	2.25
EU Abdominal Confirmed CRE off label (000s)		40%	28.30	14.29	14.29	28.59	28.87	29.16	29.45	29.75	30.05	30.35	30.65	30.96	31.27	31.58	31.89
Plazomicin Abdominal Confirmed CRE Penetration					4%	2%	5%	9%	14%	19%	22%	25%	25%	25%	25%	25%	30%
Plazomicin Abdominal Confirmed CRE Patients					0.57	0.57	1.44	2.62	4.12	5.65	6.61	7.59	7.66	7.74	7.82	7.89	9.57
EU UTI Confirmed CRE off label (000s)		40%	4.99	2.52	2.52	5.04	5.10	5.15	5.20	5.25	5.30	5.36	5.41	5.46	5.52	5.57	5.63
Plazomicin UTI Confirmed CRE Penetration					1%	1%	2%	3%	4%	5%	6%	7%	8%	8%	8%	8%	8%
Plazomicin UTI Confirmed CRE Patients					0.03	0.03	0.10	0.15	0.21	0.26	0.32	0.37	0.41	0.41	0.41	0.42	0.42
TOTAL EU CRE Confirmed Plazomicin Patients (000s)						1.03	3.69	6.07	8.75	11.43	12.76	13.85	14.02	14.16	14.30	14.44	16.46
Treatment duration in days	4					10	10	10	10	10	10	10	10	10	10	10	10
Cost per day	\$	1,000				\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000
TOTAL EU PLAZOMICIN CONFIRMED REVENUE (m il)						\$ 10.26	\$ 36.86	\$ 60.73	\$ 87.49	\$114.27	\$127.61	\$138.52	\$140.18	\$141.58	\$142.99	\$144.42	\$164.63
			2018E	1H19E	2H19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EU Bloodstream Suspected CRE on label (000s)		40%	49.95	25.22	25.22	50.45	50.95	51.46	51.98	52.50	53.02	53.55	54.09	54.63	55.17	55.73	56.28
Plazomicin Bloodstream Suspected CRE Penetration					2%	2%	4%	6%	9%	12%	13%	14%	15%	15%	15%	15%	15%
Plazomicin Bloodstream Suspected CRE Patients					0.50	0.50	2.04	3.09	4.68	6.30	6.89	7.50	8.11	8.19	8.28	8.36	8.44
EU Pneumonia Suspected CRE on label (000s)		40%	33.30	16.82	16.82	33.63	33.97	34.31	34.65	35.00	35.35	35.70	36.06	36.42	36.78	37.15	37.52
Plazomicin Pneumonia Suspected CRE Penetration					0.5%	0.5%	1%	3%	4%	5%	<i>6</i> %	7%	8%	8%	8%	8%	8%
Plazomicin Pneumonia Suspected CRE Patients					0.08	0.08	0.34	1.03	1.39	1.75	2.12	2.50	2.70	2.73	2.76	2.79	2.81
EU Abdominal Suspected CRE off label (000s)		40%	191.05	96.48	96.48	192.97	194.90	196.84	198.81	200.80	202.81	204.84	206.89	208.95	211.04	213.15	215.29
Plazomicin Abdominal Suspected CRE Penetration					0.5%	0.5%	1%	2%	3%	4%	4%	5%	5%	5%	5%	5%	5%
Plazomicin Abdominal Suspected CRE Patients					0.48	0.48	1.95	3.94	5.96	7.03	8.11	9.22	10.34	10.45	10.55	10.66	10.76
EU UTI Suspected CRE off label (000s)		40%	33.72	17.03	17.03	34.05	34.39	34.74	35.08	35.44	35.79	36.15	36.51	36.87	37.24	37.62	37.99
Plazomicin UTI Suspected CRE Penetration					0.5%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Plazomicin UTI Suspected CRE Patients					0.09	0.09	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TOTAL EU CRE Suspected Plazomicin Patients (000s)						1.16	4.33	8.05		15.08	17.13	19.21	21.16	21.37	21.59	21.80	22.02
Treatment duration in days	•					3	3	3	3	3	3	3	3	3	3	3	3
Cost per day TOTAL EU PLAZOMICIN SUSPECTED REVENUE (m il)	\$	1,000				\$ 3,000 \$ 3.47	\$ 3,000 \$ 12.98	\$ 3,000 \$ 24.16	\$ 3,000 \$ 36.09	\$ 3,000 \$ 45.23	\$ 3,000 \$ 51.38	\$ 3,000 \$ 57.64	\$ 3,000 \$ 63.49	\$ 3,000 \$ 64.12	\$ 3,000 \$ 64.76	\$ 3,000 \$ 65.41	\$ 3,000 \$ 66.06
TOTAL FILPLAZOMICIN REVENUE (m.il)						ć 10.7C	\$ 49.84	ć 04.00	Ć100 F2	\$159.50	£170.00	\$196.16	\$203.66	\$205.70	\$207.76	\$209.83	£000 00
TOTAL EUFLAZUMICIN KEVENUE (IIIII)						-13./3	48.84	7 84.89 ¢	3123.0B	108'0 <u>0</u>	31/8.88	≯180*1₽	\$203.0B	\$205.7U	\$207.76	3ZU9.83	\$23U.08

Source: Cowen and Company.

Cowen and Company

Equity Research

Achaogen

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Valuation Methodology And Risks

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

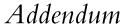
Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

Our price target is based on our projection that the ongoing pivotal Phase III clinical trial of plazomicin will generate positive data to support both FDA and EMA approvals. However, although Achaogen has completed a Phase II clinical trial in cUTI and data from both *in vitro* and preclinical studies suggest strong activity of plazomicin for CRE infections, there is no guarantee that the Phase III clinical trial will be successful. Moreover, any failure in management's execution will affect the product launches and market uptake even after FDA approvals. We believe plazomicin is highly differentiated from currently available antibiotics and other drug candidates in clinical development for Gram-negative pathogens. However, any new products entering the market may potentially change the competition dynamics and can negatively impact the market shares that plazomicin can garner.

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Stocks Mentioned In Important Disclosures

Ticker	Company Name
AKA0	Achaogen
ICPT	Intercept Pharmaceuticals
RPTP	Raptor Pharmaceutical Corp.

Analyst Certification

Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

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Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

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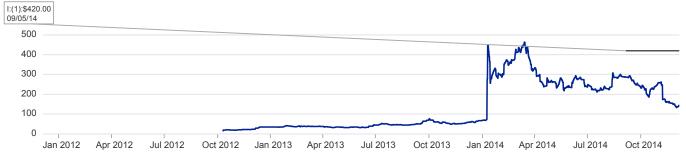
Achaogen Rating History as of 12/05/2014

powered by: BlueMatrix



Intercept Pharmaceuticals Rating History as of 12/05/2014

powered by: BlueMatrix



Closing Price — Target Price

December 8, 2014

Raptor Pharmaceutical Corp. Rating History as of 12/05/2014





Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

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