

# A Little Model Maintenance; Phase III Timeline Remains On Track

#### What's Incremental

Achaogen reported 3Q14 financials and provided clinical development updates last week. The ongoing pivotal Phase III study of plazomicin for CRE enrolled the first patient in 3Q and all U.S. clinical sites have been activated. We believe the earlier operational delay should have minimal impact on study completion and management continues to expect top-line data in 1H17. We remain bullish on Achaogen shares and reiterate our Buy rating.

- The pivotal Phase III study is officially up and running. In addition to all the U.S. sites, the majority of European sites have also been activated and Latin American sites opening is expected in 4Q14. Achaogen is targeting 72 sites and expects all sites to be active by the end of 1Q15. Achaogen is evaluating and may implement strategies, such as to enlarging patient population to include colistin-resistant CRE patients, broadening indications to include HABP, facilitating patient enrollment. We believe the opening of new clinical sites in geographic regions with a high CRE prevalence and the company's increasing recruitment experience should also have a positive impact on enrollment. Achaogen is in discussions with the FDA and the EMA regarding additional clinical trials to support regulatory filings for plazomicin and management expects to provide an update on the development plan in 1Q15. The pivotal Phase III study will enroll approximately 360 patients randomized 1:1 and the FDA requires 300 patients to be in the safety database. Achaogen plans to conduct a supportive efficacy study in parallel with the Phase III study and we expect the details of the study design and timeline to be announced in 1Q15. The next milestone would be the first interim analysis of the Phase III study in 2H15 after one third of patients are enrolled.
- Achaogen maintains a strong balance sheet. The company reported 3Q14 EPS of (0.47) as compared to the consensus of (0.23) and our estimate of (0.20). The difference is mainly due to a \$4MM development milestone payment to Isis Pharmaceuticals upon dosing the first patient in the pivotal Phase III study. The company ended 3Q14 with \$72.0MM in cash, cash equivalents and short-term investments. With the a committed \$60MM BARDA grant and another \$24.3MM in uncommitted BARDA funding to support the plazomicin clinical program, we believe the company is well funded through the completion of the pivotal Phase III study.
- Follow-on program will begin in 2015. Achaogen plans to file an IND in 2015 for either the LpxC inhibitor or the therapeutic antibody program. Both target multi-drug resistant Gram-negative bacteria including *Pseudomonas aeruginosa* and *Acinetobacter baumannii*, which lack optimal treatment options and pose a significant threat to the healthcare system.

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# Buy

**Price Target: \$22.00** *Prior:* \$22.00

Price (Nov. 18, 2014)	\$9.44
52-Wk Range	\$18.95-\$8.00
Market Cap (\$M)	\$167
ADTV	47,105
Shares Out (M)	17.7
Short Interest Ratio/% Of Float	4.9%
Dividend/Yield	\$0.00/0.0%
TR to Target	133.1%
Cash Per Share	\$4.05
Total Debt	\$0.0
Long-Term Debt/Total Cap	0%
Cash And Equivalents (\$M)	\$72.0
Enterprise Value (\$M)	\$103.4
Total Debt: Total long-term debt	

	2013A	2014	ŀΕ	2015	E					
		Curr.	Prior	Curr.	Prior					
EPS										
1Q		(\$1.00)A	(\$1.00)	(\$0.26)	(\$0.21)					
2Q		(\$0.20)A	(\$0.20)	(\$0.25)	(\$0.21)					
3Q		(\$0.47)A	(\$0.20)	(\$0.25)	(\$0.20)					
4Q	(\$0.58)	(\$0.23)	(\$0.19)	(\$0.23)	(\$0.19)					
FY	(\$3.08)	(\$1.38)	(\$0.99)	(\$0.99)	(\$0.81)					
P/E	NM	NM		NM						
Revenu	Revenue (\$M)									
FY	\$19	\$21	\$25	\$24	\$28					
EV/Sale	s 5.6x	4.9x		4.3x						
Conser	sus EPS									
FY		(\$1.11)	(\$1.11)	(\$1.12)	(\$1.12)					
FYE D	ес									



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

	2012A	Q1-Q3:13A	Q4:13A	2013A	Q1:14A	Q2:14A	Q3:14A	Q4:14E	2014E	Q1:15E	Q2:15E	Q3:15E	Q4:15E	2015
Plazomicin Sales Revenue	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
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	0.0	0.0	0.0
Contract Revenue	17.9	12.3	6.2	18.5	6.0	5.2	4.5	5.3	21.0	5.5	5.8	6.2	6.5	24.0
Total Revenues	17.9	\$12.3	\$6.2	\$18.5	\$6.0	\$5.2	\$4.5	\$5.3	\$21.0	\$5.5	\$5.8	\$6.2	\$6.5	\$24.0
COGS	-	_	-	_	-	_	_	-	_					_
Research and Development	26.6	16.7	6.8	23.5	6.6	6.2	10.7	7.0	30.5	7.6	7.8	8.0	8.1	31.5
General and Administrative	7.3	5.4	1.6	7.0	2.6	2.3	2.2	2.5	9.6	2.5	2.6	2.7	2.7	10.5
Sales	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	33.9	22.1	8.4	30.5	9.2	8.5	12.9	9.5	40.1	10.1	10.4	10.7	10.8	42.0
Income (Loss) from Operations	(\$16.0)	(\$9.8)	(\$2.2)	(\$12.0)	(\$3.2)	(\$3.3)	(\$8.3)	(\$4.2)	(\$19.1)	(\$4.6)	(\$4.6)	(\$4.5)	(\$4.3)	(\$18.
Interest Expense and Other, net	(2.4)	(1.1)	(0.2)	(1.3)	(0.2)	(0.2)	0.0	0.0	(0.4)	0.0	0.0	0.0	0.0	0.0
nterest Income and Other, net	0.1	0.3	(0.1)	0.2	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)	(\$10.6)	(\$2.5)	(\$13.1)	(\$3.5)	(\$3.6)	(\$8.3)	(\$4.2)	(\$19.5)	(\$4.6)	(\$4.6)	(\$4.5)	(\$4.3)	(\$18.
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
ncome 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	0.0	0.0
let Income (Loss) Attributable to Common Shareholders	(18.4)	(10.6)	(2.5)	(13.1)	(3.5)	(3.6)	(8.3)	(4.2)	(19.5)	(4.6)	(4.6)	(4.5)	(4.3)	(18.0
GAAP EPS, Basic and Diluted	(\$4.80)	(\$2.50)	(\$0.58)	(\$3.08)	(\$1.00)	(\$0.20)	(\$0.47)	(\$0.23)	(\$1.38)	(\$0.26)	(\$0.25)	(\$0.25)	(\$0.23)	(\$0.9
Weighted Average Shares Outstanding - Basic and Diluted	3.8	4.2	(ψ0.30) 4.3	4.3	3.5	17.7	17.7	17.8	14.2	18.0	18.1	18.2	18.3	18.2

Source: SunTrust Robinson Humphrey



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

	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	14.5	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	7.8	17.6	24.7	30.3	40.4	47.8	55.8
Contract Revenue	18.5	21.0	24.0	23.0	17.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenues	\$18.5	\$21.0	\$24.0	\$23.0	\$17.5	\$14.5	\$106.5	\$199.1	\$269.9	\$316.6	\$371.3	\$427.0	\$470.8
COGS	-	_	_	_	_	2.2	13.8	23.6	29.4	31.5	33.1	37.9	41.5
Research and Development	23.5	30.5	31.5	32.0	30.0	28.0	28.0	28.0	30.0	32.0	35.0	35.0	35.0
General and Administrative	7.0	9.6	10.5	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	30.5	40.1	42.0	40.0	38.5	44.2	60.8	72.5	82.2	87.7	93.8	100.1	105.2
ncome (Loss) from Operations	(\$12.0)	(\$19.1)	(\$18.0)	(\$17.0)	(\$21.0)	(\$29.7)	\$45.7	\$126.7	\$187.7	\$228.8	\$277.5	\$326.9	\$365.6
nterest Expense and Other, net	(1.3)	(0.4)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
nterest Income and Other, net	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)	(\$13.1)	(\$19.5)	(\$18.0)	(\$17.0)	(\$21.0)	(\$29.7)	\$45.7	\$126.7	\$187.7	\$228.8	\$277.5	\$326.9	\$365.6
Tax Rate	0%	0%	0%	0%	0%	0%	0%	8%	13%	18%	23%	27%	35%
ncome Tax	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	(13.1)	(19.5)	(18.0)	(17.0)	(21.0)	(29.7)	45.7	116.5	163.3	187.6	213.6	238.6	237.6
GAAP EPS, Basic and Diluted	(\$3.08)	(\$1.38)	(\$0.99)	(\$0.90)	(\$0.82)	(\$1.12)	\$1.38	\$3.43	\$4.66	\$5.21	\$5.77	\$6.28	\$6.09
Weighted Average Shares Outstanding - Basic and Diluted	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: SunTrust Robinson Humphrey



#### **Company Description**

Achaogen is a biotechnology company focused on the clinical development of new antibiotic agents to fight the most highly resistant pathogens with limited clinical options. The company is in Phase III development with plazomicin for the treatment of bloodstream infections and hospital-based pneumonia caused by the CRE pathogen. The company's Phase III pivotal trial is the first Phase III pivotal trial in the antibiotic space that has been designed as a superiority study. Achaogen has received significant funding from BARDA for the development of plazomicin, which we believe underlines the government's support and need for this therapeutic.

#### **Investment Thesis**

The pathogen-focused approach taken Achaogen 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 \$103.8MM 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.

### **Valuation and Risks**

Our 12-month price target of \$22 is determined by taking an average of three different model methodologies. We reach a 12-month price taget of \$21.61 with a discounted earnings model, a price target of \$22.73 with a discounted cash flow model, and a price target of \$22.78 with a clinical net present value model. Details of these models are contained within this report. The risks associated with an investment in Achaogen are the same as they are for all early-stage biotechnology companies. There is clinical risk, which encompasses the failure of the molecule being tested to successful complete clinical trials. There is regulatory risk whereby approval is not given or is delayed by the regulatory agency for a number of reasons. Finally there is the financial risk of not having enough funding to complete clinical development and if approved there is always the commercial risk associated with a launch. Specifically to Achaogen, we believe the prime risk is the inability to complete the Phase III enrollment in a timely manner that will allow for the interim analyses to read out as planned.

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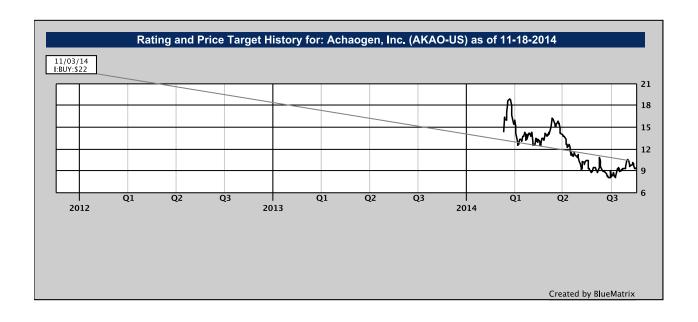
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Legend for Rating and Price Target History Charts:

D = drop coverage

I = initiate coverage

T = transfer coverage

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