

Equity Research

November 18, 2014

Price: \$9.35 (11/17/2014)

Price Target: \$23.00 (Prior \$22.00)

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: AKAO
52-Week Range:	\$19.69 - 7.72
Market Cap (MM):	\$166.0
Net Debt (MM):	\$(4.1)
Cash/Share:	\$27.33
Dil. Shares Out (MM):	17.8
Enterprise Value (MM):	\$94.0
ROIC:	NA
ROE (LTM):	NA
BV/Share:	\$3.85
Dividend:	NA

FY (Dec)	2014E	2015E	2016E
Earnings Per Share			
Q1	\$(1.00)A	\$(0.19)	-
Prior Q1	-	-	-
Q2	\$(0.20)	\$(0.27)	-
Prior Q2	\$(0.27)	-	-
Q3	\$(0.47)	\$(0.32)	-
Prior Q3	\$(0.32)	-	-
Q4	\$(0.47)	\$0.00	-
Prior Q4	\$(0.35)	-	-
Year	\$(1.67)	\$(0.78)	\$(1.04)
Prior Year	\$(1.43)	\$(0.77)	-
P/E	NM	NM	NM
Consensus EPS	\$(1.49)	\$(1.23)	\$(1.43)

Consensus source: Thomson Reuters

Revenue (MM)

Year	\$22.6	\$28.0	\$23.0
Prior Year	\$26.0	-	-
EV/S	4.2x	3.4x	4.1x

Company Update

Transitioning Coverage: Ph3 Off The Ground; Focus On Enrollment Rate

The Cowen Insight

We think plazomicin could become an important treatment for life-threatening carbapenem-resistance enterococcus (CRE) infections. Plazomicin retains potent activity against CRE and many other resistant strains. Resistance in general, and CRE in particular, is a growing public health problem and we think AKAO's Ph3 trial in CRE pneumonia and bloodstream infections has a good chance of success.

We think Ph3 plazomicin is a potent antibiotic with significant utility against life-threatening gram-negative infections resistant to current antibiotics

Plazomicin is a next-generation IV aminoglycoside in development for life-threatening resistant bacterial infections. Plazomicin's chemical modifications allow it to retain potent activity against many strains that have resistance mechanisms against other aminoglycosides and numerous other antibiotics classes. Resistant strains are strongly associated with poorer clinical outcomes and higher mortality, and their increasing prevalence represents a major public health concern. We think AKAO and plazomicin development and commercialization may benefit from new government and public health organization initiatives to promote the development and adoption of new antibiotics.

We think the current plazomicin Ph3 trial has a good chance of success, despite its superiority design, which normally means a high bar to success

Many in-vitro/preclinical models strongly support the potency of plazomicin against strains that are susceptible or resistant to current antibiotics. Antibiotic preclinical data more often than not translates into clinical efficacy. While CRE strains resistant to plazomicin are rare, mostly geographically restricted to Asia, and likely less fit. AKAO conducted a Ph2 trial of plazomycin vs. levofloxacin in cUTIs caused largely by susceptible strains. Data showed comparable antibiotic efficacy and good safety. Notable side effects included the aminoglycoside class effects of hearing/balance changes and kidney function changes. Plazomicin patients also had mild numbness and tingling in their extremities which was reversible. AKAO is currently running a pivotal Ph3 in CRE bloodstream and lung infections which is powered to detect superiority in 28 day survival versus SOC comparator.

We think plazomicin will be armed with significant improved survival and pharmacoeconomic data that will support premium pricing, good market uptake, and our estimates of \$595MM peak WW sales

We note that AKAO is taking a unique approach to plazomicin commercialization with its current Ph3 superiority trial. Most recent antibiotic approvals have been based on non-inferiority trials, and have not provided data that easily supports premium pricing. This is especially problematic given the cost-sensitivity of hospitals, and the genericization of older antibiotics. As such, recent antibiotics launches have disappointed the Street. We think, however, that the current pivotal Ph3 trial will generate data showing better survival as well as pharmacoeconomic savings to the hospital, such as shorter ICU/overall stay and shorter time on ventilator.

Please see addendum of this report for important disclosures.

At A Glance

Our Investment Thesis

Plazomicin 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

Price Performance



Source: Bloomberg

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 push back from payers

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

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 be the first antibiotic specifically developed for CRE pathogens. Achaogen also has preclinical programs for *Pseudomonas aeruginosa*.

Analyst Top Picks

	Ticker	Price (11/17/2014)	Price Target	Rating
Raptor Pharmaceutical Corp.	RPTP	\$9.83	\$24.50	Outperform

Investment Thesis

We think Plazomicin could become an important treatment option for life-threatening infections caused by gram-negative organisms.

Plazomicin is Achaogen's Phase 3 novel modified aminoglycoside antibiotic that we think has significant clinical promise for treatment of resistant gram-negative strains including strains resistant to a number of other first-line and second-line antibiotics such as Carbapenem resistant Enterobacteriaceae (CRE). CRE for instance is frequently resistant to beta-lactam class antibiotics and frequently co-resistant to most other antibiotics. Plazomicin has shown impressive activity in a number of serious infection models and in-vitro studies with multiple resistant gram-negative pathogens including those expressing aminoglycoside-modifying enzymes, carbapenemases, and fluoroquinolone target-site mutations. Efficacy in these experiments has been better than standard of care, that we think may lead to better clinical outcomes such as improved survival, shorter ICU time and shorter hospital stays.

We think there is a significant and growing unmet need for new antibiotics especially as resistant strains become more prevalent across the world.

There has been significant public health focus on the rising prevalence of infections caused by resistant strains. These resistant 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. We believe there is nearly as much public health focused legislative momentum and FDA focus on expediting the development and increasing access to new antibiotics for resistant pathogens as there are for orphan drug development. We expect the US government and FDA will implement additional measures in the near-term to further incentivize and streamline antibiotic development and facilitate their use in the clinical setting.

We also note there are number of companies that are pursuing new antibiotic candidates for gram-positive bugs and far fewer that are targeting gram-negative organisms. Gram-negative organisms have separate membranes on the inside as well as outside of their cell walls. This structural feature makes it more difficult to design drugs that will adequately penetrate the bacteria. Therefore, class of organism intrinsically possesses a high barrier to entry in clinical development.

We think in-vitro and pre-clinical data suggests that plazomicin has significant efficacy against resistant gram-negative strains with potency superior current antibiotic options.

Achaogen has run a number of in-vitro trials that suggest that plazomicin is more potent against resistant strains than even components of current standard of care for such resistant infections, such as levofloxacin, colistin, meropenem and currently approved aminoglycosides such as amikacin or gentamicin. Common resistance mechanisms that reduce the potency of all these mechanism do not appear to significantly reduce the potency of plazomicin. Plazomicin's structure is modified from the naturally occurring aminoglycoside sisomicin, with features that make the drug impervious to degradation enzymes which is how resistance is mediated.

Achaogen has conducted numerous animal studies that show increased survival with plazomicin treatment versus standard of care drugs. We note that in antibiotic treatments overall there tends to be a higher translatability of activity and clinical success between preclinical model and pivotal clinical trials. As a result, we think there is a very good chance plazomicin will prove to have better potency, which will translate to better survival and faster clinical improvement in patients treated with plazomicin. The only mutation that appears to confer resistance to plazomicin is ribosomal methyltransferase, which is very rare and has thus far been geographically isolated in small pockets in Asia.

Plazomicin's Phase 2 trial in complicated UTI's provides positive clinical proof of concept for the drug both on efficacy and importantly on safety.

Achaogen conducted a Phase 2 dose-finding study of plazomicin versus levofloxacin in patients with complicated Urinary Tract Infections (cUTIs) under treatment for 5-10 days. Data suggested that plazomicin was as effective as levofloxacin in resolving infection based on both mITT and microbiologically evaluable analyses. Of note, the cUTIs were caused by non-resistant organisms where one would not expect higher rates of clinical resolution versus the comparator. Achaogen was able to determine the pivotal dose for plazomicin, and of critical importance, determine that the drug was safe and well tolerated. The only observed side effects of note were those associated with the aminoglycoside class (such as slight declines in renal function, as reflected by mild, reversible elevations in serum creatinine). There also appear to be very mild, reversible signals of impact on hearing/balance, another class effect of aminoglycosides.

We think Achaogen's current pivotal trial of plazomicin in CRE related pneumonia and blood stream infections has a good chance of success.

We think Achaogen's Phase 3 CRE pneumonia/blood stream infection trial is well designed to show very meaningful potential benefit (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. Achaogen believes precedent data suggest plazomicin could have a significantly higher benefit on mortality and believes the trial assumptions are very conservative.

We note that trial enrollment will be challenging as it is limited to those patients who have confirmed CRE infections (a minority of infections) and then further, limited to those CRE infections that are in the bloodstream or in ventilator-acquired pneumonia. Finally, patients must also enroll no later than 72 hours after infection onset. Early trial enrollment has already gone slower than expected, and Achaogen is even now evaluating methods to increase enrollment. The company is considering increasing the number of sites especially in areas with high CRE rates, as well expanding CRE pneumonia to hospital-acquired cases, not just ventilator acquired. Should other enrollment criteria be loosened, it may increase the heterogeneity of the trial population to the point of potentially impacting trial success.

We think efficacy and pharmacoeconomic data likely to be produced in the current pivotal CRE trial will not only support approval but also strong pricing.

Superiority trials have been very few and far between in antibiotic drug development largely because they represent a very high efficacy hurdle and, therefore, high risk. Most antibiotics studies have traditionally been non-inferiority trials which represent a lower bar of clinical risk, but also do not show hard evidence that a new drug is really any better than an old drug from a clinical perspective. As a result, developers have historically had very little hard evidence to support premium pricing to current standard of care, especially when a current care standard may be an extremely cheap generic. We think statistically significant improved mortality would a concrete support for a premium priced antibiotic appropriate for a niche-market. Our market model currently estimates a \$1,250 per day treatment cost in the US and \$1,000 per day treatment cost in the EU.

Further, the plazomicin pivotal trial has a number of key secondary endpoints that should make the quantification of pharmacoeconomic benefits of plazomicin very easy to quantify. These include length of overall stay, length of ICU stay, and time on ventilator. We think the cost of each day of care in the hospital and each hour in the hospital is relatively well understood and shorter stays with plazomicin would translate to potential direct cost savings, even without trying to quantify the value of increased survival.

Given Achaogen's clinical development strategy and commercial strategy for plazomicin, we think the drug will commercially succeed where other novel antibiotics have not.

Given all these factors, should the plazomicin pivotal trial meet its primary endpoint of superior survival compared to standard care, we think the drug would see very healthy market uptake starting from a potential 2H18 approval. We note that AKAO intends to start a second shorter supportive efficacy trial in early 2015, the design of which they are currently finalizing. We think there is a chance that this trial could provide even more clinical and pharmacoeconomic arguments to support approval and premium. There is a small chance that further negotiation with the FDA could allow for that smaller trial to support approval. We await further clarity on this potential regulatory path in 1Q15.

Financials and Models Discussion

We value Achaogen on a probability weighted net present value of the lead clinical programs of Plazomicin in CRE in the US and EU. We value Achaogen on a pNPV basis and assign a 60% probability of success for plazomicin in the CRE indication for both the US and EU markets. With 80% profitability in the US and 100% profitability in the EU, we reach a target price of \$23.

We expect Achaogen to file for US approval for Plazomicin in CRE in 2H17 and secure approval by the second half of 2018. We expect an similar regulatory path in the US with a filing in 2H18 and the start of a rolling launch in top 5 EU markets in the second half of 2019.

Guided by proprietary AKAO market research, we estimate there are approximately 850k cases of empirically treated CRE infections worldwide. Of those worldwide cases, 110k are then confirmed to be CRE cases with the rest being determined to be caused by other pathogens, relegating them to 'initially suspected' CRE status.

We break these subsets down identically into each of the four most predominant forms of CRE infection: bloodstream, pneumonia, intra-abdominal, and UTI. We estimate 30k bloodstream and pneumonia confirmed CRE infections, of the 110k confirmed CRE, which breaks down into a 60/40% split between bloodstream and pneumonia, respectively. The balance of confirmed CRE, 80k cases, breaks down into a 85/15% split between abdominal and UTI infection. We assume a conservative 1% growth rate in our market model. We believe this percentage breakdown applies to both US and EU confirmed CRE cases as well as US and EU suspected CRE breakdowns.

With these worldwide subgroups, we then divide into two separate target markets: the US and EU top 5 via a 60/40% split, respectively. By aggregating the infections into confirmed and suspected cases we can assign a plazomicin treatment duration and price. Confirmed CRE infection cases in the US undergo an estimated 10 days of treatment and we estimate a \$1,250/day treatment cost. Suspected CRE infection cases in the US undergo 3 days of treatment (before switch to a cheaper but still effective treatment) and we estimate a \$1,250/day treatment cost. We follow the same 10/3 day treatment course in the EU for confirmed and suspected, respectively, but with a \$1,000/day treatment cost driven by standard EU pricing paradigms.

We forecast plazomicin capture of market share based on the severity of infection. Therefore, we estimate in the US confirmed market: 60% penetration for bloodstream infections, 40% penetration for pneumonia infections, 30% penetration for abdominal infections, and 10% penetration for UTI infections. We estimate in the EU confirmed market: 50% penetration for bloodstream infections, 40% penetration for pneumonia infections, 30% penetration for abdominal infections, and 8% penetration for UTI infections.

We estimate in the US suspected market: 20% penetration for bloodstream infections, 10% penetration for pneumonia infections, 10% penetration for abdominal infections, and 0% penetration for UTI infections. We estimate in the EU suspected market: 15% penetration for bloodstream infections, 8% penetration for pneumonia infections, 5% penetration for abdominal infections, and 0% penetration for UTI infections. We assign Achaogen no value for the US and EU suspected UTI infection as it is considered the least severe of all aforementioned infections and we think there is little incentive to use a premium priced antibiotic of last resort here.

We forecast the confirmed peak penetration rates for CRE in both the US and EU markets for bloodstream, pneumonia, abdominal, and UTI to be 4, 5, 6, 7 years, respectively (recall we expect the EU launch to be in 2019, one year after the US launch). We forecast the suspected peak penetration rates for CRE in both the US and EU markets for bloodstream, pneumonia, abdominal, and UTI to be 7 years.

We estimate CRE peak US sales of \$391MM and CRE peak EU sales of \$204MM.

Figure 1 - Achaogen pNPV Table

Assumptions / Results										
Total NPV										23.2
Number of Shares (m)										17.7
Pharma PE										14.6x
Discount rate										30%
Current year										2014.75

Product Development										
Drug name	Indication	Status	Launch	Success	Peak Sales (US\$m)	Royalty	Profitability	Probability weighted Peak Profit (US\$m)	Discount 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

Figure 2 – Pivotal Phase III Trial

Study Design	Randomized (1:1), parallel assignment, open label
Treatment duration	7-14 days (@ clinician's discretion)
Enrollment	360
Dose	<p>Experimental: plazomicin with second adjunctive antibiotic therapy of either meropenem or tigecycline</p> <p>Comparator: colistin with second adjunctive antibiotic therapy of either meropenem or tigecycline</p>
Primary Endpoint	All-cause mortality at 28 days
Secondary Endpoints	<ul style="list-style-type: none"> • Time to death through 28 days • All-cause mortality at 14 days • Adjudication committee's determination of clinical response for end of treatment (14 days), for test of cure (21 days), and for end of study (28 days) • Overall incidence of adverse events at 60 days • Plazomicin PK parameters including AUC0-24, Cmax, and Cmin at 14 days • Frequency with which the use of TDM leads to a dose adjustment of plazomicin at 14 days • Changes in oxygenation from baseline to day 3 • Other outcome measures: microbiological response at end of treatment (14 days), at test of cure (21 days), and at end of study (28 days)
Key Inclusion Criteria	<ul style="list-style-type: none"> • APACHE II score between 15 and 30, inclusive • Presumptive identification of a carbapenem resistant-member of the Enterobacteriaceae as defined by rapid testing methods from an appropriate culture specimen ≤ 72 hours prior to study OR Definitive • Diagnosis of blood stream infection as defined by at least one positive blood culture meeting the above microbiological criteria associated with at least one of the following signs of infection: <ul style="list-style-type: none"> -Fever or hypothermia; New onset arterial hypotension -Elevated total peripheral white blood cell (WBC) count > 10,000 cells/mm3, > 15% immature neutrophils (band forms) regardless of total peripheral WBC count, or leukopenia with total WBC count < 4500 cells/mm3 • Or, diagnosis of nosocomial pneumonia in a patient on mechanical ventilation, as defined by lower respiratory tract or pleural fluid culture meeting the above defined microbiological criteria, and associated with the following clinical signs of pneumonia: <ul style="list-style-type: none"> -A chest X-ray or computed tomography (CT) scan with findings consistent with a diagnosis of pneumonia -Worsening gas exchange; Purulent deep respiratory specimen -AND one of the following: <ul style="list-style-type: none"> -Elevated total peripheral WBC count > 10,000 cells/mm3 ->15% immature neutrophils (band forms) regardless of total peripheral WBC count -or leukopenia with total WBC count < 4500 cells/mm3 -Fever or hypothermia
Key Exclusion Criteria	<ul style="list-style-type: none"> • Patient has received more than 72 hours of empirical therapy • Infection with CRE isolate with reduced susceptibility to colistin • Presence of refractory septic shock • Objective clinical evidence for any of the following clinical syndromes that necessitates antimicrobial therapy for greater than 14 days: endovascular infection including endocarditis, osteomyelitis, prosthetic joint infection, meningitis and/or other central nervous system infections • Objective clinical evidence of infectious involvement of intravascular material not intended to be removed within 4 calendar days of initial positive culture • Pulmonary disease that precludes evaluation of therapeutic response including known bronchial obstruction or a history of post-obstructive pneumonia, tracheobronchitis, primary lung cancer or malignancies metastatic to the lung, bronchiectasis, known or suspected active tuberculosis • Patients with severe liver disease (Child-Pugh score of Class C) • Patients in acute renal failure or on intermittent hemodialysis (IHD) at the time of screening
Powering	<p>70% powering to detect a 12% absolute mortality difference @ 28 days</p> <p>80% powering to detect 9% absolute mortality difference @ 28 days with an assumption of 35% control arm mortality</p>
Data Due	2H17

Source: Cowen and Company, clinicaltrials.gov

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	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
<i>Tax Rate</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>8%</i>	<i>13%</i>	<i>18%</i>	<i>23%</i>	<i>27%</i>	<i>35%</i>
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.

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.

Figure 5 - Achaogen US Market Model

		1H18E	2H18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
US Bloodstream Confirmed 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 <i>Confirmed CRE Penetration</i>			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 <i>Confirmed CRE Penetration</i>			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 <i>Confirmed CRE Penetration</i>			4%	2%	10%	15%	20%	24%	27%	30%	30%	30%	30%	30%	30%	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 <i>Confirmed CRE Penetration</i>			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	per 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
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 <i>Suspected CRE Penetration</i>			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 <i>Suspected CRE Penetration</i>			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 <i>Suspected CRE Penetration</i>			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 <i>Suspected CRE Penetration</i>			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 il)				\$ 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)				\$ 25.01	\$132.06	\$227.76	\$321.50	\$391.12	\$439.79	\$481.45	\$506.82	\$511.88	\$517.01	\$522.18	\$527.40	\$532.67

Source: Cowen and Company.

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	7.80	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%	50%	50%	50%	50%	50%	50%	50%	50%
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%	30%	35%	35%	35%	35%	35%	35%	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					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
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%	6%	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	12.03	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	\$ 1,000				\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000	\$ 3,000
TOTAL EU PLAZOMICIN SUSPECTED REVENUE (m il)					\$ 3.47	\$ 12.98	\$ 24.16	\$ 36.09	\$ 45.23	\$ 51.38	\$ 57.64	\$ 63.49	\$ 64.12	\$ 64.76	\$ 65.41	\$ 66.06
TOTAL EU PLAZOMICIN REVENUE (m il)					\$ 13.73	\$ 49.84	\$ 84.89	\$123.58	\$159.50	\$178.98	\$196.16	\$203.66	\$205.70	\$207.76	\$209.83	\$230.69

Source: Cowen and Company.



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.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
AKAO	Achaogen
RPTP	Raptor Pharmaceutical Corp.

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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

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

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

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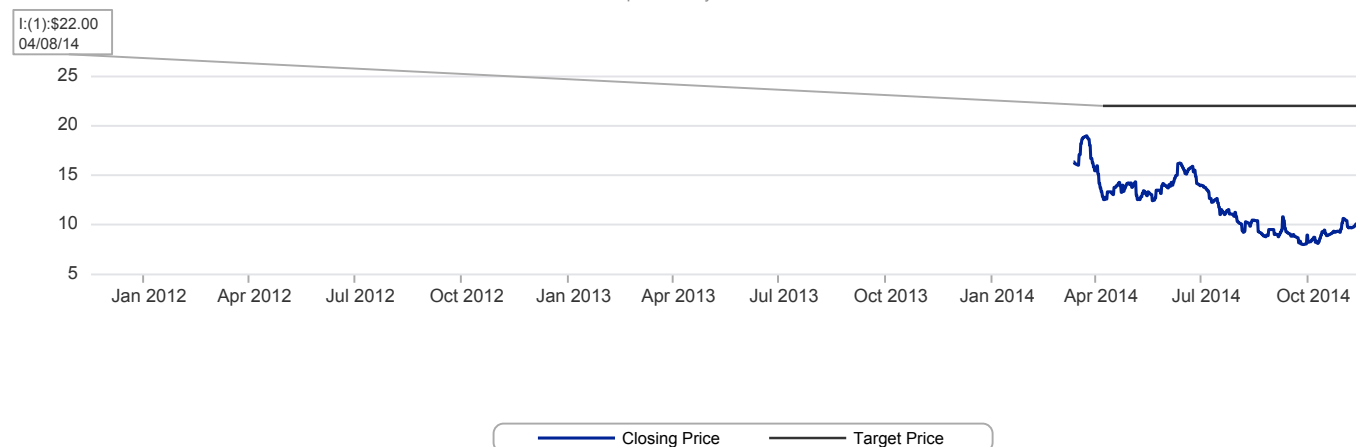
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	440	59.95%	105	23.86%
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Achaogen Rating History as of 11/17/2014

powered by: BlueMatrix



Raptor Pharmaceutical Corp. Rating History as of 11/17/2014

powered by: BlueMatrix



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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