

Equity Research

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Achaogen, Inc. (AKAO-\$10.05)

Rating: BUY

Target Price: \$13.00

Plazomicin Phase 3 Enrolling, Development Update Expected in 2Q:15

<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	(1.00)A	(0.20)A	(0.47)A	(0.27)A
<i>Prev</i>	—	—	—	(0.21)E
2015E	(0.28)E	(0.29)E	(0.29)E	(0.30)E
2016E	—	—	—	—
<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	6.0A	5.2A	4.5A	4.3A
<i>Prev</i>	—	—	—	5.5E
2015E	4.2E	4.2E	4.2E	4.2E
2016E	—	—	—	—
<u>FY</u>	<u>2014A</u>	<u>2015E</u>	<u>2016E</u>	
EPS	(1.42)A	(1.17)E	(1.22)E	
<i>Prev</i>	(1.35)E	(1.24)E	—	
P/E	(7.1)x	(8.6)x	(8.2)x	
REV	20.0A	16.8E	16.0E	
<i>Prev</i>	20.7E	20.0E	—	
P/S	9.1x	10.8x	11.3x	

- **Phase 3 CARE Trial Enrolling.** The phase 3 superiority trial that AKAO is conducting of a plazomicin-based regimen vs. a colistin-based regimen in blood stream infections and pneumonia is currently enrolling globally. The majority of sites in the U.S. and E.U. have openings, and additional sites, as well as those in Latin America, are expected to open during 1Q:15. Enrollment remains slower than anticipated and AKAO is currently looking at options designed to accelerate enrollment, including but not limited to discussions with the FDA on changes to the study protocol. AKAO expects to provide an update of the development strategy during 2Q:15.
- **Robust Preclinical Pipeline of Novel Antibacterials.** Antibiotic development has focused on modifying only a few known classes of drugs in order to overcome resistance. In preclinical development, Achaogen has antibacterial antibodies and a LpxC inhibitor. Both these assets, we believe, have novel mechanisms of action, raising the hurdle for resistance, though they have also been untested in the clinic. We expect AKAO to submit the IND for one or more of these preclinical assets to the FDA in 2016 and begin phase 1 studies shortly afterwards.
- **AKAO Reported Earnings of \$(0.27) per Share for 4Q:14.** The net loss of \$(0.27) beat FactSet consensus of \$(0.33), though relatively in-line with our estimate of \$(0.21). AKAO ended the quarter with \$64M in cash and equivalents, which we believe will fund operations into 2017.

Current Statistics

Market Cap (\$Mil)	\$181.2
Avg. Daily Trading Volume (3 mo.):	77,972
Shares Out (Mil):	18.030

Milestones

Exhibit 1: Potential Near-Term AKAO Catalysts

Plazomicin	Indication/Setting	Comment	Timing
Phase 3 first Interim	BSI/Pneumonia	360 patients, Plazomicin vs.colistin, 28 day all cause mortality.	YE:2015
Phase 3 second Interim	BSI/Pneumonia	360 patients, Plazomicin vs.colistin, 28 day all cause mortality.	YE:2016
Phase 3 Top Line	BSI/Pneumonia	360 patients, Plazomicin vs.colistin, 28 day all cause mortality.	YE:2017
Other Programs	Indication/Setting	Comment	Timing
Antibody or LpxC	Gram-Negative Infection	File IND	2016

Source: Company reports and Cantor Fitzgerald estimates

Valuation

We assign Achaogen a BUY rating based on a \$13 price target. This rating is, in turn, based on a net income NPV model, which we believe is the most appropriate method with which to value AKAO shares. We model risk net income out to 2025; this assumes the primary driver of cash flow is plazomicin sales, which we believe will become generic in 2031 at the end of patent exclusivity. Based on these assumptions and a weighted average cost of capital of 12.5%, our NPV valuation indicates a target price for AKAO at \$13.

Risks

Clinical trial risk. Pre-clinical studies and Phase I/II clinical trials of plazomicin may not be predictive of success in subsequent larger clinical studies or in clinical studies in new disease settings. Also, efficacy against infection in one tissue type is not predictive of efficacy in other tissues.

Regulatory risk. Commercialization of plazomicin is dependent on FDA approval in the United States and/or approval by comparable regulatory agencies in Europe and other countries. There can be no assurance that Achaogen's ongoing and planned trials for plazomicin, even if successful by some measure, will be adequate to satisfy FDA or foreign regulatory approval standards for approval.

Commercialization risk. Achaogen will need to develop a sales force to commercialize plazomicin in the United States. Currently, Achaogen does not have the ability to co-promote or co-commercialize plazomicin in any country outside the United States.

Pipeline risk. While plazomicin represents only one of Achaogen's drug development assets, and the company presently has other compounds in clinical development, we believe it will be the primary driver for Achaogen's stock. The failure of plazomicin to achieve successful clinical trial endpoints, delays in clinical or development of plazomicin, unanticipated adverse side effects related to plazomicin, or any other adverse developments or information related to plazomicin would significantly negatively impact the company's common stock.

Exhibit 2: AKAO Income Statement (in millions, except per share data)

Achaogen

INCOME STATEMENT

Cantor Fitzgerald & Co

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Fiscal Period: ends Dec. 31

	2013	1Q	2Q	3Q	4Q	2014	1QE	2QE	3QE	4QE	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Plazomicin	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 8.8	\$ 19.4	\$ 36.1	\$ 53.8	\$ 72.6	\$ 92.6	\$ 113.8	\$ 136.4
Product sales, net	-					-					-	-	-	13.3	29.2	53.9	79.9	107.2	136.0	166.3	198.2
Collaboration and Contract Revenue	\$ 18.5	6.0	5.2	4.5	4.3	\$ 20.0	4.2	4.2	4.2	4.2	16.8	16.0	-	-	-	-	-	-	-	-	-
Other Revenue	\$ -					\$ -					-	-	-	-	-	-	-	-	-	-	-
Total Revenue	\$ 18.5	\$ 6.0	\$ 5.2	\$ 4.5	\$ 4.3	\$ 20.0	\$ 4.2	\$ 4.2	\$ 4.2	\$ 4.2	\$ 16.8	\$ 16.0	\$ -	\$ 13.3	\$ 29.2	\$ 53.9	\$ 79.9	\$ 107.2	\$ 136.0	\$ 166.3	\$ 198.2
Cost of product sales	-	-	-	-	-	-	-	-	-	-	-	-	-	2.26	4.38	6.47	9.59	12.87	16.32	19.95	23.78
Gross Profit	18.5	6.0	5.2	4.5	4.3	20.0	4.2	4.2	4.2	4.2	16.8	16.0	-	11.0	24.8	47.4	70.3	94.4	119.7	146.3	174.4
Research and development	\$ 23.5	6.6	6.2	10.7	6.6	\$ 30.1	6.7	6.8	6.9	7.0	\$ 27.40	\$ 27.68	\$ 27.95	\$ 15.27	\$ 16.92	\$ 17.78	\$ 20.77	\$ 21.45	\$ 27.20	\$ 33.26	\$ 39.63
Selling, general and administrative	\$ 7.0	2.6	2.3	2.2	2.5	\$ 9.6	2.5	2.6	2.6	2.7	\$ 10.41	\$ 10.52	\$ 10.62	\$ 10.35	\$ 11.09	\$ 11.86	\$ 17.57	\$ 23.59	\$ 29.92	\$ 36.58	\$ 43.60
Other Expenses	\$ -					\$ -					\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total operating expense (including COGS)	30.5	9.2	8.5	12.9	9.1	39.8	9.2	9.4	9.5	9.7	37.8	38.2	38.6	27.9	32.4	36.1	47.9	57.9	73.4	89.8	107.0
Operating Income	(12.0)	(3.2)	(3.3)	(8.3)	(4.9)	(19.8)	(5.0)	(5.2)	(5.3)	(5.5)	(21.0)	(22.2)	(38.6)	(14.6)	(3.2)	17.8	32.0	49.3	62.6	76.5	91.2
Interest Income	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest expense	\$ (1.3)	(0.2)	(0.2)	0.0	0.0	\$ (0.4)	-	-	-	-	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Other Income/ Expense	\$ 0.2	-	-	-	-	\$ -	-	-	-	-	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Loss on extinguishment of debt	\$ -					\$ -					\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Net Income Before Taxes	(13.1)	(3.5)	(3.6)	(8.3)	(4.9)	(20.2)	(5.0)	(5.2)	(5.3)	(5.5)	(21.0)	(22.2)	(38.6)	(14.6)	(3.2)	17.8	32.0	49.3	62.6	76.5	91.2
Provision for Income Taxes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2.1	5.4	12.3	20.0	24.5	29.2
Net Income After Taxes	\$ (13.1)	\$ (3.5)	\$ (3.6)	\$ (8.3)	\$ (4.9)	\$ (20.2)	\$ (5.0)	\$ (5.2)	\$ (5.3)	\$ (5.5)	\$ (21.0)	\$ (22.2)	\$ (38.6)	\$ (14.6)	\$ (3.2)	\$ 15.6	\$ 26.5	\$ 37.0	\$ 42.5	\$ 52.0	\$ 62.0
Basic Weighted Average Shares	0.4	3.5	17.7	17.7	17.8	14.2	17.9	18.0	18.1	18.2	18.0	18.2	18.4	18.6	18.8	19.0	19.2	19.4	19.6	19.8	20.0
Diluted Weighted Average Shares	0.4	3.5	17.7	17.7	17.8	14.2	17.9	18.0	18.1	18.2	18.0	18.2	18.4	18.6	18.8	19.0	19.2	19.4	19.6	19.8	20.0
Diluted EPS as-reported (GAAP)	\$ (33.83)	\$ (1.00)	\$ (0.20)	\$ (0.47)	\$ (0.27)	\$ (1.42)	\$ (0.28)	\$ (0.29)	\$ (0.29)	\$ (0.30)	\$ (1.17)	\$ (1.22)	\$ (2.09)	\$ (0.78)	\$ (0.17)	\$ 0.82	\$ 1.38	\$ 1.90	\$ 2.17	\$ 2.62	\$ 3.09
Adjusted Net Income (non-GAAP)	\$ (13.1)	\$ (3.5)	\$ (3.6)	\$ (8.3)	\$ (4.9)	\$ (20.2)	\$ (5.0)	\$ (5.2)	\$ (5.3)	\$ (5.5)	\$ (21.0)	\$ (22.2)	\$ (38.6)	\$ (14.6)	\$ (3.2)	\$ 15.6	\$ 26.5	\$ 37.0	\$ 42.5	\$ 52.0	\$ 62.0
Adjusted fully diluted EPS (non-GAAP)	\$ (33.83)	\$ (1.00)	\$ (0.20)	\$ (0.47)	\$ (0.27)	\$ (1.42)	\$ (0.28)	\$ (0.29)	\$ (0.29)	\$ (0.30)	\$ (1.17)	\$ (1.22)	\$ (2.09)	\$ (0.78)	\$ (0.17)	\$ 0.82	\$ 1.38	\$ 1.90	\$ 2.17	\$ 2.62	\$ 3.09
Cash and Equivalents	\$ 11					\$ 64					\$ 46	\$ 28	\$ 94	\$ 77	\$ 73	\$ 86	\$ 111	\$ 146	\$ 188	\$ 238	\$ 299

Source: Company reports and Cantor Fitzgerald estimates

Company Description

Achaogen, Inc., a clinical-stage biopharmaceutical company, developing novel antibiotics for Gram-negative bacterial infections. The company's lead product is plazomicin, which has initiated phase 3 clinical trials for treatment of Multidrug resistant blood stream and pneumonia infections, including carbapenem-resistant Enterobacteriaceae. The company also has novel classes of antibiotics in preclinical development, including antipseudomonal drugs. The company, which was founded in 2002, is based in South San Francisco, CA and has 43 employees.

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Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	91	64.54	25	27.47
HOLD [H]	45	31.91	8	17.78
SELL [S]	5	3.55	1	20.00