

Equity Research

May 14, 2014

Price: \$13.33 (05/13/2014)

Price Target: \$22.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: AKAO
52-Week Range:	\$19.69 - 11.66
Market Cap (MM):	\$235.7
Net Debt (MM):	\$0.0
Cash/Share:	\$4.80
Dil. Shares Out (MM):	17.7
Enterprise Value (MM):	\$150.8
ROIC:	NA
ROE (LTM):	NA
BV/Share:	\$(312.67)
Dividend:	NA

FY (Dec)	2013A	2014E	2015E
Earnings Per Share			
Q1	-	\$(1.00)A	-
Prior Q1	-	\$(0.80)	-
Q2	-	\$(0.27)	-
Prior Q2	-	\$(0.29)	-
Q3	-	\$(0.32)	-
Prior Q3	-	-	-
Q4	\$(0.58)	\$(0.35)	-
Prior Q4	-	\$(0.34)	-
Year	\$(3.08)	\$(1.43)	\$(0.77)
Prior Year	-	\$(1.40)	\$(0.76)
P/E	NM	NM	NM
Revenue (MM)			
Year	\$18.5	\$26.0	\$28.0
EV/S	8.2x	5.8x	5.4x

Earnings Update

Recent IPO Strengthens Coffers For Phase III In CRE

The Cowen Insight

Achaogen reported quarterly financials for the first time as a public company after successfully completing an IPO in March. We believe the lead candidate plazomicin, with strong potency against CRE strains, has limited risk in the ongoing pivotal Phase III study and significant market potential. We reiterate our Outperform rating on Achaogen shares and \$22 PT.

Plazomicin has a high likelihood of success in the pivotal Phase III study

The pivotal Phase III clinical trial was initiated in 1Q14 and is designed to demonstrate the superiority of plazomicin as compared to colistin in patients with bloodstream infections and pneumonia caused by carbapenem-resistant Enterobacteriaceae (CRE). *In vitro* studies have demonstrated the strong potency of plazomicin against CRE pathogens and results from animal infection models, in combination with PK/PD modeling, suggest efficacy in human patients as well. The study will randomize a total of 360 patients 1:1 to plazomicin- and colistin-containing treatment regimen and the primary endpoint of the Phase III study is 28-day all cause mortality. The study is 70% powered to demonstrate an absolute reduction of 12% as compared to colistin (23% vs. estimated 35% for colistin). A meta analysis conducted by Achaogen suggests an absolute reduction of 21% when the pathogens are susceptible to the antibiotics used for the treatment so we believe the design is rather conservative. Moreover, Achaogen has received an SPA from the FDA for the Phase III study and both the FDA and the EMA have agreed that one single pivotal study, if successful, will be sufficient to support regulatory filings in the U.S. and the EU. Plazomicin is the only drug candidate currently in clinical development specifically for CRE pathogens. Therefore, it will face limited competition and a demonstrated survival benefit should entitle the product to a premium pricing, in our opinion. Our model suggests a market opportunity of approximately \$500MM for plazomicin in the U.S.

The BARDA contract provides strong financial support

BARDA has committed a total of \$103MM in grant funding to Achaogen, including \$60MM to support the ongoing pivotal Phase III study. The BARDA contract further contains an un-exercised option for additional funding, which we believe could be used to support additional studies planned for plazomicin's Phase III program, such as the supportive efficacy study to be initiated by YE14 and the safety study to be initiated in 2015. Achaogen raised net proceeds of approximately \$73.9MM in an IPO and we believe the total available resources should be sufficient through the Phase III top-line data readout in 1H17. Achaogen has planned two interim analyses in 2H15 and 2H16, upon completion of one third and two thirds of target patient enrollment, respectively. The company reported 1Q14 EPS of \$(1.00) as compared to our estimate of \$(0.80) and the consensus of \$(0.48).

At A Glance

Our Investment Thesis

The pathogen-focused approach in developing plazomicin for the treatment of CRE infections, which cause high mortality due to lack of optimal treatments, has won Achaogen strong support from both the FDA and BARDA. The ongoing pivotal Phase III clinical trial is being conducted with an SPA and plazomicin has been granted Fast Track Designation. Additionally, BARDA has committed a total of \$103MM in grant funding for plazomicin development, including \$60MM to fund the pivotal study. Plazomicin has demonstrated strong potency against CRE pathogens and PK/PD modeling in combination with preclinical studies in animal infection models suggest a high likelihood of success in the pivotal study. The study is designed to demonstrate the superiority of plazomicin over currently available therapies. We believe a well-established survival benefit will entitle plazomicin to premium pricing and will provide Achaogen with strong revenue potential.

Forthcoming Catalysts

- Initiation of the supportive efficacy trial by year-end 2014 and top-line data in 4Q15
- First and second interim analyses in the pivotal Phase III clinical trial in 2H15 and 2H16, respectively
- Initiation of the safety study after the first interim analysis

Base Case Assumptions

- Patient enrollment proceeds as guided and top-line data from the pivotal Phase III clinical trial are reported in 1H17
- Plazomicin meets the primary endpoint of the pivotal study and receives regulatory approvals in both the U.S. and the EU
- Achaogen is able to price plazomicin at a premium upon launch

Upside Scenario

- Achaogen achieves faster than expected patient enrollment and is able to expedite the clinical development process
- Plazomicin achieves faster than expected market penetration
- Achaogen is acquired at a premium for the company's clinical pipeline and technology

Downside Scenario

- Patient enrollment in the pivotal Phase III study takes longer than expected, slowing down the overall clinical development process
- Plazomicin fails to meet the 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

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 III 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 1H17. 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 (05/13/2014)	Price Target	Rating
Acadia Pharmaceuticals	ACAD	\$18.84	\$33.00	Outperform
Intra-Cellular Therapies	ITCI	\$15.35	\$28.00	Outperform
Horizon Pharma	HZNP	\$13.42	\$20.00	Outperform

Achaogen, Inc. Quarterly P&L Model (\$MM)

	2012A	Q1-Q3:13A	Q4:13A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E
Plazomicin Sales Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Plazomicin Royalty Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Contract Revenue	17.9	12.3	6.2	18.5	6.0	6.5	6.6	6.9	26.0
Total Revenues	17.9	\$12.3	\$6.2	\$18.5	\$6.0	\$6.5	\$6.6	\$6.9	\$26.0
COGS	-	-	-	-	-	-	-	-	-
Research and Development	26.6	16.7	6.8	23.5	6.6	8.8	9.4	10.2	35.0
General and Administrative	7.3	5.4	1.6	7.0	2.6	2.3	2.7	2.9	10.5
Sales	-	-	-	-	-	-	-	-	-
Total Operating Expenses	33.9	22.1	8.4	30.5	9.2	11.1	12.1	13.1	45.5
Income (Loss) from Operations	(\$16.0)	(\$9.8)	(\$2.2)	(\$12.0)	(\$3.2)	(\$4.6)	(\$5.5)	(\$6.2)	(\$19.5)
Interest Expense and Other, net	(2.4)	(1.1)	(0.2)	(1.3)	(0.2)	(0.2)	(0.2)	(0.2)	(0.8)
Interest Income and Other, net	0.1	0.3	(0.1)	0.2	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	(\$18.4)	(\$10.6)	(\$2.5)	(\$13.1)	(\$3.5)	(\$4.8)	(\$5.7)	(\$6.3)	(\$20.3)
<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>
Income Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss) Attributable to Common Shareholders	(18.4)	(10.6)	(2.5)	(13.1)	(3.5)	(4.8)	(5.7)	(6.3)	(20.3)
GAAP EPS, Basic and Diluted	(\$4.80)	(\$2.50)	(\$0.58)	(\$3.08)	(\$1.00)	(\$0.27)	(\$0.32)	(\$0.35)	(\$1.43)
Weighted Average Shares Outstanding - Basic and Diluted	3.8	4.2	4.3	4.3	3.5	17.7	17.8	17.9	14.2

Source: Cowen and Company

Achaogen, Inc. Annual P&L Model (\$MM)

	2012A	2013A	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	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	7.8	17.6	24.7	30.3	40.4	47.8	55.8
Contract Revenue	17.9	18.5	26.0	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	\$26.0	\$28.0	\$23.0	\$17.5	\$3.0	\$108.5	\$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	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	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	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)	(\$19.5)	(\$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)	(0.8)	(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
Net Income (Loss)	(\$18.4)	(\$13.1)	(\$20.3)	(\$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>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	10.1	24.4	41.2	63.8	88.3	128.0
Net Income (Loss) Attributable to Common Shareholders	(18.4)	(13.1)	(20.3)	(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)	(\$1.43)	(\$0.77)	(\$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	14.2	18.2	18.8	25.5	26.5	33.0	34.0	35.0	36.0	37.0	38.0	39.0

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
ACAD	Acadia Pharmaceuticals
AKAO	Achaogen
HZNP	Horizon Pharma
ITCI	Intra-Cellular Therapies

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

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

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

Sell – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	407	57.08%	85	20.88%
Hold (b)	288	40.39%	8	2.78%
Sell (c)	18	2.52%	1	5.56%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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Achaogen Rating History as of 05/13/2014

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Acadia Pharmaceuticals Rating History as of 05/13/2014

powered by: BlueMatrix



Horizon Pharma Rating History as of 05/13/2014

powered by: BlueMatrix



Intra-Cellular Therapies Rating History as of 05/13/2014

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

Points Of Contact

Analyst Profiles



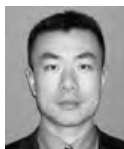
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