Achaogen, Inc. (AKAO)

SunTrust Robinson Humphrey

4Q14 Model Maintenance; Update on Additional Trials In 2Q15

Patience With Slow Trial Enrollment Could Win The Day

Buy

Price Target: $22.00
Prior: $22.00

Price (Mar. 16, 2015)	$10.05
52-Wk Range	$18.95-$8.00
Market Cap ($M)	$181
ADTV	72,828
Shares Out (M)	18.0
Short Interest Ratio/% Of Float	3.7%
Dividend/Yield	$0.00/0.0%
TR to Target	118.9%

Cash Per Share	$3.54
Total Debt	$0.0
Long-Term Debt/Total Cap	0%
Cash And Equivalents ($M)	$63.7
Enterprise Value ($M)	$117.3

Total Debt: Total long-term debt

What's Incremental

Achaogen reported 4Q14 and full-year 2014 financial results. Patient enrollment in the ongoing pivotal Phase III study continues to be slower than anticipated and management expects to provide an update on the development plans for plazomicin in early 2Q15. We await more clarity on the clinical development timeline but continue to believe the rapidly increasing bacterial resistance to antibiotics has created a significant unmet medical need and that the FDA will continue to demonstrate flexibility in antibiotic development. We reiterate our Buy rating and $22 price target on Achaogen share.

EPS	4Q14	FY2014
Actual	($0.27)	($1.42)
STRH estimate	($0.23)	($1.38)
Consensus	($0.33)	($1.57)

BALANCE SHEET	31-Dec-13	31-Dec-14
Cash (MM)	$63.7	$10.7
LTD (MM)	$0.0	$1.7

CATALYST FUNDING TO DATE

Date	Price	(MM)	Type
Mar-14	$12.00	$82.8	IPO
Apr-13	NA	$60.4	BARDA
Sep-12	NA	$15.8	BARDA
Aug-10	NA	$27.6	BARDA
Mar-09	NA	$26.6	NIAID
Jan-09	NA	£4.1	Wellcome Trust
Oct-06	NA	$24.7	DTRA

UPCOMING MILESTONES

2Q15	Update on the development plans for plazomicin
2H15	First interim analysis of plazomicin Phase III clinical data
2H16	Second interim analysis of plazomicin Phase III clinical data
1H17	Top-line data from plazomicin Phase III clinical trial
2015	IND for either the LpxC inhibitor or the therapeutic antibody program

- **Achaogen is in discussions with the FDA on potential protocol modifications to improve patient enrollment.** We believe the modifications will focus on patient inclusion/exclusion criteria. The original criteria were designed to target the optimal patient population to demonstrate clinical benefit with plazomicin treatment as compared to colistin. We believe Achaogen may seek to loosen the criteria to boost patient enrollment. Recall the pivotal Phase III study is powered at 70% to demonstrate an absolute reduction of 12% (from 35% to 23%) in 28-day all-cause mortality. A meta-analysis suggests an absolute reduction in mortality of 21% when an effective antibiotic (such as plazomicin for CRE) is included in the treatment plan. Therefore, we believe there should be sufficient margin to allow Achaogen to implement protocol modifications while still maintaining a high likelihood of success.
- **Achaogen may conduct additional clinical trials to support regulatory filings for plazomicin.** Achaogen originally planned a single-arm, open-label supportive efficacy study in approximately 50 patients with serious CRE infections to be initiated in 2014. Additionally, a non-randomized safety study was planned to begin after the first interim analysis in 2H15. The main purpose of these two studies is to satisfy the requirement for a 300-patient

	2014A	2015E Curr.	2015E Prior	2016E Curr.	2016E Prior
EPS					
1Q	($1.00)	($0.25)	($0.26)	--	
2Q	($0.20)	($0.25)	($0.25)	--	
3Q	($0.47)	($0.25)	($0.25)	--	
4Q	($0.27)	($0.23)	($0.23)	--	
FY	($1.42)	($0.99)	($0.99)	($0.90)	($0.90)
P/E	NM	NM		NM	
Revenue ($M)					
FY	$20	$24	$24	$23	$23
EV/Sales	5.9x	4.9x		5.1x	
Consensus EPS					
FY	--	($0.92)	($1.12)	($1.13)	($1.34)
Consensus Rev					
FY	--	$22	--	$22	--

FYE Dec

Edward Nash
212-319-5578
edward.nash@suntrust.com

Yun Zhong, Ph.D.
212-303-4193
yun.zhong@suntrust.com

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safety database for global regulatory approvals. We believe Achaogen may now have a different plan since management commented on "*additional opportunities for plazomicin*" when meeting with us in January.

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

	2013A	Q1:14A	Q2:14A	Q3:14A	Q4:14A	2014A	Q1:15E	Q2:15E	Q3:15E	Q4:15E	2015E
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
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
Contract Revenue	18.5	6.0	5.2	4.5	4.3	20.0	5.5	5.8	6.2	6.5	24.0
Total Revenues	$18.5	$6.0	$5.2	$4.5	$4.3	$20.0	$5.5	$5.8	$6.2	$6.5	$24.0
COGS	-	-	-	-	-	-					-
Research and Development	23.5	6.6	6.2	10.7	6.6	30.1	7.6	7.8	8.0	8.1	31.5
General and Administrative	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	30.5	9.2	8.5	12.9	9.1	39.8	10.1	10.4	10.7	10.8	42.0
Income (Loss) from Operations	($12.0)	($3.2)	($3.3)	($8.3)	($4.9)	($19.8)	($4.6)	($4.6)	($4.5)	($4.3)	($18.0)
Interest Expense and Other, net	(1.3)	(0.2)	(0.2)	0.0	0.0	(0.4)	0.0	0.0	0.0	0.0	0.0
Interest 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
Net Income (Loss)	($13.1)	($3.5)	($3.6)	($8.3)	($4.8)	($20.2)	($4.6)	($4.6)	($4.5)	($4.3)	($18.0)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Income Tax	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) Attributable to Common Shareholders	(13.1)	(3.5)	(3.6)	(8.3)	(4.8)	(20.2)	(4.6)	(4.6)	(4.5)	(4.3)	(18.0)
GAAP EPS, Basic and Diluted	($3.08)	($1.00)	($0.20)	($0.47)	($0.27)	($1.42)	($0.25)	($0.25)	($0.25)	($0.23)	($0.99)
Weighted Average Shares Outstanding - Basic and Diluted	4.3	3.5	17.7	17.7	17.8	14.2	18.1	18.2	18.3	18.4	18.3

Source: SunTrust Robinson Humphrey

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

	2013A	2014A	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	20.0	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	$20.0	$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	30.1	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	39.8	42.0	40.0	38.5	44.2	60.8	72.5	82.2	87.7	93.8	100.1	105.2
Income (Loss) from Operations	($12.0)	($19.8)	($18.0)	($17.0)	($21.0)	($29.7)	$45.7	$126.7	$187.7	$228.8	$277.5	$326.9	$365.6
Interest 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
Interest 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)	($20.2)	($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%*
Income 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)	(20.2)	(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)	($1.42)	($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	18.3	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 target 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.

Analyst Certification

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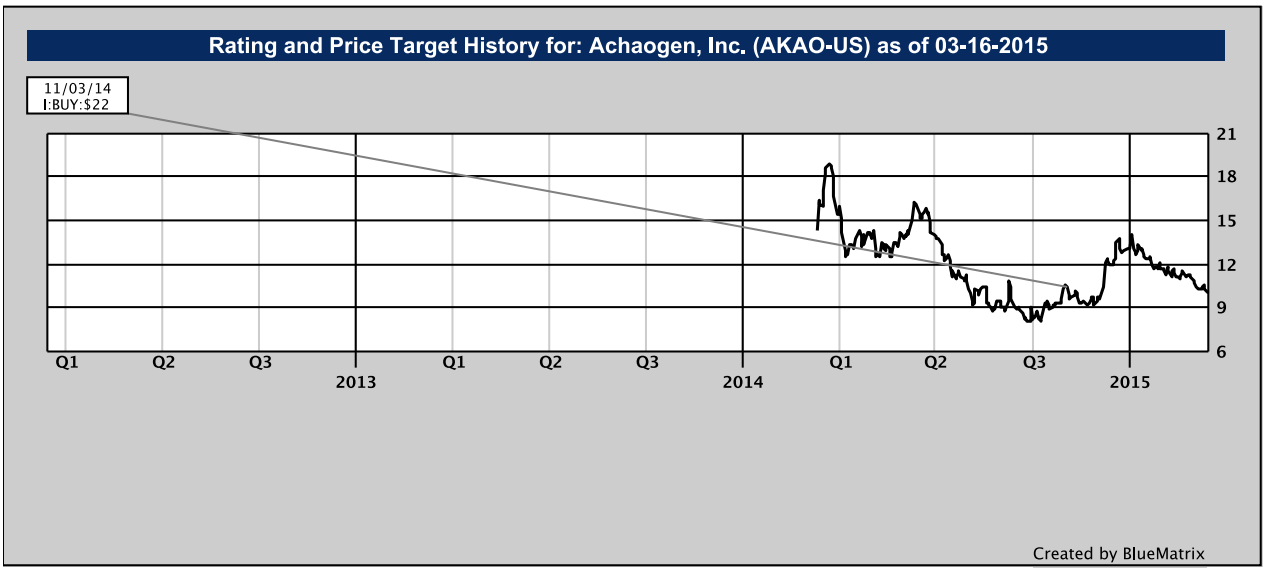

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3 designations based on total returns* within a 12-month period**

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- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
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- **CS** – Coverage Suspended

*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
***Low Beta defined as securities with an average Beta of 0.8 or less, using Bloomberg's 5-year average Beta

Legend for Rating and Price Target History Charts:
D = drop coverage
I = initiate coverage
T = transfer coverage

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Coverage Universe			Investment Banking Clients Past 12 Months		
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Neutral	251	46.22%	Neutral	44	17.53%
Sell/Reduce	10	1.84%	Sell/Reduce	2	20.00%

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